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ON
GENETICS, HEALTH, AND SOCIETY
(SACGHS)

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C O N T E N T S

Page No.

Opening Remarks
Steven Teutsch, M.D., M.P.H. 9

Genomic Data-Sharing

Discussion of the Ethical Implications of Genomic Data-Sharing
Charmaine Royal, Ph.D., SACGHS Member 10

Genetics Education and Training

Draft Report on Genetics Education/Training: Literature and Survey Findings
Barbara Burns McGrath, R.N., Ph.D, SACGHS Member 47

Committee Discussion of Draft Recommendations 72

Public Comment Session

Amy Miller
Personalized Medicine Coalition 101

Luisel Ricks
National Human Genome Center 104

Ted Rumel
Association of University Technology Managers 110

Susan Polin
Kennedy Institute of Ethics 117

Lisa Schlager
FORCE, Howard University 121

Direct-to-Consumer Genetic Testing

Presentation of Revised Draft Paper on Direct-to-Consumer Genetic Testing
Sylvia Au, M.S., CGC, SACGHS Member 130

Committee Discussion/Decisions: Direct-to-Consumer Genetic Testing 150

Gene Patents and Licensing Practices

Final Draft Recommendations and Draft Report 200

CONTENTS *(continued)*

Page No.

Closing Remarks
Steven Teutsch, M.D., M.P.H. 264

Adjournment 266

PROCEEDINGS

[Reconvened 8:03 a.m.]

Opening Remarks

Steven Teutsch, M.D., M.P.H.

DR. TEUTSCH: Good morning. Hope everyone had a good evening. Those of us that went to dinner I think all enjoyed it, at least I enjoyed it, and this is good. We have at least the voting members enjoyed it, so that was great, and I think we accomplished a tremendous amount yesterday. It was some pretty hard slogging. I know there are some strongly held differences of opinion and it was good to work through all of that and we'll get a chance to see what we did at the end of the day and get that put to bed, we hope.

So this morning, we're going to begin by considering proposed actions to continue the Committee's work in the area of ethical implications in genomic data-sharing, and Charmaine has been leading -- Charmaine? Oh, she's way up there.

DR. ROYAL: I'm way up here.

DR. TEUTSCH: Whoa. Okay. So Charmaine Royal has been working on putting together some thoughts for us

which she's going to share this morning.

So, Charmaine, take it away.

Discussion of Ethical Implications of Genomic Data-Sharing

Charmaine Royal, Ph.D., SACGHS Member

[PowerPoint Presentation.]

DR. ROYAL: Thank you, Steve. I don't know why I'm so fortunate to be thrust into this so early, but I'm going to talk a bit about the ethical implications of genomic data-sharing.

I am [also] going to lead a discussion of where we think SACGHS should go on this topic, what do we think we should do, and the issues in terms of genomic data sharing that have come out of large-scale sharing of genomic data, not the least of which is the NIH requiring that research funded by the NIH and conducted by the NIH, genomic from that research, GWAS studies, should be entered and submitted to DBGAP to allow for sharing and usage, and ultimately for additional information, as much as we can find out about health and disease.

The goal, of course, has been to develop methodologies to improve health, public health.

So the collection and broad sharing of individual genomic data. Later on, we will also talk about data related to groups, not just individuals, when de-identified. The issue of de-identification, as we know, has raised a lot of issues.

We talk about de-identification, but research papers have come out, one last year from TJAN and another earlier this year, showing that it is actually possible to identify individuals from aggregate data. So that raised concerns about data being out in the open and available to researchers broadly.

The implications for consent, privacy, discrimination, those are some of the issues raised, and we could think about this in terms of the stakeholders that could be involved in this, the researchers, the physicians, patients, communities at large, industry.

So the issues span a broad spectrum in terms of what we might think about. Some of the questions that have been raised have to do with consent or traditional ways of thinking about consent, individual consent, consent where we actually know what is going to happen and we put that in the consent form, but with sharing

data, we have no idea, in some cases, of what kinds of studies will be done, who is going to have access to data.

So the issues of consent and how do we deal with new ways of thinking about consent.

Genomics has really brought about a change in thinking about the lines between research and clinical care and that line is becoming increasingly blurred. We already see cases where genomic data, outcomes data actually, can be used to help us think about the clinical validity of genetic tests. That could be considered research, genomic GWAS studies that produce information that could be clinically relevant to participants, and communicating that information back.

So the lines between research and clinical care is an issue that this kind of research raises.

There is also concern about whole-genome sequencing being a unique identifier that can be linked with data that might be obtained or stored in other contexts. And then, this also raises issues of privacy protection.

So these are some of the issues that we think

about or that the issue of sharing data, genomic data raises.

In terms of what SACGHS has done, I'm going to talk about meetings that I never attended, and so my information certainly is coming from those who were at those meetings. In December, SACGHS identified this area, the ethical implications of genomic data-sharing, as one that it would place as a priority area for consideration, and here we are trying to figure out what specifically we are going to do in this arena.

At the meeting in March, there were briefings on the IOM Report on Privacy, the HIPAA Rule, and then from the Secretary's Advisory Committee on Heritable Disorders and thinking about informed consent.

At the end of that session, there were suggestions that SACGHS should coordinate their efforts with the Office of Civil Rights, and they have been very much involved in GINA, which, GINA, of course, we think about in terms of privacy protection. That office was represented yesterday.

The Secretary's Advisory Commission, SACHRP, their work on informed consent could really help inform

our efforts here. The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, they recently released a report with recommendations on dried blood spots for newborn screening and issues of consent, issues of access are things that that report raises in the recommendations there.

The HIT and David Blumenthal were here at our last meeting. [David's] groups, the Policy Committee and the Standards Committee, are also entities that we have been talking with about this issue. The HIT is involved in the meeting next week, on electronic health information, that I'll be attending as well.

One area that seems really ripe for collaboration is another collaborative effort that SACGHS has been exploring. In September, ASPE awarded a one year contract to the Lewin Group. Is Sandy here? No? Okay. Sandy is the one, the primary contact there.

The goal of that contract is to develop a report and that report would be informed by review of the literature as well as interviews with experts on the issue of genomic data sharing and that contract is designed to provide input to SACGHS but also our work.

Our thinking is that our work would also inform that of the Lewin Group and we'll talk more about that project and how SACGHS might inform or be informed by the efforts of the Lewin Group.

And in order to complement some of what that group is doing, one of the things that we're proposing is a session at next year's meeting to explore models of genomic data sharing. So today, we're going to try to come to some decisions about what the Committee will do with regard to ethical implications of genomic data sharing.

One of the things we're proposing is to form a steering group, a steering group of three to five, three to six people and ex-officios, as appropriate, to explore models of genomic data sharing, and we plan to discuss that at the February meeting. That's the thinking, that we would explore models of genomic data sharing.

We talk about genomic data sharing and the Lewin Group will be doing a lit review and they will be doing interviews, but we thought it might be helpful to see what is going on out there in terms of genomic data sharing before we can really be qualified to talk about

where it might go.

We're thinking of this session for the February meeting and then also to provide input to the Lewin Group and these are the things we're proposing. So there are a number of questions for discussion and I'm going to go through these questions and then sort of come back. Just to give you an idea of what the questions are, I'm going to go through them and then we'll come back to discuss them to see what we think we might do.

So we want to first talk about whether we should organize such a session at the February meeting to look at genomic data sharing. Should we form this steering committee? Are there other things that we should do with regard to this topic, in addition to or in lieu of having a session? What should the session focus on in terms of models of data sharing? Should we focus on academic models? Should we focus on industry? Where should we place our emphasis in terms of looking at models of data sharing?

Should we focus on clinical data versus data from research? Types of diseases, rare diseases versus common diseases? Should we focus on specific elements of

these data sharing agreements? We probably need to look at them to see what the common elements might be first before we even think about what we might focus on. Should we look at particular populations?

At the last meeting, I understand there was a discussion about vulnerable populations, and we'll talk more about that and even what the definition of vulnerable populations is and where we might focus there, if we think we should.

Are there any drawbacks to organizing such a session, and what should come out of this session?

So I'm going to go back to our discussion questions and ask whether folks think we should organize such a session. Is Greg Downing around? Greg, would you come join us at the table?

DR. TEUTSCH: Actually, Kevin, why don't you join us, as well? Kevin had been spearheading this effort up until his recent departure from our group.

DR. FITZGERALD: Just when I thought I was out.

DR. ROYAL: You'll never be out, Kevin, never.

DR. TEUTSCH: He'll never leave this group.

DR. ROYAL: Yes. So these three questions on

this slide will actually determine what we do next. They will determine whether we even need to answer the other questions. The first question is: Should we organize a session on models of genomic data-sharing.

Let me go to the last one: Are there things, other things, that people think we should do as opposed to doing a session, or in addition to doing a session.

So the question about a session at February's meeting, where we explore models of genomic data-sharing, of course, needing to do some background work leading up to that meeting so that we can actually have these models to discuss.

DR. TEUTSCH: Greg, we know you've been giving this a lot of thought. Do you want to share some of your ideas about what this could be and how it could contribute to the departmental efforts?

MR. DOWNING: I would be happy to, Steve. First of all, thank you again for all of the hard work that this committee has been doing, and in particular to Charmaine, who we've had a couple calls with to share information, and I have been working very closely with Sandy Howard in the procurement of the study that's going

on.

I think, as the initiative for that has taken shape, that there are some commonalities around a variety of things that we see happening, broadly speaking, around the elements of clinical genomics. So I think there is an opportunity here.

I have learned my lessons well when coming before this group: be careful what you ask for. There is no mandate here by any means, I want to be clear about that, but it seems as though one of the higher-level cultural things we're seeing going on, [and] what we think are good things for innovation and long-term benefits for healthcare, is a lot more collaboration amongst institutions and collaborators, not necessarily as a consequence of any particular funding initiative, but just as the basis of trying to get work done that requires larger populations than one can collect in their own institutions.

So I think, obviously, the ethical aspects of this has lots of hard questions associated with it. I think one of the things that we've been looking at is some of the new partnerships that are emerging across the

organizations, and what are the models for addressing the consent issues, the data-sharing issues, the publication issues, and so forth.

Obviously, this builds on a lot of the work that your committee and others have done with GWAS-related studies, but we see that as just the one step forward here, that there will be other areas where these comprehensive databases are evolving. The relation of that data to other kinds of data brings enormous power and influence, if you will, to many aspects of not just biology but to health and society.

So it seemed appropriate to us. We don't have specific questions or a destination that one would want to necessarily arrive at, but it seemed as though this body might be interested in questions like that.

The other elements that I think Charmaine's [report] brought out is that this committee has engaged many other advisory committees in their discussions around health IT and newborn screening.

I think, one thing, in my observations over the years, is that the communication has gotten better across different advisory committees and the coordination

elements. So I think there is an opportunity here, and we don't want to influence the Committee's bias, in one direction or another, toward any particular outcome.

The other thing I want to share is that, from the perspective of looking at data and technology overall, there is a great deal of interest in the aspects of how technology supports the movement of data, and the applicability of data to solve problems. There are many efforts in the government, right now, to enhance and mobilize data from a variety of different sources. All of our agencies are feeling that.

From the standpoint of being able to support this kind of information being used in a variety of different facets of human life, having not only the technological and scientific means to share that information but having the public policy perspectives prepared, or at least be thought of as that mobilization of data takes more shape, that we are not so much ahead of the game but at least trying to catch up faster. I don't know if that makes any sense.

I'm guessing that most of you are starting to feel the imprints of Facebook and MySpace and Twitter,

and all of these technologies. It's really only a matter of time when the capabilities of that hit other elements of data sharing.

So principally, I think we are interested in models that portray the thoughtfulness that the people who developed the foundations for collections of data [demonstrate] about themselves. Obviously, we use Framingham as a reference. The President spoke about that in his NIH remarks earlier this year, that that is really a badge of honor in many ways, and finding the respectful ways in which new technology [can be utilized], and ways to disseminate and use information, that we respect the aspects and take the time and have the policies in place to do that.

I think Charmaine has thought about these issues over the years, and I think we were delighted when she stepped up and shared her interest. So again, I want to emphasize, no mandate for any particular outcome of this, other than a careful examination of what these new capabilities [are] and the power this information provides.

So I would be happy to answer any specific

questions and, Steve, I hope that helps provide some clarity.

DR. TEUTSCH: Yes, it does. We'll open it for discussion in a minute, Greg. Appreciate those thoughts.

Kevin, did you want to give -- I know you've given a lot of thought to this, and then we'll open it up for some general discussion.

DR. FITZGERALD: Well, thank you, Steve. Actually, I did give a lot of thought to this and whoever came up with this idea, this silly idea should have been thrown off the Committee and never invited back. Thank you. No.

Actually, we have given a lot of thought to this idea and, in fact, Greg's being a little humble here, as always. He helped us put together at Georgetown a meeting looking at the consequences for genomic research in some of this database sharing with vulnerable populations, in particular indigenous communities, because we thought this would be an interesting group to engage, obviously groups that have been marginalized for some time, particularly in the healthcare arena, but also groups that are of interest to genomic researchers, due

to their somewhat isolated genomic characteristics.

So I think there is a lot to be learned here, and I think, as one could pursue this, you could actually see this as sort of a microcosm for some much broader issues.

What are the goods and the goals that are desired coming out of this research at all, period, across the board? This gives you at least some leverage to break that open a little bit more because you have to ask people what it is they expect and desire if they do engage in this sort of thing.

So I just see this as another opportunity for SACGHS to again continue to explore this area that is your mandate, genetics, health, and society, and how the research is going to continue to sort of ramp up the importance of these issues and make them very much a part of everyone's lives.

DR. TEUTSCH: Thanks, Kevin. All right. Why don't we open this up for discussion? I will harken back to our messages that I mentioned from Francis Collins to be forward-looking, anticipate issues going forward, and figure out how we can move these fields constructively

forward. So think about that and let's open it up.

Charmaine, do you want to coordinate this discussion?

DR. ROYAL: Sure. I can do that. Go ahead, Sylvia.

MS. AU: I totally support this as an activity of SACGHS, especially since I won't have to be on the task force. But, I mean, with the other committee, one of the things that, of course, is a big concern with us is newborn screening and retention of residual blood spots and data and so this obviously is something that's really important to the states because we all do newborn screening.

DR. ROYAL: Marc.

DR. WILLIAMS: I would also support pursuing this and to bring Sylvia back in on it. The other thing that I think is interesting that isn't represented in your very nice presentation are the issues relating to the direct-to-consumer aspects of data collection.

For the purposes of our blog that I'm inflicting on all of you, look through the User Agreement of one of the direct-to-consumer companies. I think

there's some very interesting things there relating to how they're choosing to use this data and Jim had mentioned yesterday about this new research model, again which I think is still an open question as to whether or not this really represents a new and innovative way to do research or whether this is not really going to point out.

But I would certainly increase the scope to include that, as well, since there's probably less in the way of any sort of -- I'm not using oversight in the very specific federal term here, but there's much less scrutiny of that, I think, than many of the other things that were referenced.

DR. ROYAL: Thank you, Marc. Very good point.

MR. DOWNING: I think there's some ways in which the work of this may have practical applications for some of the work that government agencies do, and I would like to share one experience that we had not long ago with a publication that provoked some interesting remarks that I heard about from -- it was a Friday afternoon in the early part of the summer and who the heck is really actually even reading anything, and all of

a sudden I started getting e-mails from all over the place about particular reaction to a publication that I'm sure no one had read but just saw the title of it, and it really related to the genetic findings associated with certain patterns of human behavior associated with substance abuse.

And the notion of being able to relate the sort of behavioral elements and patterns and genomic characteristics together by assimilating information from a variety of different sources that actually did address a salient biological issue really provoked a lot of -- particularly from folks that didn't have backgrounds in biology, were trying to understand, well, what were the messages coming out of this.

So the thing that really struck us after a series of dialogues that I was trying to understand what is the real root cause of the anxiety of all of this, and it was the notion that the information wasn't being placed in a context that broader communities could understand the meaning of that.

So there were elements that came up about the implications that this would have for people actually

seeking help because of these genetic findings were leading to some conclusions that would probably isolate certain populations and so forth.

And as we had a lot of phone calls about this with a variety of people across the department, and it really became obvious to us that we didn't have the informational resources that help put into context the meaning of population-based studies and associations and how, if this work is going to go forward, we have to do a better almost preemptory kind of stage-setting for why we're asking the question, aside from just getting the answers and knowing more knowledge, and the implications of that.

And one of the things we've been working on with our public affairs groups across the department on trying to set the stage for what does it mean when you're being able to take these large genomic databases and isolate factors, whether it's in diabetes or depression, that these things have real meaning to people and yet the context of what those research projects means by being able to take these large population datasets often have implications that we're not able to explain very easily.

So there's a communication side to this that I think the work that you can do from the policy and the science side might inform the public communications apparatus around the department that helps do a better job around that.

So we would like to use technology in new ways to help explain these research findings so that when you're just getting a publication out there, there's other kinds of technologies or videos or podcasts or things that provides a social construct for what are the implications of the research thing.

So your committee doesn't have to go that far, but I'm just trying to lay a stage for how other parts of the work that goes on here could be used and consumed by other pieces of the department.

DR. ROYAL: Thanks, Greg. That issue cuts across populations, but when we think about vulnerable populations, that's a major issue in terms of how the data is going to be used, who's going to have access, what kinds of questions are they going to be asking, and that has some implications for whether not just the participants who are the folks who are in these cohorts

but the researchers and their willingness to open up their data for sharing.

What I found in some of the groups that I've been involved with, cohorts of African American patients or participants, and it's the researchers that are -- who knows what the consumers, what the people think. The studies haven't been done yet for some of these to see what the participants actually feel about their data being shared, but the researchers of these studies or some of those that have contacted me about them being required to share their data and not wanting to do that because of the group that they're studying.

So those issues are really very, very salient to the issue of vulnerable populations but also other populations, as well.

DR. AMOS: I just want to get a little bit better idea of this, sort of your vision for the scope of this effort from the standpoint of will it include some of the more practical things.

Greg and I have talked about some of the sort of nuts and bolts of how you actually share data and how you actually -- some of the IT tools that have to be

developed to ensure the interoperability of all these systems, and I just want to get an idea about if you're thinking about tackling that, as well.

DR. ROYAL: I didn't think of it specifically. This forum is for us to explore what the scope might be, and if the Committee thinks that that is an area that we need to look into, then we probably will explore it.

I really want it to be open for discussion about how the Committee moves forward because there are other organizations and agencies looking at this issue, the broad issue of data sharing, and what is it that SACGHS can bring that could add to that that will complement and supplement that rather than duplicate it, necessarily.

DR. TEUTSCH: Mike, we're of course on record, as you know, and having met with David Blumenthal last time, we sent notes to the Secretary, really talking about the importance of getting those standards in place so that this kind of work can proceed.

I think it is something we can talk about, whether we need to do more going forward, but we've at least made some statements in that regard.

DR. AMOS: I just want to make sure, if you think you need our help, that we get the right people involved.

DR. ROYAL: Gwen.

MS. DARIEN: This may be a little bit of a detail, but one of the things that we talked about a little bit when I came on the Committee was being the only advocate/consumer representative on this committee, and I think this would be an incredible opportunity to bring in some more of the health advocacy voices.

Sylvia knows because she went to Sarah Lawrence, but I've been doing work with their Health Advocacy Program, and there are a lot of people that are dealing with issues like this. I mean, I know from the tissue-banking and the tissue-collection issue point of view where, at least the advocates I work with who are cancer advocates and patients, come down on this.

So I think that is a way of bringing other voices into this, which could make it very rich.

DR. McGRATH: Thanks. I would like to also support the formation of a group like this. It is sort of circular. The very first report that I was involved

in when I came was the large population study, and it addressed a lot of these issues.

One of the comments that came from the interviews and public comments, and from the experts, was a concern, an underlying concern that those sorts of studies are really the best use of limited resources for addressing population health.

So if this group is formed, it is dealing with the downstream of that, the data that emerges from large studies. I don't know how you integrate that, but it seems like that question hasn't gone away in our country, that is, this is the best way to really improve the health of the greatest numbers of people.

So when we talk about communicating results to consumers and talking to researchers about that, there might be a way to continue to realize that that is still a public priority, to make sure that the questions asked are the appropriate questions; not just the doable studies, but the important studies.

DR. ROYAL: Doug.

MR. OLSEN: Yes. I just wanted to say, because of the nature of the way VA provides services and the

fact that we have an enduring population, we have a lot of plans to do these kinds of studies. We're doing a lot of gearing up for large data collection and improving the capabilities for data sharing. So we have a real interest in this area, and a real interest in the ethics of the informed consent and how to do these things right.

DR. ROYAL: Greg.

MR. DOWNING: I forgot to mention earlier, one of the important contributions that I took away from the workshop that Kevin coordinated was the different models of community consultation.

I don't know if Jennie Weiss is here or not, but we went looking for literature on this and struck out in terms of finding, what are effective models for engaging communities on an ongoing basis for the uses of that information. We learned a lot from our experiences in going to Framingham, and want to thank a number of you who helped us do that in the past.

The different communities have different needs, we found, and I just think this is more of a social-science issue kind of thing: how do you find out what the communities' needs and information needs are, and how

they play roles. There isn't one common model that we found.

Many studies are now international in nature; so, how do you take into consideration the various cultural perspectives on ownership and asking. Through the Native American population here, we've learned a lot, but there are various other models that we've been seeing.

Kevin, I don't know if you want to comment on that, too, but that was one of the rich points that I took away.

DR. FITZGERALD: I agree completely. I think that was what came out of our gathering, but also, the fact, I think it's important for us to acknowledge, that there are other nations and places in the world that are ahead of us in this game, that have been looking at these issues, that have been pulling together some methodologies and some models. Canada and Mexico, in fact, have been doing a lot of work in this area.

So we don't have to reinvent the wheel, in some regards. There is a lot that we can tap into, and then I think [we can] use that richness to help us move forward.

So I think there are ways in which this could move quickly.

DR. ROYAL: Just to piggyback on that, I think you said it's social science, Greg, but I think it's all part of this. I think we do need to look at the perspectives of various stakeholders and the patients. Participants are a critical group.

So I think the social science needs to be combined with the biomedical research. It's all part of who we are. I think it's absolutely important.

MS. LLOYD-PURYEAR: Good morning. I'm the executive secretary of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, and we would be glad to work with this committee on this issue.

I would also like to add that the Newborn Screening Committee and the Rare Disease Committee have already begun to grapple with many of these issues, funding projects and newborn screening around long-term follow-up or effective follow-up, and looking at the communication issues in order for that process to take place. That includes engaging communities, and also looking at standards development to allow that

information exchange.

So I would like to add that the issue of standards development needs to go hand in hand with this effort, because communication won't take place unless you have those standards to communicate. So it is a really important issue to think ahead prospectively about that.

DR. DALE: I'm David Dale. I just was going to comment briefly. For about 20 years, I have overseen an international registry of a relatively rare set of conditions, where we have built a pattern of cooperation. The hard part has been linking the biological and the clinical data, but that's the richness of the registry.

The challenge has been to deal with the continued evolution of the requirements regarding informed consent, particularly where we were on a path of discovery of genes that cause diseases, particularly in children, and the diversity of causes.

Our original request was highly simple, but over time, it was worthwhile to look at other genes. So the flexibility to do that. I think it's also a framework or foundation for building understanding in a community of interested people about the value of genetic

studies as it relates to long-term health.

So it's a model, actually, which could be expanded to consider more common conditions in larger populations. The key feature is linking the clinical data to whatever genetic or analytical data you might have that comes from a laboratory.

DR. ROYAL: Marc.

DR. WILLIAMS: I'm going to put Alan on the spot here, because I don't know if there has been an official announcement or not, but there has at least been some indication that NIH is going to be investing some additional monies into issues relating to the ethical allele of social issues.

I'm just curious as to whether or not this is ripe, then, for some input from a group like SACGHS or this consortium, or whatever, to help to direct some of the distribution of those funds.

MR. DOWNING: I'm not sure exactly what you're speaking of, but I don't think it would be a very good precedent to have SACGHS directing funding. I think it's great for SACGHS to make suggestions to the Secretary, et cetera, et cetera, but I think it is the science that

ought to direct the research, and therefore the funding.

Now, that said, of course the LC Program, for many years, has looked at the issues that get into this, and I think will continue to do so. I'm actually either not aware of, or I'm not hooking up the specific thing that you're thinking of.

DR. WILLIAMS: I don't have enough specific information about what exactly it is I'm talking about. I didn't mean to imply that we would direct funding, but it seemed like if there is some overall sense of the direction that a number of different groups would want to go, that that would at least be of some interest.

MR. DOWNING: Yes. I mean, I think it would go back and forth. I would think that, obviously, it has very much been part of what I think the chairman has been talking about, that this would be informed by the research that has already been done, et cetera, et cetera, but I clearly do think whatever came out from such a group, which I think is a very good idea, would help inform NIH and others, particularly NIH, about future areas to explore more. Absolutely.

DR. ROYAL: We'll go to Mike.

DR. CAROME: I just wanted to make two comments and mention one area SACHRP is working on in this area.

Charmaine, you mentioned the issue, one of the important issues is the blurring between clinical practice and research, and you see this topic as being important in that area.

I'll just note that that certainly has been an ethical concern and issue, dating back three decades when the Belmont Report was issued by the National Commission on Human Research, and it's an issue our office struggles with frequently when we're trying to separate out what was research and what wasn't research.

It's unclear to me, at this point, why this area of genetics further blurs that line in a way that's different. And if that's true, it would help us to be better informed about why that is. That might be a topic the group could address. And if so, what should be done about it, if it's making the line more blurry.

The other thing, we have had longstanding policy positions regarding de-identified tissue or coded tissue samples, and have described circumstances in which that doesn't involve human subject research. One

question of interest to us is whether these new technologies and advancements would cause us to rethink those positions and, if that's the case, any advice from this group could be beneficial to our office.

Lastly, in terms of SACHRP, they are currently working on, as you mentioned, informed consent issues regarding biospecimens. Their thoughts on that are broad, looking at research in general.

So they are not specifically focused on genetic research. They are focusing on, in general, any research uses of biospecimens: when is informed consent needed; when specimens exist that have been banked, either for clinical reasons or research reasons; when can you continue to use those, given the consenting that was done. Those are the issues that they are currently looking at.

DR. ROYAL: Thank you, Mike. On the issue of blurring, we can move on, but we recognize that it is not a new issue but that there are questions about the sharing of data, data being available to everyone. There are new questions that could be raised from data moving from the clinician who collected the data to whomever

else.

So that's another area that we will talk about, whether we want to focus on research or clinical, or look at those lines.

In general, I am getting the sense that there is agreement that we should have a session on this in February, and the specifics. We talked about models of genomic data-sharing, which is one area that we will focus on, but we talk about so many others that there might be other things that we might want to incorporate into that meeting. We will talk about that later as we move to plan the meeting.

The formation of a steering committee, I don't know. Steve, do we take volunteers now?

DR. TEUTSCH: I agree with you, that I'm hearing that this is a subject of considerable interest. I didn't hear any dissention. So I think it would make sense that we get a small group together to help shape the meeting in February.

DR. ROYAL: Yes.

DR. TEUTSCH: Then we can decide where we're going to go, after we have had a more complete

discussion. It sounds to me like we are in the market for interested volunteers and/or appointees. So, Charmaine, I hope we can count on you to start, and we probably need to draft with Kevin because he can give you some assistance. He's sitting here, so he can't escape.

DR. ROYAL: Yes, he can't escape.

DR. TEUTSCH: We could use a few others who would like to work on it. It would initially be primarily about this committee. I see David, I see Sheila.

MS. WALCOFF: Although I really do want Sylvia to come with me.

DR. ROYAL: I do, too, actually.

MS. WALCOFF: I'm just kidding. I was really just kidding. She has done a lot of work.

DR. ROYAL: I'm not kidding.

[Laughter.]

MS. AU: As long as Kevin's on it.

DR. FITZGERALD: I'm already on it.

DR. TEUTSCH: So we've got Mike, Sylvia, Sheila, David, Kevin, and Charmaine. I think that's a great group to start with.

DR. ROYAL: I think so.

DR. TEUTSCH: And, Rochelle, I think we may call on you at some point if we need to, as we're making these different groups up.

Oh, Sandy. Sandy, don't go away. We've been talking about you. Sandy, I don't know, we had talked about the contract with Lewin that you've got in place. I know you haven't had the benefit of this whole conversation, but could you say something about the status? We understand the contract's let and the scope, and how you see it fitting in with this committee.

MS. HOWARD: All right.

DR. TEUTSCH: Thank you, as always, for your strong links with us and helping us move these things forward.

MS. HOWARD: ASPE is happy to work with you on this. We have a shared interest in a number of things, and I'm sure Greg has mentioned that. He and I are working together on some things related to genetics. We did award a contract to provide analytical support to the Committee, and [for] its work and guiding ASPE in its policy development, as well, to the Lewin Group, just a

couple of weeks ago.

We haven't kicked off the contract yet, but we will in a couple of weeks. As our guide to that, we used the white paper that the Committee put together -- was it last year, or earlier this year? -- and we structured it around the questions that were asked. We hope to find some answers or some examples of things that you could think about through literature review and expert panel interviews.

We will be in discussions with the people who have signed up to work on this from your subcommittee, and we hope it will be a fruitful interchange, because we want to produce something that is going to be useful to you.

DR. TEUTSCH: Yes. I mean, these have been extremely valuable to the Committee over the last few years.

Doug.

MR. OLSEN: I just wanted to volunteer because I think this is the one area that our office is most uniquely in a place to help.

DR. TEUTSCH: Terrific. Happy.

MS. LLOYD-PURYEAR: Steve, I would like to have our involvement early, only because our next meeting is in January and I would like to be able to present this.

DR. TEUTSCH: Terrific. This is an obvious area where we need to work together. So that's terrific.

Okay. Charmaine, thank you so much. That's great. Thanks for moving it forward. Thanks to everybody, [to those that] have done a lot of the work in prep for all of this, over the last few years.

DR. ROYAL: We won't bother to go through that. We'll just leave the rest of the questions for the subcommittee at this time.

DR. TEUTSCH: Yes. I think, over the next couple of months, if you can sort through that, that would be great. I'm sure we will revisit those as we decide how the Committee wants to actually move forward after February.

So the next topic is the Genetics Education and Training. As you can see, we have only allowed a half hour for this, and that is because we really want to give you a preview and get some input into the recommendation.

The Task Force has made a lot of progress since

our last meeting, under Barbara Burns McGrath's leadership, and she wants to review with you what the findings have been from their workgroups and get some initial input into the draft recommendations, which we will see in a more final form, probably in February.

So, Barbara, thank you for all your work.

Draft Report on Genetics Education/Training: Literature and Survey Findings

Barbara Burns McGrath, R.N, Ph.D., SACGHS Member

[PowerPoint Presentation.]

DR. McGRATH: Thank you. So I think the plan is for me to present some things and then really open up the room for discussion about these.

So this is a Task Force on Education and Training. In terms of the lifespan of task forces, I think patents might be considered at the end of its life, it's ready to leave this stage.

[Laughter.]

DR. McGRATH: Speaking metaphorically. So if we think of it that way, I think our report is in its late teens with all that that might imply. Think about it as that as we're talking about it.

I wanted to put up the roster first because these are the people who are doing the heavy lifting on this committee. It looks unwieldy because it fills the slide, but it really isn't. You know all the people on there. They represent, really, a broad base of expertise and everyone's expertise has been used to some extent in this large report.

The Committee charged us with a really big task. Because of that, we then subdivided into three groups, which in another world might be considered three separate committees or task forces, but these are considered workgroups under this big umbrella. We divided them into looking at the Education and Training Needs of Healthcare Professionals. Greg Feero started as chair on that, and David Dale has assumed that position as Greg rotated off.

The Public Health Provider Workgroup, Joseph Telfair has rotated off the SACGHS, but he has wonderfully been involved, stayed involved in the Committee, and will continue until it's over. Sylvia Au is here today, able to represent that committee if issues come up.

Consumer and Patient Group is chaired by Vence Bonham who is here, and Sarah Harding, also from his shop, has been very involved in it.

So these are the chairs of each of the workgroups, and they function very autonomously. Each of these chairs and their teams have been the ones collecting the data as well as crafting the recommendations.

Today, we'll be reviewing some of the findings of this report, and I'll emphasize that I'm going to do it very briefly. In your briefing book is a summary of some of the findings. The full text of that report you will be receiving in January or February. So we're not providing all of the findings for you, and I'll explain why in a little bit. I'll just go over some of them, very briefly, to give you a flavor of it, but most of the time that we have today, we would like to talk about recommendations.

We're going to solicit help today in a number of areas. One is -- I say this at every meeting -- we would really like to craft these recommendations as actionable, the recommendations to the Secretary of HHS.

We would like them to be something that she can take and decide what to do or not to do with them, in that, we would like to move beyond abstract and generic recommendations that cause the eyes to glaze over. I think we've all seen lots of those.

We would like to be forward-thinking about the future of genomics and not just make recommendations for today but to think about how these might anticipate trends that happen in the future.

We also are trying to be very sensitive to the reality of competing healthcare needs, and also to avoid a GINA-centric tone or perspective to this report, and that all of education for health providers and public health officials and consumers really ought to be focused on genetics first and genetics only. So those are some areas.

We would like, in our recommendations, to be sure we are covering key points, but also, think about pruning these down to a modest number by either combining them or eliminating some that are covered in other reports or other committees, or are just redundant.

The recommendations you will see today are not

final. We will be revising them over the next couple of months and putting them into the report. So we're not at the stage that we were yesterday with patents, of crafting the language and the meaning.

What we would like to do today is really focus on the content to see, with the wisdom in this room, if we have covered the major areas that we think we should, and then the Committee will take it on to craft them into that language.

The timeline for the overall report. Today, we will be talking about these draft recommendations. Between now and January, the Committee will be going back to the drawing board. All the data has been collected, but we need to present it in a more readable format, with some interpretations. We're working on that. We will take suggestions today for the recommendations and put those into a language that makes sense.

That will result in what is called a "Public Consultation Report," which we will present here in February. That report is for your review and approval, and that report then goes for public comment. Again, you saw all of this process with the patents, and that

happens in early Spring.

Next June, we will have a meeting like we had yesterday with patents, to go over the final recommendations, and that is the point where we will really be fine-tuning it. Then [we will] transmit it to the Secretary in July.

These draft report outlines, you're familiar with how they look, but just in quick summary, they always start with the executive summary and recommendations. That is the most important part, we've learned. The introduction has been written, and this is describing the scope of the problem, and some of the history of it.

Background literature is completed on all three groups, the education and training needs of all three of those groups that we outlined in the workgroups. Each group collected its own data, and that will be discussed in summary, and then the appendices will include all of the raw data.

The recommendations that we're going to be talking about emerged from a number of data sets, including what is in here. One was that we started off

two years ago with a roundtable of experts. They gave us some suggestions about what areas need to be looked at. So that has informed the recommendations, the background literature that was conducted, as well as that original data that we collected.

One of our early tasks was to see what has been done, because there was a resolution written in 2004 from the SACGHS Committee, a different one, making some suggestions for increasing the genetic literacy. So we did go back and look and see what has been done in the last couple years, and there are some things to call out to.

One is, the CDC expanded its education mission to include health professionals and the public. We are familiar with the "My Family Health Portrait" that is being widely used. NCHPEG has been very busy and productive, producing lots of educational products for specific groups and assessing the needs of various groups.

Between that time, the nurses have developed their own genetic certifications. The Genetic Counseling Workforce has increased, and soon there will be a series

of articles in "Genomics," and "NEJM," I think early in the year, that addresses some of these issues specifically. So things are moving, but the Committee felt that there is still much work to be done.

Starting with the Healthcare Professionals Group, I'm going to highlight some of the key findings that were found from the literature review, and then the research for each group.

So first, the literature review regarding Healthcare Professionals. Just very generally, we found that integration of genetics into healthcare is limited by a lack of or inappropriate genetic education. The needs are dynamic, and they reflect career trajectory and level of training. So there is no such thing as professional education. It needs to be looked at in terms of basic education, starting at basic training, advanced training for those wanting to go into specialty areas, and then continuing education for both of those groups. Different groups, different modes of education are needed, different needs.

The licensure, certification, and accreditation requirements have not kept up to date, and based on the

American College of Medical Genetics data, there is an estimate that there is only 41 percent of the number of medical geneticists needed in the U.S. workforce.

This is a figure that gets quoted a lot and is very familiar to a lot of people, but I think it's important to sit in the larger context of the whole genetic workforce and look at it in terms of evidence that other professional groups', nurses and genetic counselors, physician assistants, numbers are growing. Their interest in genetics is growing, as well. So this figure of the 41 percent needs to be looked at within the larger context, even though it's the one that most people are familiar with.

In terms of the data collected by this group, there were two efforts. The first one was to survey the federal agencies. One of the agendas was to see what changes happened between 2004 and 2009 or '10. We're going to be reporting on that data separately, so I won't talk too much about it right now, but the larger effort was devoted to surveying health professional organizations.

These were things like professional

organizations, AMA, ANA, genetics organizations, educational organizations, certification groups, and things like that. They distributed 33 surveys and had a 58 percent survey return rate.

Very briefly, the findings. These reflect the overall tone. Of course, there are a lot more findings. There are pages and pages of findings. Among other things, we found that 70 percent of those respondents viewed genetic education as part of their role, but they see the need for more funding. More program evaluation also rises to the high [end] of their needs, and they find that if there is greater interest within their own organizations' leadership, that this will facilitate greater genetics education.

They report moderate proficiency and comfort, by their leadership, in genetics and genomics education. So they feel like the leadership understands, but there needs to be more emphasis. Of course, competing priorities are a barrier to providing genetics and genomics education. That is a theme that we will hear time and time again.

The second group, the Public Health Providers

Literature, suggests that the current public health workforce is not well prepared to receive and assimilate genetic and genomic information into public health. So they identified a gap.

Barriers that they identified are quite varied, including the diverse roles of the public health workforce, the various education and training path represented by that diverse group, out-of-date formal training, and a general sense within the workforce that the utility of genetics is not clear to them, how they're going to use it, why they need to learn more about this.

The data that this group collected resulted from a consensus process they followed to identify 12 competencies they thought were important for the public health workforce. These were then developed into a survey instrument and distributed to 500 individuals.

They got back a 133 responses, lots of responses. This was a little interesting to do some numbers on this, because what happened is the survey would be distributed to one person in, say, a public health department, who would then look at it and say, well, I don't do genetics in this department, and forward

it on to the two or three people they think do.

We lost control, very early on, of who received the survey, so we can't have good data on response rates, but we know who did fill out those surveys. It was an interesting and surprising process.

Some of their findings -- I'm just listing three of them here -- in terms of those 12 competencies, the one that was the highest rated was this one that read:

"Demonstration of basic knowledge of the role of genetics in the development of disease, and in screening and interventions for programs of disease prevention and health promotion."

Those of you who do surveys can see this is probably a double-barreled kind of question. So it's a little hard to interpret, but this was an overall one that got the highest endorsement. The lowest competency was in conducting outcome evaluations, similar to the Health Professionals Group that felt this was the area of lack for them.

Two-thirds felt that the genomic resources were inadequate for implementing the competencies within

whatever group they were part of.

Finally, the Consumers and Patient Group. Their literature found that the sources of information for consumers and patients are many, including the media, TV, a lot from the Internet, as we're learning about, and also from their healthcare providers. There is a sense, from many surveys, from their own self-assessment, and from others reporting on them, that the consumers generally recognized that genes and behavior are related to health outcomes.

So it's relevant information, but less is known about complex traits, and probably common diseases and multifactorial conditions. This was an area that was identified in the literature as consumers would need more education on if we're going to be looking forward to more research in that area.

Consumers expressed continued concern about confidentiality and disclosure of genetic information. I think we're familiar with that, and most educational resources have been geared to those actively seeking information. These are people who go on the Web to look for a specific question or answer versus general

consumers, general public who are just getting health information from many sources.

The data collected from this group started off with 11 semi-structured interviews with diverse individuals. These were people who were identified from the group as having some interest or expertise in genetics education among consumers, consumer advocates or people involved with those groups.

Based on analysis of those interviews, a survey was developed and administered on the Web to more than a thousand organizations, and these were considered "seekers of genetic information." This is a term that is used in the literature. These are people, again, who are actively looking for this information rather than passively receiving information about genetics. They had a great response rate of 300 individuals.

To supplement the fact that this was directed towards seekers of information, they then analyzed the cogent consumer survey analysis, and this was a survey that was distributed to the general public, and cogent agencies shared their data with us. This group then integrated the analysis of that survey into their

findings.

Some of their findings generally were that consumers often wish to get information about testing from primary care providers. This would be their preferred source of information, but they're not confident that those providers have adequate knowledge. So there is a little bit of unsettlement there.

The government is seen as a trusted source for information, and many consumers and patients felt that a role for the government was as a clearinghouse for information. Family history is seen as an important tool to understand health and disease. That message has made it through.

That is a quick overview of the findings. Again, you will see them in all their great glory in a few months, but we decided that we could go ahead and talk about recommendations before you see all of them, because this is an area we're all familiar with. There is nothing in the report that is going to shock you.

That is different than what we reported, and so we thought we would try to use this time to help us craft these in a way, as I said earlier, that we can move this

field forward because it has been talked about for so long.

Now, a word about recommendations before I launch into them. People in this room have lots and lots of experience crafting and voting on recommendations, and know that any process that is searching for consensus is very iterative. When I say "iterative," I mean iterative in bold letters, very, very iterative.

One of the things that happens in that sort of process is that really good ideas can get lost in all the talking and consensus-building, and there can be a tendency for recommendations to drift to the midline. When I read our recommendations over, these draft ones today, I am alert to that possibility, that we may have drifted a little bit to the midline here and lost some in all of the deliberations that have happened over the months.

So I am calling on the whole group to help us make sure that we haven't left out some really great ideas that have come up at various meetings of the Task Force, and highlight those so that we can go back and craft them into recommendations and try to get a little

harder edge to some of our recommendations.

Generally, we can say, from the literature and from the data that we've collected, that there are challenges in achieving healthcare workforce genetic literacy, as well as within the other two groups. There is a strong sense, and I think complete agreement, that innovative approaches are going to be needed that tie efforts across disciplines so we're not just thinking about silos of health providers, and across layers of education, knowing that one individual's learning is lifetime learning.

So we should also think about ways to avoid that siloing of education into blocks, and these innovative methods may require public and private partnerships with federal and state government institutions.

Now, the needs of consumers and patients are not the same as healthcare workforce, but they also are going to require innovative approaches that take into account not only the new technologies that are available for education, such as social networking, things like that, but also the needs of diverse communities which we

talked a lot about in this community and the different learning styles of different communities as our population continues to get more and more diverse.

We're going to launch into it, and I think what I would like to do is read through them all and then talk about them at the end so you see them as a whole.

We have a total of 13, thank you, recommendations, so it's not a million. There are two or three that apply, or came out of each workgroup, and then there are two or three at the end that cross groups. I am going to go through all of them first.

The first one came out of the Health Professionals Group, and it talks about integration and the recommendation is HHS should encourage the integration of genetics and genomic content into all levels of health professional education and training programs relevant to the needs as identified by specialty groups. That last phrase is thought to be important, that the needs would be identified by the groups rather than from above.

This is obviously a broad recommendation and is kind of speaking out to the levels of education and

speaks a little bit to academic curriculum and clinical practice settings.

The second one is similar but has more of a healthcare delivery tone to it. See if it's distinct enough. Should fund multidisciplinary public/private genomics/genetics education advisory panels whose function it is to prepare a model framework for education, licensure, accreditation, and certification requirements in preparing a personalized genomic healthcare, dah-dah-dah. So that has more of a delivery tone to it.

The third one, again reflecting healthcare professionals, is speaking to interdisciplinary collaboration. HHS should support formal and informal genetics knowledge sharing by facilitating interdisciplinary collaborations.

Now here we're acknowledging that these collaborations are much more practical in large settings and, indeed, often happen in large settings but is more problematic in rural areas. So there's a call-out in rural and underserved areas. Should employ innovative technologies, such as telemedicine conferencing, to share

knowledge and expertise again across disciplines. Then acknowledging that there are barriers to this, reimbursement is one, added another notion that should encourage reimbursement for these interdisciplinary teams as well as for these distant consultations that we just referred to in the rural area.

The public health providers, the first one, is to assess the size and scope of the public health workforce that have genetic and genomic responsibilities to ascertain current trends and plan for future needs.

We know that public health providers are a very divergent and -- I shouldn't say divergent, diverse. They are the nicest people. They are not divergent, and heterogenous workforce, and their role is likely to change with any sort of healthcare reform we may be getting. So it may be very timely to conduct a systematic assessment of where they are, who they are, and what they're doing.

The other issue around the size of the workforce is whether the numbers are keeping track with the future needs, particularly in the genetic workforce area.

Because that group dealt with competencies, this one makes sense. HHS should facilitate the development of relevant core competencies for all federal and non-federal public health providers and specific competencies for those whose role requires such knowledge.

So this is speaking to the reality that there are some public health providers out there whose job responsibilities require very explicit genetic knowledge and competencies. Now others require just basic knowledge and we're trying to distinguish between the two and not distinguish between the two.

So this recommendation is responding and referring to two quite different groups within the public health workforce. Embedded in this is the reality of competing demands that are always in there for all these kinds of health professionals.

Next one is similar to the interdisciplinary practice of the earlier group, is collaborative training, and this one is suggesting that there be promotion of collaboration for genetics/genomics education and training between medical and public health professionals

to benefit population health and as an example, schools of public health and medical schools and AMA and APHA.

This is referring to the traditional schism between medicine and public health and seeing if we can narrow that schism at least in this area of genetics and the importance of doing so.

Recommendations that came out of the Consumer Group are first to improve genetic literacy. Efforts to improve literacy of consumers and patients should be based on educational theory and be coordinated with other federal departments and agencies and community-based organizations.

A question here is whether or not to include language about K-12 or K-college education. This was decided very clearly as outside of the scope of this task force, K-12 education, but a lot of the suggestions that came from consumers is to have a literate adult consumer population, the education needs to start earlier. So it's really hard to draw that line in the sand to say where education should start. So that was one area we grappled with.

The next one is about resources. They should

support the continued and expanded development of education resources to enhance the public literacy. This one, embedded in here is the idea, is the need for creative resources to match how people are getting information currently, and again we've talked about those methods, it's pretty exciting now, but also again always with this to not lose sight that there's some of under-served and ethnic communities that use other sources of information, such as ethnic media and things like that, and that their needs must also be met. So we shouldn't go down the path of getting all excited about high-tech educational resources and lose the fact that this is a very -- it's only one segment of the population that accesses that, though it's a very interesting and growing area.

Family history. HHS should support continued efforts to publicize the importance of family history, ensure access to tools in various formats and inform consumers about the importance of sharing this information with primary care providers.

This one may stand out a little bit, but in thinking about priorities, what came out of a lot of the

literature and the recommendations from the Consumer Group and Patient Group was if there was one thing that you could teach consumers, what is the highest priority area, what do most people feel would be the biggest bang for your buck, family history sort of rose to the top of that.

This is about genetic research. Should inform the public about their risks and benefits of participating in genetic research through national and local efforts. This is really calling out to the committee that was just formed, I think the Genetic Data Sharing Committee, whatever the name of it's going to be, Charmaine's committee, and I think we just talked about that last month, so that one's pretty self-evident, I think.

A couple recommendations apply across the group and this next one, Number 11, is a whopper. In consultation with several agencies, HHS should ensure funding of a national strategic planning mechanism for genetic and genomic education and training of the healthcare workforce.

This planning group should include various

individuals we often don't include on these governmental groups, individuals who are experts in the content and the educational needs of specific disciplines and experts outside of these traditional fields who are innovative thinkers regarding the incorporation and adoption of knowledge in a technology-explosive area while looking toward the future in genomics education.

So I'll leave it at that and say this is a large recommendation, but the tone of it, you can see, is to let's try something different. Let's form a group that maybe hasn't been formed before and pull together people who aren't usually sitting at the same table.

Next one is about faculty training and it crosses all groups because faculty, healthcare professional faculty as well as public health provider faculty, due to the identified shortage of clinical and public health educators with formal training in genetics, HHS should facilitate increased training for academic healthcare educators and an example is provided through HRSA training grants but there's other mechanisms.

Translation, of course, crosses all groups, should support research and assessment on development of

effective methods for translating science to healthcare professionals, public health providers, and consumers and patients.

This one might be seen or interpreted as a call for the redistribution of funds from basic science to translation science and that's it on the recommendations.

We also need to do a shout-out to prior SACGHS reports that address the educational needs and this is an area that was identified from the first SACGT meeting as a priority. So there's lots of reports that talked about it. As a matter of fact, almost every report that comes out of this group has one bullet point to increase genetic education and training among somebody.

So the three that we identified so clearly were the coverage and reimbursement report, oversight, and pharmacogenomics, and they all talk about education from different perspectives and we're sort of pulling together the specific recommendations from those to highlight those, and they're in the folder.

Okay. I think we have like about a half hour, something like that.

Committee Discussion of Draft Recommendations

DR. TEUTSCH: Yes. We have a half hour.

DR. McGRATH: Great.

DR. TEUTSCH: And as Barbara said, I think the important part is to go over these recommendations. How do we make them sharper, more actionable? I think, clearly, we make our recommendations to the Secretary. Some of these also talk about other groups that might do them, but I think we need to think about how we do those so that we get them addressed to both audiences.

But, Barbara, I would welcome that. It looks like you've got some, and Jim.

DR. McGRATH: Jim.

DR. EVANS: Great. So, Barbara, first of all, congratulations. This is a huge task and I know I've been rather preoccupied at patents but hopefully can reintegrate here.

One of the things I wanted to mention that might have gotten a little bit lost is -- two things. One is a discrete suggestion, the other is more nebulous.

In Recommendation 2, as somebody who teaches students and who teaches residents, I'm acutely aware of the fact that the formal didactic mechanisms we have for

teaching are woefully inadequate and people forget these things and I think it might be useful to have a sub-bullet or something along these lines.

Genomic education should be directly integrated into patient care when clinically useful and necessary to get at the issue of like just-in-time-type things. I think that when you look at the competing priorities that clinicians have, they very understandably don't do as much didactic stuff as we would like. That's a way of not only getting them educated at the right time when the patient will benefit, it also might be a way, and this leads into my nebulous comment, of addressing the fact that we do want to emphasize this education when it has been shown to be clinically useful.

I think that we can be easily criticized if we're not careful for trying to kind of sell genetics to the rest of medicine and when you look at the important comment on Slide 11 where one of the barriers is, a general sense of the utility of genetics is not clear to public health providers at this time, I think the same can be said for clinicians and it's valid, right.

We need to make sure we are advocating

education when it is clinically useful and not just to promote our own kind of --

DR. McGRATH: Can I think ask a follow-up question back to you? So the first one is about curriculum?

DR. EVANS: It is. I just don't like the word "curriculum" because what it evokes is the idea of sitting in class or sitting and taking a course.

What I would like to see is some emphasis that says how can we integrate this curriculum, if you will, into the practice of medicine where applicable, where useful.

DR. McGRATH: Right. And that's what I meant when I said curriculum. So this group and the Secretary of Health and Human Services, what is her role? What are we directly asking her to do with trying to take healthcare professionals' curriculum training to a different level to respond to that?

DR. EVANS: Yes. Other than saying we're asking her in that context to do the same thing that we would in all these other contexts, which are more didactic in their emphasis, I'm not sure.

DR. McGRATH: Okay. All right. Sam.

DR. NUSSBAUM: Barbara, I think these are a absolutely terrific set of broadly encompassing recommendations and to your point of making them more actionable and actually, Jim, building on yours of making these relevant, there's a whole process that's going forward in professional organizations of recertification and I know it's happening certainly in medicine, nursing professionals and others, and so one way of getting there is to actually encourage building these into the very real practice improvement modules. They're called PIMs, the American Board of Internal Medicine and others, and the way that this could be really focused is by recommending to the Secretary that she look at ways, innovative ways of reimbursement.

So, for example, if you successfully complete recertification with genetics and other training modules that you might even have as a composite, getting greater reimbursement for primary care and other areas. So I think it can be directly applicable through reimbursement as an incentive for those organizations to include these as learning laboratories.

I know it's in the detail, but I think unless those are built in, there will be so many competing activities, and I think, while you can begin to focus in the current curriculum for undergraduate education and graduate education, there's so much lifelong learning that needs to take place in the field that's rapidly advancing, this might be one of the ways of facilitating that.

DR. McGRATH: That's an interesting idea. Thanks.

DR. AMOS: I just have one of these silly naive questions that I always ask. I just was curious. I mean how do insurance companies get their information? I mean in the spirit of healthcare reform and that's what everybody's talking about, I mean, I know they have people that do that, but is there a role for HHS to interact closer with the private insurance companies to provide them with better, more useful information, considering the fact that reimbursement does drive adoption?

DR. McGRATH: That's a group, when we first were tasked with what groups, what our focus should be,

that was a group that was called out as well as healthcare administrators, clergy, judges, various other groups that we know have a very important role in all of this, but we did have to draw a line in the sand some place and say that's for the next task force to do.

So I don't know how to answer that question, how they get their information. I guess we all sort know how they do, but I don't think that's within the purview of us looking at that here, though. It certainly absolutely has an impact and we do have a paragraph written about that we define the group this way, but we recognize that other groups have an impact on all of these topics. That would be one I would say.

MS. LLOYD-PURYEAR: The Secretary's Advisory Committee on Heritable Disorders is also sending forward a recommendation concerning primary care education specifically. They focus on primary care providers since those providers are pivotal in educating about newborn screening.

I would be glad to share that recommendation. It is very specific.

DR. McGRATH: Thank you. That'd be perfect.

We need that.

Sheila.

MS. WALCOFF: I was just going to follow on to Sam's comment, and I would say if we're going to suggest any funding, I think that trying to integrate into the resource use some sorts of incentives is a really good idea rather than funding more committees because I think there's an opportunity to tuck some of that stuff into existing work that's already being done at CDC and other agencies and then look for more specific ways to directly impact the objective of the recommendation. So I think that's a good idea.

I don't know exactly how that would be done, but since there's so much debate and discussion going on, particularly depending on how health reform works itself out, that there might be some opportunities to incorporate some incentives in that regard as those are being redeveloped under new provisions that might be enacted.

DR. McGRATH: Muin.

DR. KHOURY: Barbara, first, I would like to compliment you for all the hard work that all three

groups have done and your leadership in this. I know I've been dropping in and out of the Public Health Group and just to see it in total, I guess it's sort of a lot of stuff in here.

I'm wondering, I mean I want to echo two things that I've heard from Jim Evans, from Michele and others, and also my own kind of agency-centric view, that when I get this at the end because I'm part of HHS, what will I do that I'm not doing now? That's sort of what I'm thinking.

So, for example, Number 5, develop core competencies for public health providers. I think we've done that seven years ago. Are you directing me to do something that I didn't do? So, I mean, we have to be a bit more specific.

Assessing the public health workforce. That's Number 4. It's very crucial actually because, I mean, as you mentioned, Barbara, the heterogeneity of the public health workforce and their various needs, I mean, we have state epidemiologists who do disease outbreak investigations. Their needs for training in genetics are very different from the educators and the administrators

or the environmental health specialists or whatever, and we've tried to come up with that assessment over the years, although it's been incomplete. It's very hard.

The workforce is shifting and maybe we should work on this between now and January so that when we come back, those recommendations have to be a bit more crisp and rather than sort of like broad brush develop core competencies. I think that's good, but tell us more. I would like to see if we can do that together.

I like these creative multidisciplinary advisory panels, although I have no idea what it means, for healthcare professionals, but I suspect that it will be cross-cutting, involves public health and consumers, that Number 2, and maybe someone from that group can explain what that means a little bit more to me.

One additional comment on public understanding of genetic research, Number 10. I think we need more than just public understanding of genetic research. I think the word "understanding" implies that they are very passive recipients of information and what we need is more public involvement, public understanding in the way that they own the stuff, it's their genome, and maybe I'm

looking for a different word.

So I think this is great stuff here. I like the focus on family history because, as part of my public health adventures over the last 10 years, everywhere I went, people kept telling me, well, you have nothing to sell, except family history, which 10 years later I say, okay, okay, we'll sell that to you, but that's fine. So it's a good thing.

So, I mean, forgive me for my wide-ranging musings right now, but I think this is the beginning of something that could be focused, targeted, and by putting the three together, I think we're going to find more points of synergy, and coming back to Michele's earlier point about providers and primary care, because, I mean, the healthcare providers are not all the same and I think talking to the specialists is one thing who are more in tune with genetics, but the primary care providers are more like public health professionals or more like lay audiences in some sense, and I think those need to be pieced out of the healthcare professional morass and dealt with in a much more comprehensive way.

Thank you.

DR. McGRATH: Thanks. I would like to follow up on a couple of those, just the last one. The emphasis of the first group was really on primary care providers, although there is some data on specialists, but we've followed that suggestion. So we're really looking at sort of point of care as how we define that group. So it is heavily a primary care orientation.

But I wanted to follow up on the idea of the panels, advisory panels or groups kind of in response also to Sheila's comment, but before that, Sylvia, I wondered whether you could help us understand the point that Muin just made on the core competencies, that they have already been done seven years ago.

Is there something different that you think needs to be done in terms of core competencies for the public health workforce around genetic competencies?

MS. AU: I don't think something different needs to be done and, yes, I think that it just pretty much reinforced that those were the same competencies that the public health workforce needed. It's just that when they were done then, nothing happened. We've just reinforced that they still need to be done and maybe our

recommendation needs to be what we should be doing or how we should be moving this forward because obviously it's been seven years.

We've reinforced that the competencies are still relevant, except we've condensed them down to 12.

DR. KHOURY: Maybe you can sharpen the recommendation, rather than just developing but more applying, recommending.

MS. AU: We can sharpen the recommendation.

DR. McGRATH: That's perfect. Thanks for that. Marc.

DR. WILLIAMS: I just wanted to make specific and hopefully tie together some of the comments that have been made.

In my view, the most important aspect of what we're putting forward here is to try and get outside of the traditional educational thinking box and really figure out how to do something innovative because, as I view this, not being a professional educator, the real disconnect is that we seem to have this, as Jim might phrase it, this curriculum that we present at some point for a certain amount of time to our various groups,

whether they be public health professionals or physicians or other providers, and then we say go forth and be knowledgeable and then when they encounter the clinical world, whether it's as a third year medical student or as a public health person doing an internship or whatever, they get no exposure to it because the generation of folks that are out there in practice aren't incorporating that in their practice and we know that it's that type of modeling when you're actually in the clinical environment that actually builds your life-long practice patterns.

And so it's really an idea of how do we -- one could argue that perhaps this is just something that will fix itself in 20 years because, just as we have now a group of physician trainees that are coming in that are very computer savvy, so we think that the electronic health record problem will probably get better as they get into practice, maybe this will be the same issue, but I would argue that that's a gap that's probably not reasonable to allow to happen.

So how do we get this into that clinical training so that people can see the relevance of this for those purposes where we do have good evidence so they can

begin to think about it and then, once they're in a post-training environment, how can we leverage the things that we're now developing through the electronic health records and that, so that we can provide information to them that they can incorporate on a regular basis?

You know, for me, of all the recommendations, it's trying to develop a group that is going to have a very different perspective and take a very different approach to this because I think we are suffering from the thing. We've been talking about this for a very long time, yet arguably we haven't made any progress, and as Einstein said, you know, a definition of insanity is doing the same things over and over again expecting different results.

DR. McGRATH: That came through so strongly throughout all of these. The hard thing is how because what you've just outlined is you've got different organizations. Primary care providers are lots of disciplines. You've got undergraduate training. You've got clinical training. You've got postgraduate training and then you've got licensure certification. So you've got lots of bodies involved and so one suggestion, I

think that big one at the end is talking about forming the walking on water advisory board.

Is that the best way to implement change, to push ideas like that forward? I don't know how to, beyond saying this should happen; what is the way.

DR. WILLIAMS: Well, I think the other thing that could potentially be under the Secretary's discretion would be inasmuch as there are some monies that are directed towards evaluating health professional education, that if we could develop some -- I think this is an area that in the innovation world would be described as needing slack resources and what I mean by that is that you need to have a place where innovators can take nutty ideas and try them out and the problem is, is that when we run nutty ideas through a traditional vetting process, everybody says that's a nutty idea, we're not going to fund that.

So we need to have some space and have some resources where people can really explore dramatically unconventional ways to do this, expecting that there's going to be a relatively high failure rate, but that there may in fact be a few things that emerge from that

that are really quite unique and important, and at least in industry, that type of a model is a great germination field for innovation, but it's something that we don't have the room to do for the most part. We don't have room in most curricula to be able to set aside a space for craziness.

DR. McGRATH: Thanks. Be way fun. David.

DR. DALE: I'll just make one comment. There's a very good group that's, I think, engaged through the Institute of Medicine and some other sponsors in health literacy where they have tried to tease apart the levels of education and the specifics for helping people to understand their prescription bottle or the specific terms related to their illness, acknowledging the low general level of education of our population, and I think it would be a practical suggestion to engage with them in terms of where are we and what do people know if you say DNA and so on.

The other comment I would make in follow-up to Marc is I think it would be constructive to encourage the Secretary to engage in defining areas of success and education of practitioners as modeling for success.

An example would be anti-coagulation for people with atrial fibrillation. That's become a standard of practice and another would be beta blockers after myocardial infarction, a standard of practice. So many organizations try to achieve high levels of compliance with those specific recommendations. So that's guidelines at a high level that can be taken forward in terms of practice evaluation.

And to dig deeper is to encourage the Secretary to provide the funds and the modeling to find the specific ways, as Jim points out, where it makes a difference.

DR. McGRATH: Great suggestion. Julio.

DR. LICINIO: I just have a comment that ties with what is being discussed here with what was discussed before, that some years back, I did a whole bunch of community engagement in L.A. with Mexican Americans and one thing that came out that became very obvious and actually I had to be funded for that eventually is that it's very hard to engage a community in an area that they know nothing about.

So it's necessary to really do education and

training in parallel with engagement because, yes, it can take a very like ethnograph position and say like what do they understand, what do they want to know, what the questions are, but if they really don't have the background knowledge, the engagement process is very difficult.

So I think that there could be some effort to tie the two things together, especially since we are discussing them both here, but establish some kind of connection between the two.

DR. McGRATH: Rochelle.

MS. DREYFUSS: Thank you. I'm sure it's widely naive, but just to follow up on Julio's question.

DR. McGRATH: I doubt it.

MS. DREYFUSS: I think for a large segment of the population, what they know about DNA is forensic DNA. I mean, they know they might be identified as a suspect in a crime, and I wonder if there's any way to build on some of the things that they do in the juvenile justice system to help bring more understanding of genetics to young people.

DR. McGRATH: I know there's a lot of talk

about the CSI knowledge that a lot of people are getting. We've been talking about that.

Do you want to address this? Okay. Great. Michele.

MS. LLOYD-PURYEAR: Well, actually, you bring up, I think, a very important point about genetics education in general, and I think an analogy could be HIV/AIDS education.

The government did make a big effort during that time period to focus on health profession and public education around HIV/AIDS, but the key here was that it had to be -- it was needed, that knowledge was needed. It was being incorporated into every-day practice. It was a need for the public to understand and so your point about focusing on something that's tangible, that can be used, I think, is very important, and I think, with the recommendations, and it goes back to what Muin, I think, was saying, what are you asking anyone to do right now? Is genetics or genomics ready to be used by primary care providers? Is that perhaps the problem?

When we, with NIH and AHRQ, began the Genetics in Primary Care Project in 1999, there was a great deal

of enthusiasm, but what was wrong with it is that there was nothing that -- very little primary care providers could do with that knowledge in every-day practice, and I think that's still an issue and my advice actually would be to focus on public education, that is a big gap, and family history, I mean really to go out towards that area because it's tangible and it is part of every-day practice.

DR. McGRATH: I think you're responding to something that we found in the literature as well as from our surveys, is that there's a question about how much does the public need to know, and if you divide them into two groups, seekers of knowledge, if you have a condition or for some reason you're interested in something, there's access for that. People are getting that on the Internet. They can go to their provider, if they have one, or whatever.

But the other question is what does the public know and is it even important for the public to understand DNA structure and GWAS studies or is it more the downstream how that is going to affect them and that's why family history rose to the top. Is that

something that people can do something with right away?

Sort of following on the idea that lots of us follow practices without understanding the science of it. Most people take their cholesterol drugs aren't really understanding exactly the whole notion of placque formation. Does that matter or is it just more important for them to know their family history of cardiovascular disease and medication adherence?

So it's kind of an interesting question about we may want people to know lots of genetic information but competing for their attention about what is important for them in terms of public health, we have to be sort of wise about that, as well.

I was actually going to ask -- I saw Vence here earlier. Oh, there he is, hiding. Whether you wanted to speak to that notion of the public's literacy and that boundary of not being geno-centric but also recognizing there's a need for education as well as engagement.

DR. BONHAM: Thank you. I think the key issue that was raised through the data that we gathered was the need to be able to be informed to make good decisions and asking the right questions, not having a foundation, as

stated by Barbara, around the specific types of technologies but to be able to make informed decisions when you're at a time when you need information and the distinction that we did see between those that were seeking information, either because there was a genetic condition within their family or making decisions with regards to participating in direct-to-consumer genetic testing, and those that are the general public when they do need information, that they have enough knowledge to be able to ask the right questions and to seek out the information at that point in time.

DR. McGRATH: Perfect. I guess one more question. Thanks.

DR. AMOS: I just have a comment. I take my professional hat off and looking at all the information that comes out in the newspaper and in the popular press and every day, especially over the last three or four years, there's been this new gene that's been discovered and it's like drinking from a fire hose because all this information is coming out but yet it's so vague and where is it really going to happen and every report, it's like, oh, you know, the possible cure for this and possible

cure for that.

So I would really support the role of HHS as providing a real clearinghouse. It's very, very confusing for anyone, I think, to really understand the utility of this and certainly for families who have got genetic disorders or illness in their family, the resources are available and they're critical, but what is it live and Memorex? What should anybody be paying attention to is the critical question.

DR. GUTTMACHER: I would just like to pick up on the theme that Michele and some other people have been talking about, about the relative importance perhaps of public education versus professional education.

I have NHRI and I have personally been involved over the last decade in lots of different kinds of education in my field. We're equal opportunity education attempters or something, but I must say that I over the years have grown more and more of the view that health professions are such a practical lot. Give me something I can use tomorrow, I'm going to learn to use it.

Clearly, what we're trying to do here, and I think it's an important effort, is to make sure that we

don't waste this window of opportunity when we see these tools are about to arrive so that when they really do arrive, people are ready to use them, but there's only so much that can be done there.

I think efforts, like NCHPEG's efforts, I think, were wonderful. We should do everything we can to encourage and support those, et cetera. At the same time, I really do think it's the public education and creating greater genetic literacy across the landscape that's important.

I think of all the education efforts we've been involved in over the last decade. Probably if I had to choose one that I think is the most significant, it probably is really the Surgeon General's Family History Initiative and that web-based tool that lots of people in the room, Greg Downing particularly in the last few years, have been involved in furthering, that and electronic health records, et cetera.

But family history really does have a role for, I think, bringing the public into this. In some ways, I think to tackle this question, I would even provocatively say I guess we're advising the wrong Secretary, that the

agency that doesn't appear in this report that maybe we should think about encouraging the Secretary to talk to is the Department of Education, that if we really want to educate the public broadly about anything, how do you do that? You do it through the public school system in the United States, and there have been some inroads there, but I don't think we've paid nearly -- the genetics community, all of us, I'll make myself personally responsible here, we've not paid enough attention I think to that venue in some ways.

If we really want to try to educate the public broadly, that's the place to go, and we probably should be increasing efforts. Something new that this committee could, I think, help focus things on, everything that's in this, it's hard to argue against any of the mom and apple pie that's in here, but in terms of making some new added value, that might be a direction that we would want to encourage.

DR. McGRATH: Gwen, do you have one? And then I think we're done.

MS. DARIEN: I have something very quick to say which builds on Rochelle's comment and also builds on

what we said yesterday about GINA and the fear of the infringement of privacy, not being able to find a lot of privacy, and I think one of the issues we have to think about when we think about educating the public is the public's fear of what genetics will do and their association of DNA and all of this science with criminology through the media and so I think that that's something just to be aware of when we frame all of this because I think people -- I think that their DNA or their genetic information is going to be taken and used to do something that is detrimental to them, whether it's from a criminal standpoint or whether it's from a discrimination standpoint.

DR. McGRATH: Right. Well taken.

DR. BONHAM: Alan, the committee, the Public Education Consumers Committee, specifically stated that that would be extremely important if we could reach out to other Secretaries and to other agencies around genetics education for the public.

DR. TEUTSCH: Great. Lot of important information. I think some of the things I think we are going to need to take home is make sure that everybody

understands what the real need and what the real opportunities are at this point in time for genetics and how it fits in against all of those competing needs.

One thing I didn't hear from this discussion but builds on sort of how do you get information out and get it actionable gets back to the electronic medical record and the clinical decision support thing, to get people the information when they need it, and they need to have the skills to be able to understand that, but it's all part of the quality improvement processes that we've talked about, too.

So I think as we go through this report, I would like to see as clear an assessment as we can of what are the impacts of these recommendations because they're very broad and sometimes the priorities so that we can begin to help the Secretary make some choices which of these are likely to be most impactful and bring in the ex-officio members from education would be really helpful in this process because I think we've heard that they're going to be an important player in all of this.

So thank you, Barbara, for all your work and all your committee's work, and we'll look forward to

going through these in detail at the next meeting.

So let's go ahead and take a 15-minute break, and I'll make it 15 minutes because we've got a lot more to cover. We've got a lot of public comments. So we'll begin promptly in 15 minutes with the public comments, and I think most of you know you can get some coffee upstairs or go to one of the local dives.

[Recess.]

Public Comment Session

DR. TEUTSCH: Let's regroup here. We are going to proceed with our Public Comments. Folks, if I could get the Committee to re-form, we have a lot left to cover today.

So, as always, we provide a forum for the public to provide input into our deliberations and on the issues that we are discussing and should be discussing. Today, we have four presenters. So I would like to begin with Amy Miller from the Personalized Medicine Coalition.

Amy? Is she here? Amy, are you here? You're on. I'm going to hold each of you to a five-minute time limit because we are very constrained. So, Amy, you are welcome to speak from there or up here, whichever is your

pleasure.

As always, it's always good to hear from you. Welcome.

MS. MILLER: At the pleasure of the Committee. Do you want me here or at the other end?

DR. TEUTSCH: Whichever side pleases you.

Amy Miller

Personalized Medicine Coalition

MS. MILLER: My name is Amy Miller, and I'm the public policy director of the Personalized Medicine Coalition. The Personalized Medicine Coalition is an education and advocacy organization that promotes personalized medicine concepts and products for the benefit of patients.

Our members include patients, payer, provider, industrial, and academic organizations that are committed to improving the quality of healthcare through personalized medicine. I'm here to speak on our educational efforts, and will speak extemporaneously from here on out because it's better for everyone.

PMC organized a group of stakeholders to discuss an educational effort in consumer genomics. The

reason we did that is we noticed that consumer genomics was receiving more attention than any other personalized medicine product or company, and as an educational organization, we felt some responsibility to consumers that we help in that effort.

So we brought together a group of academics and geneticists, consumer genomics companies, and other interested parties to come up with some sort of consumer guide that wouldn't be biased against or for direct-to-consumer genetic testing services.

You have in your hand this guide, which is also available at our website, personalizedmedicinecoalition.org, and I wanted to make a few comments about it. It isn't a perfect document, we recognize that. We struggled with some of the terminology, and some of our members didn't like informational testing, but it's the best word we could come up with at the time.

Also, while we were developing this document, which we did with the help of Medco, a PBM that is starting a genetics-for-generics program, and they're getting a lot of interest from their consumers on these

products. So while I was walking down this road with Medco and developing this guide, it became very apparent that the government needs to do a guide like this.

I haven't read your draft recommendations, but I think there is definitely a role for a balanced guide that comes from the government to give really good health information that would have a far reach, farther than this document will have. I think this document is only going to people who are familiar with Medco, PMC, or consumer genomics companies.

Those are my prepared statements, but I can answer any questions if you would like.

DR. TEUTSCH: We have time for one or two questions for Amy.

[No response.]

DR. TEUTSCH: All right. Well, thanks for all your work.

MS. MILLER: Thank you.

DR. TEUTSCH: Our next speaker is Luisel Ricks -- I hope I pronounced that correctly -- from the National Human Genome Center at Howard [University] here in the city.

Welcome.

Luisel Ricks

National Human Genome Center

MS. RICKS: Good morning. My name again is Luisel Ricks, and I'm a research associate at the National Human Genome Center at Howard University, and also a postdoctoral fellow at the Howard University Cancer Center. We have actually worked on preparing this comment after being present at the last meeting.

Advances in the sciences and technologies emerging from the Human Genome Project have undoubtedly transformed the landscape of biomedical research and has propelled us to the frontiers of personalized medicine.

The translation of these advances, from bench to bedside, has resulted in the increased availability and utility of clinically based genetic tests as well as direct-to-consumer personal genome tests and scans. These DTC PG scans can examine as many as one million genetic variants, purportedly to provide information on genetic risk for a wide spectrum of chronic diseases and other inherited characteristics.

Several companies that offer these scans boast

the ability to predict risk of diseases such as cancer, cardiovascular disease, diabetes, among countless other diseases. These are the same diseases, which, in the U.S., have affected minorities at alarmingly higher rates than other members of the population.

Indeed, if these DTC personal genomic tests are valid and useful, these tools have the potential to eliminate the ethnic/racial disparities observed in these disease groups. However, if these tests are not being equitably utilized by all groups, they may become guilty of widening the health disparities gap. This context makes any issues related to the use of these direct-to-consumer tests in the minority population particularly deserving of special attention.

Perhaps one of the greatest indications of whether or not any technology will be utilized is the extent to which the intended consumers are aware of its existence. Presently, there is little data regarding the awareness and use of these scans among Americans, and even less is known about the awareness and the use of these tools in minority populations.

National health surveys, such as Health Styles,

the National Health Interview Survey, and the Behavioral Risk Factor Surveillance System, have evaluated questions about general awareness and use of genetic tests and personal genomic scans, in addition to media habits, interests, lifestyle, and health issues.

These surveys have all shown that ethnicity, education, and socioeconomic status significantly predicted personal genomic test awareness and use. Specifically, these surveys point out that African Americans and Hispanic Americans are less aware of these tests than Caucasian Americans.

Another potential barrier to the utility of these tests is access, in particular, affordability. According to the U.S. Census Bureau, in 2006, African Americans, American Indians and Alaska Natives, and Hispanic households earned less than 75 percent of what white households earned.

Furthermore, people from these communities experienced significantly higher rates of poverty. As a result, many racial and ethnic minorities would find it difficult to pay for the costs of these genetic tests and genome scans, making these tests only available to those

who can afford them. Therefore, by virtue of cost alone, these tests have the potential to exclude minority populations, thereby exacerbating inequalities in health and healthcare.

This challenge was summed up by William Folk of the Institute of Medicine, who said, "The challenge to public health genomics is to overcome inequitable allocation of benefits, the tragedy that would befall us if we made the promise of genetics only to those who could afford it and not for all of society."

I was present at the 19th Meeting of the Secretary's Advisory Committee on Genetics, Health, and Society, on June 11th and 12th, 2009, where I first heard the preliminary recommendations being made by the Task Force groups.

Most alarming was the report by the Consumer and Patient Workgroup, which has chosen to target information seekers for educational programs. Their charge, to provide recommendations that address the genetic education needs of consumers and patients, will be disadvantageous to ethnic minorities and the socioeconomically disadvantaged without a formal

awareness evaluation and assessment on who the information seekers truly are, although data from national surveys may have given us a clue as to the identity of these information seekers.

Given the differences reflected in the data, this may reveal potential pitfalls in the dissemination of information to a more diverse population, which can result in unequal allocation of benefits and inequities in public health programs whose goals are to provide patients and consumers with tools to enhance their genetic health literacy.

Conversely, the incomplete state of the science supporting genomic applications that exist provides the opportunity to improve public and healthcare provider educational efforts, monitor potential benefits and harms that occur from DTC genetic tests and MPG scans, and develop strategies to minimize the risks and maximize the benefits from DTC products as clinical validity and utility increases.

So there still remains a definite need to assess the public's awareness and use of these direct-to-consumer scans. A formal appraisal of direct-to-consumer

scan awareness and use will contribute to the knowledge base that will support the development and the dissemination of appropriate public health messages and educational materials for the general public and healthcare providers, as well as informing federal and state policy regarding these tests and scans.

Evaluation of stakeholder awareness is perhaps the most crucial aspect of public health and health policy as it provides a reference about general contextual knowledge. Ultimately, differences in awareness and use of DTC products could potentially dictate how diseases can be prevented, managed, and treated, and have critical healthcare implications, such as impeding efforts to eliminate health disparities.

I am happy to hear that President Obama has issued a directive to all federal agencies calling for greater transparency, public participation and collaboration which has resulted in a request for information of consumer health information interests and behaviors for seeking and using health information. I believe that this is an essential step that could identify who the information seekers truly are and how we

can make all Americans information seekers.

As we continue to apply these promising and life-changing technological advances in genetics and to realize the dream of personalized medicine, we need to ensure that these efforts, which promise to reduce or eliminate health disparities, is not guilty of widening the health disparities gap.

It is paramount, not only that we educate consumers and stakeholders to ensure awareness, but that policies are adopted to ensure affordability and equal access to genomic applications amongst all groups.

DR. TEUTSCH: Thank you. Important messages for us about disparities, something that we do care passionately about. So thank you.

The next speaker is Ted Rumel.

Ted, I'm going to ask you to speak from the front, because I understand that this microphone here doesn't do very well for our webcast.

Ted is with AUTM -- I think I've got it right -- the Association of University Technology Managers.

Welcome, Ted, and we look forward to what you have to share with us.

Ted Rumel

Association of University Technology Managers

MR. RUMEL: Good morning to you all. My name is Ted Rumel. I'm the vice president for Research Innovation and Commercialization at the University of Maryland's Biotechnology Institute.

I am here today representing the Association of University Technology Managers. As a personal note, I would just like to say it's good to see some familiar faces, here in the crowd, from my days in my career in the U.S. Public Health Service and in my 11 years in the Office of The Director of NIH as the assistant director for Technology Transfer.

We appreciate the opportunity to speak to you today. Our comments are on licensing and patenting recommendations that you discussed yesterday, and I understand will be continued to be discussed and worked on today.

AUTM is an organization of 3,500 members who work in universities, research institutes, teaching hospitals, government agencies, and companies around the globe. Their job is managing and licensing innovations

with the primary objective of making the innovations available to the public through commercial development and are strongly committed to the advancement of science and commercial development of important discoveries to improve the quality of life for people around the world.

As such, we believe we are uniquely positioned to provide insight into the management of intellectual property and licensing related to gene patents.

While we appreciate the level of research and analysis in the report, we cannot support the conclusions, primarily because they are derived from core assumptions -- there is a conflict between research and commercial application of research -- but also because the policy options outlined in the report are not connected to the research findings.

AUTM does not believe that there is an inherent conflict between commercialization and making innovations available to the public. We base this on the public benefits of licensing activity and rezoning products that come to the market. We do have some publications called "Better World Report" and "AUTM Licensing Activity Survey" that we would be pleased to provide copies to all

the members of the Committee so that you can see what those benefits have been.

Regarding policy options, AUTM is deeply concerned that the policy options in the report have no connection to the research findings and conclusions of the draft report, and rely on hints that harm might come one day.

We are concerned that, despite a statement in Chapter 5, the options will be perceived to be in correlation with the research findings with the potential to mislead the audience to construe that the recommendations are based on the results of the research.

Regarding the Bayh-Dole Act, licensing research outcomes is a complex process that requires flexibility. The elegance of the Bayh-Dole Act is that it has certain outcomes that are expected, that is, commercialization of research.

The way in which that is done is not prescriptive of any one approach. Individual technologies vary. They vary widely, and technology managers must have the freedom to determine the appropriate pathway to bring important technologies to

commercialization. No two transactions are the same.

The Bayh-Dole Act has worked well for 30 years and is now widely copied around the world as a successful practice. We strongly believe that there is no need for an executive order or legislative review to prescribe particular routes for making those developments available to the public.

With regard to march-in rights and modification of those, if this process and the criteria are modified, we are most concerned that investors and industry will be averse to investing hundreds of thousands of dollars, or even millions of dollars, to develop and commercialize these important technologies.

NIH, and my colleagues there, can provide you with data on the adverse effects from even a discussion of the possible changes to Bayh-Dole that have occurred in the interest in licensing federally funded research technologies.

With regard to regulations and oversight, requiring regulations for commercialization, patenting and licensing of genetic tests, is not supported by the research findings in the report, nor is this supported by

additional studies, conducted by British and Dutch researchers, recently presented at a workshop organized by Robert Koop Deegan, the author of the case studies in the report.

We believe there is no credible evidence that new regulations by federal agencies are needed to instruct universities how to effectively manage their inventions under the Bayh-Dole Act.

An additional comment is that the case studies in the report are over a decade old. There seems to be no effort to assess how licensing is now conducted in the field, and how it has evolved. There is no discussion of current practices that, at a minimum, mitigate many of the issues that were raised in the report. Tech transfer today is a very different process than it was 10 years ago, and is continuing to evolve.

In summary, before any substantial policy changes are considered, Secretary Sebelius, along with the U.S. public, must have an opportunity to consider all sides of the issue.

AUTM does not support additional regulations, the clarification of the USPTO role, or any statutory

changes to the Bayh-Dole Act. AUTM does recommend further data analysis and expert testimony be collected, on which appropriate policy options can be based. We recognize the concerns surrounding gene patents, and support additional guidelines to augment those developed by NIH and AUTM.

We are collaborating with the American College of Medical Genetics and the Association of American Medical Colleges to develop successful practices that reflect our collective learnings from 20 years of the genetics revolution. AUTM also would be pleased to participate in efforts for further research and testimony on this issue.

I thank you very much for your attention to our comments.

DR. TEUTSCH: Thank you again. We have the benefit, of course, of many of your colleagues in the public comments, and had extensive discussion yesterday. So unless there are some very specific questions today, I would suggest we move forward, and we will discuss that as we get back to the report this afternoon.

Our next speaker is Susan Polin, who is with

the Kennedy Institute of Ethics, here at Georgetown [University].

Welcome, Susan.

Susan Polin

Kennedy Institute of Ethics

MS. POLIN: My name is Susan Polin. I do work at Georgetown University, at the Kennedy Institute of Ethics, at what is currently called the National Reference Center for Bioethics Literature, which is funded by the National Institutes of Health, through the National Library of Medicine, through December.

We also have funding from the National Human Genome Research Institute. Recently, this fall, we got funding with the Qatar Foundation, over in the Middle East.

For Georgetown, what I do as a research associate is, I look for different things regarding bioethics and law, because I am a lawyer. However, I also spend some time working at the reference desk for the library every week.

My comments have to do with the family history and public education. I cannot agree with you more about

public education regarding family history. But, what is a family history? I can just hear people calling.

Certain groups, whether they are ethnic or political or religious, trace their histories, such as the Muslims to Mohammed, the Mormons, and I can't think of the third one, sorry, but that is a genealogy history.

You all were talking about family history. You knew what you meant, and I'm sure what you meant were the things I see in the journals with the little rounds and the squares, and the Xs through it, and who died of what, and who has what.

A family history could mean anything to the public. I really do think there needs to be a lot of work done on what is a family history: Is it a medical family history; is it a biological family history. Starting with that, let me give you some ideas about where the problems might be.

When my daughter was in kindergarten, and that's age five -- actually her age was four -- kids were told to draw out and count out how many members were in their family. That's how early awareness of the family starts on an individual level, at least locally. I'm

sure that can happen in other places at that level.

The other thing has to do with people who are at the other end of life, who are clearing out estates, such as my mother's, and I have tons of things, both photographs and writing, but nothing on my father's side. So there is an inequity in the balance. How far back do you go with the grief; what level; do you want to know where people lived, if they died of cancer, did they live in the city, did they not, such things like that; how much information do you need to know or want to know about people.

I'm sure you're going to say more information is better because I would. However, it is an individual, pointed thing. You take the child and the parent. You don't start with the tree going down, you go up from that person, and then I assume you look at siblings, offspring.

I don't know what people think of as the family history that you all think of, and I can see the public wondering, but there is a great opportunity as more people pass away, as the population ages, for people to pick up information as they are going through papers, not

at death but while they are weeding out things, plus there are also the children at the beginning age.

The problem will be that you're going to run into, with the advent of assistive technology for reproduction, families that either have secrets, such as in the past with adoption or artificial insemination, but people haven't talked to them about the fact that, yes, I am your gestational mother but I'm not your genetic mother. I know one family that has two kids out of three that way.

You're going to have people that don't want to talk about who the father is because the mother knows it was another man, and so there is a fine line between stepping on confidentiality and privacy.

I do think that the family history thing is important to know, that it's not just genetic but there is an environmental component in how far and how deep you need to go.

That's all I can tell you. Thank you.

DR. TEUTSCH: Thank you, Susan. We really appreciate that.

Our final presenter is Lisa Schlager.

Lisa, welcome.

Lisa Schlager is with FORCE, Facing Our Risk of Cancer at Howard.

Welcome. We look forward to what you have to say.

Lisa Schlager

FORCE, Howard University

MS. SCHLAGER: Good morning, members of the Committee.

Once again, I'm with FORCE, Facing Our Risk of Cancer at Howard.

My name is Lisa Schlager, and I'm an individual who has benefited from genetic testing. The knowledge that I carry a BRCA1 mutation has been a life-altering experience, and I feel that this important information has benefited me and my family; thus, I'm a strong advocate for responsible genetic testing.

If handled properly by a trained genetic counselor, genetic testing can help save lives, and to that end, I represent FORCE, which is a national non-profit organization whose mission is to improve the lives of individuals and families affected by hereditary breast

and ovarian cancer.

I'm here to follow up on the testimony presented, last year, to the Committee by Sue Friedman, our executive director, and to present our mounting concerns about the unrestricted marketing that has been used by genetic laboratories, specifically Myriad Genetics. I would like to share with you how these actions are impacting the members of our community.

As Sue Friedman testified last year, based on what we have witnessed, it is our opinion and belief that Myriad sales representatives discouraged doctors and other healthcare providers from referring patients to genetic experts.

In the past, Myriad has denied use of this strategy, and when presented with our concerns, their vice president of marketing dismissed them as the work of a few rogue marketing agents. However, in a recent publication, Myriad's CEO, Peter Meldrum, was quoted as saying that "the sales force at Myriad provides doctors with the tools to do counseling in-house, and as a result, physicians can bill the insurers directly."

The same report stated that "helping doctors to

set up genetic counseling services in their own practices is a priority for Myriad's sales team, which is currently 300 reps strong, ahead of direct-to-consumer efforts in a particular geographic region. The company has carried out DTC ads in the Northeast and the Midwest, and is continuing marketing efforts in the South. According to Meldrum, sales representatives educate doctors and nurses about who should be tested on the BRCA analysis and how to handle the patients' questions about genetic risk.

Also, the company's sales reps attempt to reach doctors and show them the DTC ads for BRCA analysis ahead of its television airing in a particular area so that they can be more prepared when the patients come to their offices with questions.

Now, having reviewed Myriad's education materials for healthcare professionals, we are very concerned that they only focus on the hereditary syndromes for which the lab markets tests. Unfortunately, we believe these materials are misleading, and in many cases they are the only information many healthcare providers, particularly those being targeted by the company, receive about cancer genetics.

This means that patients who might meet criteria for other hereditary syndromes for which Myriad does not test, are not always receiving comprehensive or accurate information because their healthcare providers are not genetics experts and are unaware of the other syndromes.

By encouraging healthcare providers with limited genetics expertise to provide in-house counseling and to order testing, it's our opinion that Myriad is establishing a minimum competency for providing genetic information to patients, which falls below published national expert guidelines.

The lab is establishing a body of healthcare providers who, rather than practicing medical genetics, are trained to market BRCA testing for the company that manufactures the test. They have also begun to train a body of patients who have undergone genetic testing to act as patient advocates and to speak out in favor of genetic testing on Myriad's behalf.

Unchecked and unregulated, Myriad has unrestricted access to providing consumers, both directly and through their healthcare providers, with unbalanced,

biased information about genetic testing for hereditary cancers.

We have heard from healthcare providers, untrained in genetics, who admit that they have consulted with Myriad's staff when determining the appropriateness of genetic testing, rather than consulting with the genetics expert unaffiliated with the lab.

We feel that this is a clear conflict of interest. Consulting with a company employee is not the same as referring the patient to a specialist. This is another way that the genetic counseling process that is a national standard of care is being bypassed.

Following up on last year's testimony, we are continuing to hear from people who have been tested without the benefit of genetic counseling and receive results from doctors or nurses who have no understanding of the significance of the test results.

We are also learning of many incorrect or inappropriate tests ordered at a significant expense to the consumer or their insurance company. In some cases, tests are being ordered without insurance company pre-approval, and individuals later learn that they do not

meet insurance criteria after they have already paid for the testing.

Recently, a patient who received incorrect information from a healthcare provider posted her experience on the FORCE website. This woman and two of her siblings received genetic testing through a breast surgeon who was untrained in genetics. She received her BRCA test kit from Myriad. The individuals were not offered, and did not receive, prior genetic counseling. All three were told that the BRCA test result was positive.

This particular woman, considering herself at high risk for breast and ovarian cancer, had her healthy ovaries removed which is the standard recommendation now for women over 40 who carry a BRCA mutation. However, a relative in another city went to have genetic testing for the same mutation and was referred to a genetics counselor, who reviewed our original member's test results and determined that in fact her results were not positive. In this case, the misinformation resulted in an unnecessary and irreversible surgery.

Further, between the woman and her siblings,

because the result was a variant, only one of the tests was really necessary. In this instance, and undoubtedly in many others, circumventing counseling before testing created additional revenue for the lab and led to unnecessary cost for the individual and her insurance company.

Since no regulatory body monitors or regulates the marketing of these tests through CLIA-approved labs, and no entity documents reports of adverse events, we really have no way of knowing just how many people are harmed every day by inappropriate genetic testing.

Although the cases involving unnecessary surgery might be extreme, based on the accounts we are receiving, we believe individuals who are receiving genetic testing without counseling may experience some degree of emotional or physical harm, and well-meaning healthcare providers are being placed at risk for malpractice. Standard medical practice calls for a referral to a specialist when expertise is required.

DR. TEUTSCH: Lisa, can we get you to come to a conclusion? Thank you.

MS. SCHLAGER: Sure. Basically, if you have a

cardiac problem, you're going to see a cardiologist. If you have an eye problem, you're going to see an ophthalmologist. It makes sense that somebody who needs genetic testing should have genetic counseling.

So, basically, we feel that Myriad has justified their marketing, claiming there is a shortage of genetics specialists, which we disagree with, and we're seeing a rise in inappropriate testing.

We urge the Secretary's Committee to recommend federal action to monitor, regulate, and track adverse events resulting from marketing by laboratories to consumers and healthcare professionals, and to require doctors to know about and inform patients about standard of care genetic counseling prior to ordering genetic tests.

DR. KANIS: I just wanted to thank you and tell you that your experience is not an isolated one, that we've seen very similar things in our practice.

MS. SCHLAGER: Good to know.

DR. TEUTSCH: Liz.

DR. MANSFIELD: I also would like to say that, even though FDA clearly isn't regulating Myriad at the

moment, anyone who has suffered an adverse event may report it to the FDA, may complain about such a laboratory. I'm not picking on Myriad in particular, but any other laboratory that is offering their own tests may report that to FDA, and we have the possibility of taking action.

DR. TEUTSCH: I would say even beyond "may," they should, because that is the only way that you become aware of all these things and can take action.

DR. MANSFIELD: Right.

DR. TEUTSCH: Thank you for bringing that to our attention.

DR. BILLINGS: Excuse me.

DR. TEUTSCH: I'm sorry. Paul.

DR. BILLINGS: Steve, this is a rather serious discussion, and so I think we are obligated to have Myriad, or at least invite Myriad, to respond since these kinds of allegations and representations are rather significant, it seems to me.

DR. TEUTSCH: Always happy to hear from them. Hopefully, they're listening.

DR. BILLINGS: I think we should make them

aware of it.

DR. TEUTSCH: That's fair enough. We can do so.

So after that sobering tale, let's move on to the topic of Direct-to-Consumer Testing. As you know, Sylvia Au and her committee have been working long and hard on a draft paper on testing which makes a number of recommendations. They have incorporated a substantial amount of revisions and have produced a paper, which all of you have. We need to go over those recommendations and finalize the report.

So to accomplish that, we will turn it over to Sylvia to lead the discussion.

Thanks for all your work on this, Sylvia.

Presentation of Revised Draft Paper on Direct-to-Consumer Genetic Testing

Sylvia Au, M.S., CGC, SACGHS Member

MS. AU: You're welcome. The paper is under Tab Track 7, in case you haven't read it. So here we are again. I thought we were done with this in June.

We are going to go over the Direct-to-Consumer Genetic Testing Paper, and hopefully finalize our

recommendations that will go forward to the Secretary. Finalize the paper, actually, because the recommendations are old recommendations that we have.

I would first like to begin by thanking the Task Force -- we had, definitely, broad-based representation -- and thank the new members that joined us in June to help us with our revisions.

For today, our session goals are to come to consensus on the key areas for the Secretary's attention, of course, look again at the prior SACGHS recommendations and action steps that would be aimed at direct-to-consumer genetic testing, and look at any remaining concerns that may require additional action by the Committee, and approve the paper for transmission to the Secretary of HHS.

As background, if you have forgotten, we started this in March, and based on Barbara's analogy of lifespan, and Jim's being here, and Barbara's as a teenager, I would say we are probably a senior citizen and we are near retirement. We had a really fast growth spurt, though.

We started in March of this year to develop the

short-term task force, because direct-to-consumer genetic testing was becoming quite a big area, and quite an area within the media. Cathy and I have been dealing with new information coming to us almost on a daily basis. I'm getting e-mails from Cathy saying, did you see that, did you see this. There was just some call for oversight in a JAMA article two days ago, I think.

So the objectives of the paper are to outline the benefits and concerns related to direct-to-consumer genetic testing, highlight our prior SACGHS recommendations that address these concerns, and identify issues that are probably not adequately addressed by our prior recommendations.

In June, we did have a draft paper and discussion and at that point. The Committee decided that we needed to go back and create an executive summary of our 29-, I believe, page paper, at that point, which we thought was about the size of an executive summary of some of our reports, and make our specific action steps from the prior SACGHS recommendations more relevant to direct-to-consumer genetic testing.

I want to turn to Sarah Botha, who is going to

talk to us about some relevant information, that came up as we were preparing this session, about some action that FTC has taken against two companies that were offering direct-to-consumer genetic testing.

MS. BOTHA: Thank you, Sylvia. I'm going to provide a bit of information -- I think the letters have been made available -- on two letters that FTC staff sent out on August 14th, closing investigations of two neutrogenetic companies, Sciona, Inc., and Genelex Corporation.

Sciona was a manufacturer, processor, and marketer of neutrogenetic testing. It's a test kit and consultation service called the MyCellf Program or the Cellf Test. Then, Genelex Corporation was a distributor of that test, so it didn't actually conduct the testing itself. It marketed and distributed the test and forwarded test samples on to Sciona for processing.

Genelex also markets its own tests that include ancestry testing and paternity testing. So it is otherwise engaged in direct-to-consumer testing.

The MyCellF Program included a cheek swab, as well as a lifestyle questionnaire that consumers would

submit. Approximately two dozen SNPs were tested, looking at five health areas, including heart health, bone health, inflammation health.

Consumers would receive a report back based on a combination of an examination of their DNA and their lifestyle questionnaire that would provide them with recommendations for diet and lifestyle choices, and there was no involvement of a physician throughout the process.

Both of the companies made virtually identical marketing claims and the ones that we were concerned with were claims that the diet and lifestyle recommendations that were given as part of the program could significantly impact consumers' health outcomes, including their risk of developing serious diseases. There were both expressed and implied claims relating to that.

There was also claims that having a neutrogenetic test could help you lose weight and keep off the weight which was kind of just a side component of the marketing, but it was a claim that we thought was unsubstantiated.

We were concerned that the scientific evidence

did not support the claims. We consulted with staff at FDA and some other experts and evaluated a large amount of clinical studies related to the particular SNPs at issue and the consensus of our experts were just that the studies at this point did not establish use of SNPs as clinically significant and so we were talking to the company, both companies about our concerns.

The weight loss study, by the way, was actually sponsored by Sciona and there were a number of flaws, including it wasn't placebo-controlled or blinded.

So the advice given by both companies, we thought, was pretty standard to diet and lifestyle recommendations that the general population receives and should receive, quit smoking, exercise, eat right, and we were concerned that there was a suggestion, a strong claim being, that for the people who had these particular genetic variations, that these interventions being recommended could impact their health outcomes more than it would have an impact on just an ordinary consumer.

So Genelex, during the course of our investigation, agreed to stop marketing neutrogenetic tests all together. So they took down their advertising

on their website for the MyCellF Program and also represented to us that they don't have any intention in the future of engaging in neutrogenetic testing.

Sciona actually has ceased operations and went into state bankruptcy proceedings and so they also agreed obviously not to market the product anymore.

We also had consent of Sciona, since they were the company that was processing the test kit, about some of the consumer privacy issues. Sciona made pretty strong confidentiality representations to their consumers through a consent form when they collected the DNA sample and the lifestyle questionnaire and we wanted to be sure that they were complying, following through with the promises that they made to consumers.

So we conferred with them about this quite a lot and they assured us that they had destroyed the consumers' DNA samples. That was one of the things they promised to the consumers in the consent form, that they would destroy the DNA sample after the testing was done.

They also have destroyed all of the lifestyle questionnaires and the reports that they provided to their consumers. They've also purged their databases of

their consumer personal information, names, addresses, other contact information. So they won't, as part of the sale of the assets of the company, they will not be selling any consumer information.

The only thing that Sciona retained were some individual SNP data that they were using to demonstrate the quality assurance of the instrumentation in their laboratory. They are selling some of their lab equipment and they represented to us that in order to maintain certification of their laboratories, they needed some of this data, and it would not be in any way traceable to individual consumers.

DR. BILLINGS: Do you have any sense of how many consumers were serviced by Genelex or Sciona?

MS. BOTHA: I'm not sure that I could disclose that information. These investigations are public to the sense that we are providing information that we conducted the investigations and why we've closed them, but that is probably proprietary information that I don't think I can disclose.

MS. AU: Is it because they had such strong confidentiality agreements with their consumers that you

could take some enforcement action if they weren't going to destroy the data and if other companies didn't have similar strong confidentiality agreements or some other type of agreement, there would be no enforcement action by a federal agency?

MS. BOTHA: Well, that's a good question. From the FTC's point of view, I can't speak to other federal agencies, but we are very concerned with consumer privacy generally. We have a Division of Privacy and Identity Protection and generally the position that we take is that it could be a deceptive or unfair practice by a business if it makes representations to consumers about how they'll be handling consumer information and it does not follow through with the representations that it made.

So from our point of view, it certainly was easier to put pressure on the company because they had made strong confidentiality promises.

DR. EVANS: So that kind of has some frightening implications for how to get around that, right?

MS. BOTHA: Well, obviously, I can't speak hypothetically to the company that didn't follow the same

practices, but, I mean, it could be a question that consumers -- there's always a question do consumers have expectation when they're providing medical data that it's going to be handled in a particular way?

I'm not saying that we definitely couldn't have asked Sciona to take these steps if they hadn't made the decision.

DR. EVANS: But it might have been a little more difficult to do so?

MS. BOTHA: Possibly, although, I mean, I don't think that they wanted to deal with enforcement action at that point.

DR. NUSSBAUM: You're also describing action against two companies. I imagine that there is a further investigation in the area. Is that something you can speak to?

MS. BOTHA: I can't disclose whether or not we have other investigations ongoing. Certainly, we're keeping aware of what is going on in the marketplace and, as I said, we coordinated with FDA on this investigation and certainly intend to keep communications open between the agencies.

MS. AU: Thank you very much, Sarah. So getting back to our paper, so again, the intent of this paper was to recognize that some -- well, okay. The intent of this paper.

We recognize that some concerns of this direct-to-consumer genetic testing paper are not unique to direct-to-consumer genetic testing, but apply broadly to provider-based laboratory testing.

We also do identify some issues that may be unique to direct-to-consumer genetic testing, if a consumer's personal health provider's not involved in the health decisions or government regulations do not adequately protect people who are getting direct-to-consumer genetic services.

We added an executive summary, as suggested by the committee, and I'm sure all of you have read the executive summary, digested it, love it. It does highlight three key areas for the Secretary's attention and five specific action steps.

So the first key area for attention is that there may be gaps in the federal oversight of direct-to-consumer genetic testing, particularly in the absence of

review of direct-to-consumer genetic testing promotional materials and claims by the FDA due to limitations under current regulatory practices and lack of evidence of clinical validity and utility for most health-related direct-to-consumer tests.

Now, I know that if you read the paper, one of the things is we call them health-related direct-to-consumer tests. That's our interpretation of them. A lot of the companies in their disclaimers of their results say that this is not health-related information. So there is a difference between what we call the tests and what the company might call the test.

The other area of attention is that there might be gaps in privacy and research protections for consumers utilizing the direct-to-consumer genetic testing because most of these are private companies and don't take federal money and so federal regulations may not apply to companies offering direct-to-consumer testing and state-level protections may be inadequate.

As our speakers yesterday talked about GINA and HIPAA, I think that those are some of the things that we're looking at, that GINA and HIPAA may not apply to

some of these companies doing direct-to-consumer genetic testing.

The third area of concern, this is the one that I call the blind leading the blind because there's a little disconnect in here, that there's insignificant knowledge about genetics among the consumers and healthcare providers, as we discussed this morning about the education of healthcare providers, and there's a limited involvement of the consumer's personal healthcare provider in providing assistance to consumers who are selecting genetic tests and making their healthcare decisions based on direct-to-consumer genetic test results.

And I think what is going to happen is Jim has actually come up with some suggestions on how we might be able to parse this out so it doesn't seem like we're in one part saying that healthcare providers have insignificant knowledge and then the other part saying that they need to lead their patients in selecting genetic tests.

DR. EVANS: So what we were thinking about, since that did seem to be somewhat confusing, would be to

split this into three bullets.

The first bullet would note that insufficient knowledge among consumers and providers exists. The second bullet would address the issue of there oftentimes being little involvement of the provider of the service, that is, for example, the DTC lab in informing the client about the implications of the test results. And then, three, that there's little involvement of medical providers in general, within parenthesis, that says, for example, see Bullet 1, to indicate this is a circular problem and needs to be attacked as a whole, something along those lines.

MS. AU: So does anyone have any comments about the key areas for attention or the change in this last one?

[No response.]

MS. AU: Great. So I think comments will probably come about our recommendations.

So when we looked at our prior SACGHS recommendations from the many, many reports that we've done, we found that there were nine prior SACGHS recommendations that could apply to some of the concerns

with direct-to-consumer genetic testing.

They would address concerns related to oversight gaps, definitely, marketing claims, promotional materials, analytical validity, clinical validity, clinical utility, standardization, privacy, and, of course, our favorite, consumer and provider education.

So the action steps that we're proposing is that -- and I want to thank Sheila, who stepped out of the room, she'll be back later, for helping us redraft the action steps because we wanted to make them more focused on direct-to-consumer genetic testing.

So based on our prior recommendations, SACGHS is proposing the following actions to the Secretary of HHS to address the gaps and inconsistencies in federal regulations and to accelerate coordination of programs that facilitate comprehensive and consistent consumer and healthcare provider genetics education.

So in order to do that, direct the FDA Commissioner and CMS Administrator to solicit broad stakeholder input through a series of public hearings, then convene jointly to draft and publish an advanced notice of proposed rulemaking that (1) analyzes gaps,

inconsistencies, and duplications in regulations related to direct-to-consumer genetic testing and (2) identifies specific proposals to address them within relevant statutory authority.

I know you guys are going to recognize these because they're just a little bit reworded from our prior recommendations to make them more fit this report.

The second bullet is include laboratories that provide direct-to-consumer genetic testing and services, if HHS establishes a laboratory registry. That's that registry under the oversight report that we talked about.

Now, convene a joint HHS-FTC task force, I love we're convening another task force, with industry, consumer, academic, and government stakeholders to propose specific guidelines for direct-to-consumer genetic testing, advertising, promotion, and claims consistent with existing statutory authority.

The task force should also identify gaps in the authority relevant to the mergent industry. These guidelines, which will form the basis of a more targeted federal enforcement of claims that are misleading and/or not truthful, should be grounded in evolving evidence

standards which are accepted by experts in relevant fields for identifying and evaluating competent and reliable scientific evidence of a direct-to-consumer genetic test performance consistent with the claims made by direct-to-consumer companies related to these tests.

In the spirit of our long recommendations, we'll have another long one.

Direct the HHS Office for Civil Rights, with support from the Office for Human Research Protections and other relevant HHS agencies, to identify specific gaps in state and federal privacy protections for personal health information that may be generated through direct-to-consumer genetic testing and propose to the Secretary specific strategies the Federal Government can undertake consistent with its existing authority to address these gaps and inform consumers of potential risks to privacy.

The next one. Develop an initiative within the Office of The Assistant Secretary for Planning and Evaluation focused on genetics education, including information specific to direct-to-consumer genetic testing and links to HHS educational resources for

consumers and health practitioners.

ASPE should also follow up its March 2009 report, "Consumer Use of Computerized Applications to Address Health and Healthcare Needs by Conducting Research and Evaluating Studies Specific to Direct-to-Consumer Genetic Testing, Developing Policy Analyses, and Estimating the Costs and Benefits of Policy Alternatives and Potential Regulations Under Consideration by HHS."

The following concerns may benefit from more evaluation by SACGHS and appropriate federal agencies. Now, these are recognized in our paper but we do not have prior recommendations that address these areas and the committee might want to look at addressing these areas in whole or some of the issues.

Non-consensual testing. That's the testing that we had talked about where the person getting tested hasn't consented to be tested, stealth paternity testing, things like that.

Limited data on the psychosocial impact of direct-to-consumer genetic testing. We had discussed that in the June meeting.

Impact of direct-to-consumer genetic testing in

children and minors. We had discussed that, too, in June.

Potential exacerbation of health disparities, one group getting tested because they have funds to pay for the testing, other groups not having funds to pay for the testing.

Inadequate protection of research use of specimens and data derived from specimens. We had discussed this because companies that have these samples and data might not fall under the federal regulations for privacy protections. Also, what happens when these companies are sold or go bankruptcy?

Impact of direct-to-consumer testing on the healthcare system is a big issue because how does the whole direct-to-consumer testing work in this healthcare system of people bringing in test results and ordering their own tests.

So what we would like to do today, of course, is finalize the direct-to-consumer paper. We want to know are there any significant issues or action steps that are missing from the paper, is the paper approved for transmission to the Secretary, and what, if any,

additional actions are warranted for issues that have not been addressed by our prior SACGHS recommendations, and I guess with that, what is the priority of addressing these issues separately or within other reports and studies that we're doing?

So with that, I think we'll open it up to discussion by the committee.

Paul.

Committee Discussion/Decisions: Direct-to-Consumer Genetic Testing

DR. BILLINGS: Thank you. Sylvia, I think you did an absolutely masterful job in this task, which was complicated, and so I want to commend you personally, and your committee, for the job you did.

I'm curious about the recommendation that calls for a new task force to look at the gaps and so forth. To what extent does that recommendation extend our previous oversight recommendations for genetic testing, in general? And if FDA, for instance, decides that this whole area is under their regulatory control, will we still need that task force?

MS. AU: Well, I guess that depends on if FDA

is going to tell us that they are deciding it's all under their control.

DR. MANSFIELD: All I can say from the information that we have about most of the direct-to-consumer tests, is that they would fall under the rubric of medical device. Therefore, FDA does have authority.

As you know, that doesn't mean that FDA does premarket review or postmarket control. So I would say that it's possible -- I mean, I don't want to tell you that it's true, but you should discuss this. Given that, do the previous recommendations from the oversight report apply or not?

MS. AU: I think that was one of the problems with making these recommendations more focused on direct-to-consumer genetic testing as recommended by the committee last time, was that at the beginning of this report, one of the goals was to highlight previous recommendations so that the new Secretary could take those recommendations in a new light and with that recommendation, I think we were looking at it as broadly genetic testing with DTC thrown in.

The way the wording has changed now because the

committee had decided that we should be more specific to direct-to-consumer genetic testing, it really does make it so it seems like it is a separate task force that would be developed.

Yes, Marc.

DR. WILLIAMS: The question that I would have that would, I think, be relevant to this is the thing that is missing from the previous oversight report, which is the role of the Federal Trade Commission relating to claims and that's the piece that I don't understand, is whether, assuming that FDA does take some ownership of this, whether that ownership would extend to these claims or whether that would remain under the purview of the Federal Trade Commission.

If it's the latter, then I think having a joint task force would probably be a valuable thing because that does fall outside the realm of what we previously recommended. If that's something that would fall completely within the purview of the FDA, then perhaps it's not necessary to do that.

DR. BILLINGS: My question was simply to say if

the current authorities will provide oversight, then we don't need another joint HHS-FTC task force. If they don't, then we might and that was really my point.

PARTICIPANT: We don't know if they will.

MS. AU: I think FTC wants to say something.

MS. BOTHA: Yes, I actually had a question about this recommendation, as well, when I was reading through because these have come in since our last conference call.

From FTC's point of view, we have a very broad statutory authority to go after unfair and deceptive acts and practices affecting commerce and we also have more specific authority to go after false advertising for healthcare products, including devices.

We have a very longstanding memorandum of understanding with the FDA regarding our overlapping authority and the understanding is that FDA takes primary jurisdiction for labeling for products and the FTC takes primary jurisdiction for advertising for products, the exceptions being prescription drug advertising and restricted medical devices.

So with regard to DTC genetic testing, I think

it clearly falls under the Federal Trade Commission Act and our very broad authority. I don't think that there's a question about there being a gap in authority for the FTC.

I think that the problem that we've had, and it made our investigations complicated, is the lack of agreed-upon evidentiary standards because for advertising claims, FTC's requirement is that there's a reasonable basis to support any expressed or implied claim and for health and safety claims, that consists of competent and reliable scientific evidence, which is evidence that would be agreed upon by experts in the field as being sufficient to substantiate the claim and that's really sort of where the gap is now because of the lack of agreed-upon standards for clinical validity, clinical utility, and that's really the problem.

DR. BILLINGS: So this sounds a little bit like the Patent Office discussion we had yesterday which is that the Patent Office is once more expertise, too, and so we are defining kind of an area of need which this committee could provide some direction to the various agencies and potential resources to the various agencies

since there are experts even on this committee.

So it does seem to me, though, that the recommendation should say convene as needed further oversight or something like that, so that if there's already very clear ownership of the issue, then really not set a task force up but provide the current agencies with the expertise that they need.

MS. AU: Yes, I think we can probably tweak that a little bit and then in the report we can make some explanation of what we meant as needed, especially for the expert opinion.

Okay. We have Marc and then Muin.

DR. WILLIAMS: And the other thing that I think, based on what Sharon just said, is that perhaps we should tighten this down and rather than giving this very long laundry list of things that this task force could potentially address, that it sounds like the prime issue here relates to this evidentiary standard which does in some ways relate to issues that we brought up in the oversight report, as well, but it sounds like that's really the priority area focus and if we could reflect that in the action step, I think that would be good.

MS. AU: I think I would like to do that with a lot of the recommendations after the patents report yesterday.

Yes, Muin.

DR. KHOURY: Just going back to the discussion about the evidentiary standards and also looking at the oversight report, which had some of the many recommendations as a creation of independent panels, like EGAPP, that would look at clinical validity and utility and put these evidentiary standards.

So we took that into perspective when I think the EGAPP Working Group has been discussing various issues over the last year and I think they have a couple of these topics on their radar screen, one for diabetes and one for cardiogenomic profiles, which probably they will come up with sort of piecemeal recommendations, but during our workshop that we held last December, an NIH-CDC workshop where we brought everyone together and we talked specifically about the scientific standards for personal genomics and they were published in the August issue of Genetics and Medicine, I mean it's very clear that there is not much evidence for clinical validity,

especially utility, for most of these things, whether they're GWAS-based or individual, I guess, genetic variants that people are selling.

So I think we can discuss that ad nauseam and if you think about the field of genetic testing where the field of personal genomics has kind of run ahead of the more established areas where you have pharmacogenomic applications, diagnostics, screening, at least they go through some hoops for validation, of validity and utility. Here there is nothing.

I mean, you take genetic variants identified in GWAS and then you put them out and with odds ratios that vary from 1 to 1.5. You may or may not make claims, like some companies make claims, so you go after them, but the more clever ones, they disguise the claims under may increase your risk, this, that, and the other, but it's clear that there are no scientific standards for validity and utility for all of the personal genomics tests that are out there.

Now, whether you need a new task force or you embed that under the recommendations for oversight, it's something the committee needs to discuss, but given that

the horse is out of the barn, so to speak, and our own surveys from Health Styles and Life Styles showed that many people are aware, many people are using them, less so than being aware, providers are being asked questions and the ones that are being asked questions, people bringing these things to them in at least three-quarters of the instances are taking action on the basis of those personal genome profiles that patients are bringing to them.

So it already is having some impact on the healthcare system. So given all these data, I mean, I think the time for action is now.

MS. AU: Liz.

DR. MANSFIELD: So given what Muin has just mentioned in the oversight report, it recommended that FDA take a risk-based approach. So perhaps rather than having the task force evaluate all of these things, it might be of some interest to indicate where these direct-to-consumer tests are believed to fall in the continuum of risk because if FDA were to go forward with any type of regulation of laboratory-developed tests, it's most likely to be on a risk basis and it would be very helpful

for us to understand exactly where you feel these fall in relation, for example, to BRCA1 and 2 testing, pharmacogenetic testing, so on, to give an analysis of that.

MS. AU: So that would be risk-based analysis of all direct-to-consumer genetic -- because it runs the range.

DR. MANSFIELD: Well, I guess to the degree you wanted to encompass all of it, but you could certainly say, well, these particular tests appear to be of high risk or these results appear to be of high risk and these results appear to be of moderate risk and these of low risk or something.

MS. AU: I remember that recommendation, but I can't remember exactly what we recommended. Was that to convene another task force?

DR. FERREIRA-GONZALEZ: They needed to convene the stakeholders to discuss further.

DR. TEUTSCH: I think one of the intrinsic things here is when it's direct-to-consumer, it's intrinsically higher risk than when it's done through a knowledgeable provider. That's one of the concerns about

DTC.

DR. MANSFIELD: Well, that is not -- well, I shouldn't say not. I don't believe that that's a basis on which FDA assigns risk.

DR. BILLINGS: I think that also --

DR. MANSFIELD: We could look into that.

DR. BILLINGS: -- there needs to be a factual basis for that claim.

DR. MANSFIELD: You could recommend that we look into that.

MS. AU: How do we do that?

DR. TEUTSCH: I think the point is that some of the things that we heard when people take action --

DR. BILLINGS: I understand, but misinformation for a very sick patient who might die shortly thereafter if a test provides misinformation is different than mostly healthy consumers searching diet information, --

DR. TEUTSCH: Oh, I understand.

DR. BILLINGS: -- let's say.

DR. TEUTSCH: I just had the same test being done in different -- the same test being done under those same circumstances is likely to be higher risk --

DR. BILLINGS: Absolutely.

DR. TEUTSCH: -- being done without --

DR. BILLINGS: An intermediary.

DR. TEUTSCH: That's what I meant. I didn't mean intrinsically all the tests.

DR. BILLINGS: Okay.

DR. TEUTSCH: I'm sorry.

MS. AU: Okay. I understand now. Gurvaneet.

DR. RANDHAWA: I want to go back to the point of what is it that we're trying to focus on here.

It's not the oversight per se. What I think we're getting into is the evidentiary standards and what Muin was discussing raises an interesting issue of evidentiary standards for what?

The clinical guideline developers have a slightly different perspective from, say, reimbursement coverage decisions which is a little bit different from regulatory decisions, and I think we need to -- if we get the task force or working group, it should be fairly narrowly defined into what is the focus of the evidentiary standards.

MS. AU: Yes, Mike.

DR. AMOS: I think one of the things that the committee could -- maybe the language could be a little stronger with regard to how good or bad are these tests. I mean, the problem is that we've talked about this for a couple years, right, and we've had people come in and talk to us about the clinical validity and clinical utility, but I would like -- I don't know exactly how to do it, but the document I would like to see a little more forceful or even ask HHS Secretary to sort of make a statement about these tests and from an education standpoint to try to keep the public from making bad decisions.

The other thing, too, is when you try to limit the information that people have where they make good or bad healthcare decisions, I don't think you can just limit it to the DTC and you might open up a can of worms because we get all kinds of information in the literature that people make good or bad decisions from, whether you should eat more oatmeal or whatever.

MS. AU: Barbara.

DR. McGRATH: Sort of following on that, I really would like to applaud the even tone of the report

that I saw when I read the revised version, that we may have opinions about DTC, good or bad, with such heavy language, but the reality is they're out there. They're going to be used and we've had other speakers talking about they're a source of consumer empowerment which is a movement that's only going to be growing with healthcare reform and just with time.

So I think I like the even tone, that we're not saying there's no place in the landscape for DTC, but rather focus our attention on looking for evidence and messaging and all those other things, but to leave the sort of do we want them to go away tone out which I was appreciative of that. I didn't read that in this.

MS. AU: I just wanted to go back again to the goals of this paper when we first envisioned it, and I think definitely it would be great rewording it, making shorter recommendations, things like that, but one of the things that it doesn't only apply to direct-to-consumer testing.

One of the things that we really were trying to do was trying to get the new Secretary to look at some of the old recommendations that we really wanted her to look

at and using direct-to-consumer testing as the new child, to kind of take it up to that level.

I think personally, I'm hoping that she would read this and say, well, there's more than direct-to-consumer testing. We should have a registry for all genetic testing and make it broader up at the Secretary's level, but because this paper is on direct-to-consumer testing and because the committee really last time thought that the recommendations were too broad, either we are going to have to keep it really focused on direct-to-consumer testing, so that this can be the vehicle that hopefully will get the Secretary to pay attention to some of the other recommendations and in her wisdom broaden the scope of it, or maybe this is just the start and, as it becomes successful, we can get her to broaden and do more within the areas that we're looking at.

So I'm just a little troubled with trying to redo a lot of the recommendations because they are our old recommendations and now that we have focused them on direct-to-consumer testing, I don't want to go back and broaden them again because we're just going to go back and forth, back and forth for years and I think Cathy and

I want to get this out to the Secretary while it's still a hot issue before the next issue comes up.

DR. AMOS: I wasn't saying to broaden it at all. I was just saying that we have to consider the fact that information is for information's sake and there's lots of information and to segregate genetic information from the other thing, people make real bad decisions for a lot of reasons.

MS. AU: Oh, yes. Like buying a house with zero percent down.

Yes, Marc.

DR. WILLIAMS: The thing that I think is a unique aspect of at least some of the direct-to-consumer tests that I'm not seeing reflected here, and you can maybe enlighten me in terms of where you envision this to be, is the issue of trying to have a company separate itself from undergoing scrutiny because they're saying we're not providing health information, and I think it would be extremely critical to have -- and I have no idea how this sort of pronouncement would be made or how this would be analyzed.

But the idea that there could be a statement

made to say, wait a second, you can't self-define this as not being about health. If you're testing about something that relates to health, then it's health testing and you're subject to whatever we have there, and I would just like to see that very explicitly put forward to the Secretary in this, although I'm a bit lost in terms of how that would actually be characterized as an actionable step.

DR. FERREIRA-GONZALEZ: Sylvia, can I follow up on Marc?

I was having trouble with that specific issue, too, due to the fact that one of the issues that we discussed at the last meeting is that these are direct-to-consumer testing for personal genomics that consider themselves that don't fall under CLIA and CMS has come out and said they don't fall under CLIA either.

So this idea that we have this specific concern for there's a need to be addressed, I was trying to figure out if that falls under the first bullet point on --

MS. AU: That was what it was supposed to fall under.

DR. FERREIRA-GONZALEZ: Okay. I know what we're trying to say, but I didn't really get clear that that's the first issue that we're trying to do through this FDA and CMS getting together to discuss this specific issue, I guess. So there is a need of statutory change to make sure that either they do or they don't fall under this.

The FDA might consider them devices, but again they're providing services and some of these companies actually, what they're doing, they're contracting with CLIA-certified laboratories to provide them the data, the data that is transferred back to the companies and the claim of that company is not subject to CLIA regulation because they don't produce analytical data.

So I think that that's an area that needs to be specifically addressed. I can open up some company out of my garage and my own laboratory could be doing the genetic testing and all the analysis and I don't fall under these regulations.

So this is a point that we were trying to make very clear that I'm not sure if it comes across on the first bullet point.

MS. AU: In the text of the report, and again I think one of the problems we have is because we're using this as a vehicle for past recommendations, how far do we revise past recommendations?

DR. FERREIRA-GONZALEZ: But we have specific recommendations and where this issue needed to be addressed and this health-related needed to be addressed.

MS. AU: Do we have a prior recommendation in the oversight report?

DR. FERREIRA-GONZALEZ: We do have in the oversight, there is a specific recommendation on that.

MS. AU: So we can pull that out.

DR. BILLINGS: Isn't the point that a direct-to-consumer test, whether it's just a data processing or interpretive thing or whether it's the full laboratory bag, is a genetic test and we want it covered by the oversight issues that we've suggested for other genetic tests? Isn't that the point, Andrea?

DR. FERREIRA-GONZALEZ: But can we bring that specific recommendation here? It wouldn't be a new recommendation.

MS. AU: Yes.

DR. FERREIRA-GONZALEZ: It would be that that needs to be addressed, and I think it's covered here when you talk about that the FDA and the CMS should get together to do an advanced notice of proposed rulemaking to analyze the gaps, inconsistencies, and duplicative regulations, and identify specific proposals to address relevant statutory authority, but we have very specific language that says that maybe the statute needs to be changed to really incorporate this into CLIA, for example.

MS. AU: Okay. We can pull that one. Jim wants to say something direct to that and then we'll move on.

DR. EVANS: Right. So I agree with what Marc said and with what Andrea said.

I think that to me, the overriding issue in all of this is reconciling reality with claims because that's where people are going to get into trouble. That's where they're being misled, et cetera.

I was pleased reading the product in the sense that I thought that the action step which says, it's not up there now, convene the joint FTC task force would go a

long way towards that.

Now, perhaps it's a little oblique, a little opaque, and what we could consider and maybe even do this at lunch or something is come up with a much shortened action step that has a one-sentence preamble about reconciling claims with realities and then therefore we recommend convening a task force and then take some of this verbiage and fold it into the rationale for the recommendations so you aren't overwhelmed by the volume of it. Does that make sense?

MS. AU: I think that makes sense.

MS. BOTHA: If I could respond, I think that would be useful. When I read this recommendation, I really wasn't clear what the goal of the task force would be because FTC, at least, is not primarily a regulatory agency. We're an enforcement agency. We have some regulations, but we're unlikely to issue regulations in an area like this, especially where the science is emerging and evolving.

So if you're looking for a guidance document, I'm just not clear on what the goal would be.

DR. EVANS: Right. And I think most of us

around the table are advocating exactly what you all do, which is, there are procedures, regulations you guys follow to decide whether claims are being substantially met or not, right?

MS. BOTHA: Right. But as I tried to explain before, it's really a pretty standard policy that we have regarding health and safety claims about competent and reliable scientific evidence and that just gets us back to the question of what would comprise competent and reliable scientific evidence in these cases.

So are you expecting that this task force would go to defining that because I don't know if FTC -- we would participate but we don't have the scientific expertise for something like that.

MS. AU: I think the task force is supposed to be helping advise FTC, right?

DR. EVANS: And, as it says, to propose those specific guidelines. So it would bring in the experts that would then provide --

MS. AU: You would need to tell them what you needed. I think that's the position of FTC on the task force, if I remember correctly.

MS. BOTHA: Well, I still have a concern that setting, then agreeing upon standards, I'm not sure of the usefulness of that when you're dealing with science that's developing constantly, and would these standards be set in stone and all of the tests are testing different things. They're making different claims. It's just difficult to establish, I think, specific guidelines, more specific guidelines.

DR. EVANS: I'm actually not sure it would be quite as difficult in the sense that, yes, the science is changing rapidly. Nevertheless, the types of issues that Muin articulated with regard to showing clinical utility, showing at least clinical validity, those are really not contingent on the type of technology, et cetera.

So I think it's doable, but obviously you'd have to work out details in such a task force.

MS. AU: I think in the task force, the experts would be able to help guide that process because they also would know that you can't have everything in black and white and never move. So that's part of the expert guidance, hopefully.

I have Muin. He has been waiting to say

something. Okay, Mike.

DR. AMOS: I was just going to say that I support Jim's language because it's really critical that these recommendations be technology independent because the technology is emerging.

Right now, the issue with GWAS is that there's nothing technically wrong with them. It's the paradigm. It's the approach to find something out. It's really the approach and the quality of the information you get back to make real decisions.

Very soon, I think, it's going to be possible to get an entire human genome done. Everybody's going to have this information. It's going to be a massive amount of data that's going to have to be managed and I think that maybe that you will find something there, who knows, but it's got to be technology independent.

DR. EVANS: Right. I completely agree. The beauty of that is that again the rules have changed in medicine, right, and we can apply clinical validity, clinical utility, et cetera, regardless of whether it's a whole genome sequence or array data, not that that's trivial, but it's doable.

DR. AMOS: And when you talk about standards, you're talking about standardization. You're talking about procedures and things like that for interpretation. It's not quite the same as materials to support the technology which is a different area, and we've actually decided to stay away from the GWAS and things like that as far as standards because we actually think they're going to go away but focus on next generation sequencing.

MS. AU: Getting back to Andrea's recommendation about the CLIA, I think Penny from CMS had some concerns about statutory changes.

MS. KELLER: Hello, everyone. I'm kind of here to answer any questions, but I can update you on what we're doing about direct-to-consumer testing because I actually read the 200-page report, that was one of my first duties, and one of the things we are doing is we are monitoring all the companies and we are just as familiar with them as the FDA and the other agencies.

What we attempt to do is contact them and go through the e-mails, calling them, whatever we can do, contacting the states, and try to educate them because a lot of the information that they posted is for

information only.

So what we do is we contact them, ask them for information about their tests, including their requisition form, their testing description, as well as the test report that they generate and send to the consumers or to the providers to see what they're actually saying, and if the information can be used for health assessment by the provider, then we educate them and say, well, no, that falls under CLIA, even if you use it for information, and you need to qualify for CLIA or one of the accrediting agencies.

So that kind of makes it complicated because not all genetic tests is considered as falling under CLIA, as Dr. Gonzalez mentioned. For example, one of the companies was testing for bitter tasting, a gene where can you taste the sour lemon or not. We didn't consider that a CLIA test and the report just tells you whether you have this gene that everybody else has who can taste it or not and so there wasn't anything else associated in that report as far as needing treatment or some kind of assessment. So we told that particular company at the present, that didn't fall under CLIA. So that's the

criteria we're using. We're using our definition as far as the assessment.

Even if they claim it's not a diagnostic, we still ask for the information and we have to educate these people, but that is what we're doing. So some of them have actually applied for CLIA. Some of them don't respond to us. We e-mail, we contact, but some of them don't get back to us and, unfortunately, unless they apply for CLIA, we don't really have the force in the statute to go after a company that isn't doing our type of testing or who does it who isn't a laboratory or falls under CLIA. I hope that helps.

MS. AU: So, Penny, --

DR. FERREIRA-GONZALEZ: Can you give me a little more clarity between those services that actually contract their testing, analytical part, with CLIA-certified laboratory? Are you going after the service, telling them that they have to comply with CLIA or would just doing the testing in a CLIA-certified laboratory be sufficient in your view?

MS. KELLER: We've checked with our General Counsel because we've had split -- well, not split.

We've had passionate conversations about this, but right now, until there's, I guess, evidence that we need to be more stringent, our General Counsel has advised us to just stick with our definitions.

So let's say, I know 23 EMEA is a big well-known name, they don't have a laboratory but they do interpretation and our counsel have said that the laboratory that actually generates the data, that has the testing personnel that run the tests, that all falls under CLIA, but what 23 EMEA are doing is they're taking literature that's out there, the advisor committee, and doing an interpretation very similar to a provider and that does not fall under CLIA at the moment.

MS. AU: So that means, Andrea, pulling your recommendation about CLIA would not cover this instance because again --

DR. FERREIRA-GONZALEZ: It's a gap.

MS. AU: It's a gap.

DR. FERREIRA-GONZALEZ: So that needs to be addressed, because what you're telling me now is that there is these groups that only does the interpretation that doesn't fall under CLIA. They're still taking

laboratory data and turning it into a report for their patients or consumers or customers.

MS. KELLER: Normally, we change that if we see a pattern. I mean, there are some states that are coming up with new state statutes that are separating that interpretation software part out of the laboratory part, but --

DR. FERREIRA-GONZALEZ: You're talking about California?

MS. KELLER: California, and there are other states that are considering it, as well. I can't really divulge it because I'm not sure where, at what stage those are at, but the current CLIA laws do not extend to that interpretation part because they look at it as the practice of medicine.

So whoever oversees the practice of medicine has to try to get involved with these companies that do that, but that's where our General Counsel has worked with us.

DR. FERREIRA-GONZALEZ: We're splitting hairs. I mean that's like what we do in a laboratory. We do an interpretation.

MS. KELLER: Yes.

DR. FERREIRA-GONZALEZ: CLIA laboratory provides a service where we provide interpretation in the context of that particular patient.

MS. KELLER: Yes, and that is a service that laboratories provide because that is very useful to the physician, but that is not something that's explicit in CLIA that you --

DR. FERREIRA-GONZALEZ: It needs to be addressed in the recommendations. There is a big gap there.

MS. KELLER: We don't, in CLIA, specify how much of that interpretation should include the practice of medicine, that interpretation. So we leave it up to the laboratories to do that. The fact they provide a lot of information to the providers, we applaud that. Obviously, it is useful to the providers, but our statutes do not cover that at the current time.

MS. AU: So that our recommendation was that we need to look at the relevant statutes and see where the gaps are so that we might have to revise and get the statutes revised. Not us, somebody. The Secretary.

David's been waiting. It's David, Gurvaneet, Marc, Jim.

DR. DALE: I pass.

MS. AU: Okay. Gurvaneet.

DR. RANDHAWA: I go back to the evidence standards and I'll be more specific here. If you can go the slide, there you go, there are two issues.

One, I thought I heard Jim say that the evidence may change but the evidence standards are more or less the same.

DR. EVANS: The technologies can change.

DR. RANDHAWA: Right. So that's one word that comes up here, evolving evidence standards. So there's a difference between evidence and evolving evidence standards, and I agree with the fact that standards actually don't need to evolve. You can look at new technology and look at the evidence and say does it meet the standard or not, but that's not what this bullet here says.

The other thing is, is it really desirable for us to have the same evidence standard for all decision-making contexts? I've heard the clinical utility being

mentioned here and we have at least one example from EGAPP when they looked at cytochrome P450 testing in depression and looked at ampli-chip as one of the tests which has undergone the FDA process and is available for use, but the EGAPP recommended against its use and clinical utility was not considered in that decision-making.

So I think we have to be very clear in terms of what the decision-making context is and what the standard should be.

MS. AU: I have Marc and Jim.

DR. WILLIAMS: So this is directed back to Penny. Just a couple of clarification issues that relate to the idea of self-defined as a non-health-related test.

So in those companies where you do have contact with them and they respond to you and you say, no, wait a second, we understand you're saying it's not but we're telling you it is, then is there any communication to say, FTC or someone else, to say the materials that are being provided do not recognize this as a health test. CMA is considering this a health test. We think there's a discrepancy in claims that would need to be addressed.

And then the second question is for those that are not responding at all, given that you don't have any sort of enforcement, is that a potential role where there could be communication to an enforcement agency, like FTC, to say could you help us get these people to respond or something?

I'm just trying to look at things that address the health versus non-health issue and a role of this potential joint task force.

MS. KELLER: One of the things we have been doing is working with the FDA on the materials that we receive from these companies because when you have a regulatory body saying, oh, yes, the information is relevant, we need scientific support, so we have asked the FDA for the technical support, and we provide these companies -- we don't just say yes or no. We give them reasons of what was inadequate or adequate. So we provide a summary so that they correct the problems and they qualify then. We're more than happy that they provide the analytical data and appropriate. But you have to look at CLIA as a whole laboratory. So we're looking at approaching them on all other quality

management systems.

We haven't been at this long enough to get to a point where we've transferred any of the information over to the Federal Trade Commission on the ones who haven't responded because we want to give them time because what I've noticed is sometimes we'll go three months before I hear anybody because everyone's busy doing something and they're not all lost, but there are some that actually use international laboratories and those are even more difficult to contact, but we do make an effort.

So there has to be a point when we decide, okay, we're no longer going to make an attempt after three attempts or four attempts. I'm not sure. We haven't really gotten to that point. We're kind of gingerly getting at this because it's not like we have an enforcement group right next to us who are going there. We have to rely on other agencies and unless there is a complaint that was lodged against that particular facility that we can forward, my inquiry by myself really doesn't generate a whole lot of interest.

I hope I answered your question.

DR. FERREIRA-GONZALEZ: Could I ask a further

question to that one?

I mean, I think one of the issues that we had in the report, also, is that we came across this issue that CMS has no enforcement. When you find a laboratory that is not complying with CLIA, you cannot go and shut them down. You have to go turn around to somebody else to inform them what is happening and so forth.

So we ask in our report to change this to give them the ability to have some enforcement. So maybe we need to pull that into this report, also, specifically, so then they can actually have some teeth to their enforcement.

MS. KELLER: Our enforcement extends to our CLIA labs. That's correct, Dr. Gonzalez. So if there's a CLIA lab who is doing a DTC test and there's a complaint about it, we'll go in, we'll take a look at it, and they'll either have to correct it or they have to discontinue the test. We have that much of an ability as far as enforcement.

But if they're not a CLIA-certified lab or accredited lab, yes, we have to ask another agency, unfortunately.

MS. AU: So, Penny, your plans are that eventually the labs that aren't responding to you, you will be turning over that --

MS. KELLER: We are -- well, I have what you call a makeshift database. It's a personal database and we're just accumulating information at the moment. We have to actually get approval by our General Counsel on what we can or cannot include in that before we share it with our regions or our states, but at the moment, like any other agency, we collect information. We keep a running record of all our communication, everything that's going on, like the letters that came out will be in our database for anyone who's inquiring.

Our regions and our state surveyors all know that if they have any questions on direct-to-consumer testing in the area, to contact us because we keep track of it, plus we might know something about it from another state that they're not aware of. So we are educating our surveyors.

MS. AU: I think Muin has a comment.

DR. KHOURY: I think to make sense of all of this, I like Appendix B. Appendix B is the place to

start from because it shines a light on what SACGHS has done over a long period of time and I think what you tried to do in those pages where you took stuff, you tried to relate one to one what you thought might be the gaps that are specific to DTC and make them a bit more spotlighted, but at the same time, we kind of lost Appendix B. Now it's an appendix.

So one suggestion may be to bring all of Appendix B back into the list of recommendations because they do apply to DTC and point out the something extra specific that needs to be done. That way, you're essentially saying this needs to be done for everything, includes DTC, and it's not relegated to an appendix, but it's really the heart of what needs to be done with all these areas, from claims to education to oversight to clinical validity, because right now Appendix B is kind of lost. One idea.

DR. FERREIRA-GONZALEZ: I think we have to be cautious in doing that because I think we went back and forth with these issues, and the idea of this white paper is to bring light to issues of direct-to-consumer because it's very publicly discussed in many different forums and

people might not realize that they can go to the oversight report to look at all these issues.

Then we're just going to highlight some areas of DTC and then refer them to the report. We put the report and oversight here.

MS. AU: Yes. I think that's what the goal of the paper was and so that's why we ended up with Appendix B because we went back and forth on how much to dilute the DTC stuff.

DR. KHOURY: It kind of lost the essence of Appendix B, in a way. By putting these kinds of broad recommendations, it doesn't give us -- maybe I should read the whole thing again. I got lost on what is important here, and you want the Secretary to act on prior recommendations. There is more urgency to act now because of DTC and all of these gaps and the oversight and other areas and lack of education, et cetera.

So, you give an extra nudge for acting on all of these areas. The registry would be great, because it forces people to deposit information. Then independent bodies like EGAPP will spring into action. All of these things could be highlighted.

So I don't think it will dilute. It may be just another way of presentation. People won't read Appendix B, I can tell you that. They only read the executive summary. So unless Appendix B is in the executive summary, no one else will read it.

MS. AU: How about if Cathy and I take a look at that and see how much we can incorporate, bring forward to that? I want to bring this back to Steve.

DR. TEUTSCH: We have about half an hour, and we need to bring this, I think, to some closure. The idea was to wrap it up this time. We can do some formatting. I don't think we were talking about any real revision.

I've heard a number of points that can be emphasized and strengthened. We've talked about simplifying some of the recommendations, making clear that we see these as, generally, about health tests with some limited exceptions, but I think what we need to do is to now go through and figure out, are these the right things to say, and get to some agreement, hopefully, that we can send it forward to the Secretary so we don't have to bring it back to this committee again.

There are a lot of issues, as we know, in DTC. It's a moving target. There are some things that, as Sylvia indicated here, that we need to monitor on an ongoing basis, and we may need to take up in a larger sense, but we need to get to a point here where we crystallize the things that we want to convey to her, basically, between now and our next meeting.

MS. AU: So I think the things that we have are definitely the preamble to the FTC Joint Advisory, what they are supposed to be doing, to make that clearer, the "Reality versus Claims" paragraph, I think that Jim talked about; the CLIA issue that we talked about that Andrea brought up with the enforcement.

Also, CLIA may be expanding their scope to these services that only use CLIA-certified labs but aren't really labs -- they are just the service that takes the data and does the interpretation -- whether CLIA should be expanded to include these type of companies.

Other than that, tightening some of the recommendations maybe, and putting in Appendix B, and formatting some of that up into the report.

Muin.

DR. KHOURY: So as part of this monitoring function that Steve alluded to -- I just don't see it in any specific recommendation -- to continue with evaluating the real impact of DTC on consumer awareness, health impact, and so on, the kinds of surveys that CDC and others are doing, we need to do more of this because that is the only way we're going to find out what is happening. Maybe it's there and I missed it.

MS. AU: I think part of it is on the things that we haven't had prior recommendations on, some of the things like DTC testing on children, psychosocial impact. Those are some of the issues that the Committee might want to take up to make new recommendations for how the Secretary might want to monitor or address some of those issues. Those aren't addressed by some of our prior recommendations that we pulled out.

The recommendations that we have, does the Committee feel that these are the adequate ones? We're going to include the CLIA one. Other than that, I think that was the only additional recommendation that we talked about.

MS. WALCOFF: I'm not sure. What is the CLIA one?

MS. AU: What happens is that some companies contract with the CLIA-certified lab and they get the data. The company that gets the data has no enforcement. They do the interpretation. Some labs do the testing and interpretation. So everything is covered under CLIA.

MS. WALCOFF: We are trying to recommend the statutory change to CLIA, or is that encompassed in one of the recommendations that we would try to do that?

MS. AU: In the oversight report, there is a specific recommendation about CLIA, the gaps, the gap that CLIA does not regulate those services. So we want to pull that recommendation out, which we don't have with us right now, but we know that there is that. Of course, Andrea knows that recommendation is in the Oversight Report.

MS. WALCOFF: Yes. I remember that and how that differs from the specific action steps that we have in the first --

MS. AU: I think it's just a more specific, explicit --

MS. WALCOFF: Just acknowledge that it's not covered by CLIA.

DR. FERREIRA-GONZALEZ: It's not clear that we also include in that part, because sometimes we talk about CLIA laboratories, they just look at that. We want to make sure this is specifically addressed.

MS. WALCOFF: CMS can have oversight enforcement over CLIA -- I mean, through CLIA over this part that is not currently encompassed by CLIA, according to general counsel, right? So that would either be through statutory or regulatory change.

MS. AU: That's right.

MS. WALCOFF: Which I think is in there.

MS. AU: It's in the report but not the recommendation.

MS. FOMOUS: I think the other thing that we want to do is add to our list of prior recommendations, the one from the oversight report that calls attention to the fact that the issue that Penny pointed out where if the lab is not CLIA-certified or CLIA-accredited, their hands are kind of tied. They can't do anything.

We had a recommendation that addressed that in

the oversight report that we want to include, that we want to add to this paper.

DR. BILLINGS: Do we need a specific recommendation that says that we need clarity about what a health test is? I mean, shouldn't the Secretary seek to finally define that, let's say, a genealogy test is not a health test but everything else that these DTC companies are doing is.

MS. FOMOUS: I think that's sort of part of that recommendation that we had from the oversight report. It was really to bring together FDA and CMS and other relevant agencies to really kind of look at what we mean by health-related tests and what is the scope of each agency related to that. So I think it's encompassed in that.

MS. AU: I think maybe we just have to be more aware.

DR. BILLINGS: So we're not as a committee saying what we think the health-related test is. We're saying the agencies are going to get together and tell us what a health-related test is, is that right?

MS. AU: Well, these experts and the agencies,

yes, but --

MS. FOMOUS: Reading from it, it says, "relevant federal agencies should collaborate to develop an appropriate definition of health-related tests."

MS. AU: So any other comments? Barbara.

DR. McGRATH: I wonder, maybe I'll put it out as a proposal to discuss, addressing the issues that weren't reported on other reports, recommendations something along the lines of increased funding priorities to study outcome -- to evaluate outcomes -- let's see.

Priority for social and behavioral research to evaluate consumer outcomes or outcome evaluations, something like that. That would cover some of the -- then on to that could be -- sorry. Including dealing with certain populations, specific populations, research with children and stuff like that.

MS. AU: So that is one of the recommendations and one of the issues that SACGHS just could take up?

DR. TEUTSCH: It's also in the oversight report under the Clinical Utility, where we discuss exactly those issues about getting the information about the value of including those subpopulations.

MS. AU: Okay.

DR. McGRATH: I would just shut up. The social and behavioral research.

MS. AU: Under Appendix B. I'm going to bronze Appendix B for you and send it to the CDC. So we're going to add that then.

Other than that and our little reformatting, does the committee think that the -- oh, and Liz now.

DR. MANSFIELD: I just have a question about the one that was the advance notice of proposed rulemaking. Can you go to that recommendation?

MS. AU: Right here.

DR. MANSFIELD: So what is the rule? Do you want to make a rule specific to direct-to-consumer testing, that says we're going to treat direct-to-consumer testing differently than all other types of testing?

MS. AU: Well, this is what happened when the committee decided that we wanted to make our recommendations specific to direct-to-consumer genetic testing. This made it go from broad, go from genetic testing to direct-to-consumer genetic testing.

MS. WALCOFF: I think the idea was to look for an actual mechanism that might be possible within the current authority of the Secretary and of the agencies to address some of the gaps, like the one that Andrea just raised, the concerns that were otherwise not addressed.

DR. MANSFIELD: Would it require additional rulemaking?

MS. WALCOFF: Yes.

DR. MANSFIELD: You want to look for things that would require new rulemaking?

MS. WALCOFF: Yes, because it couldn't ultimately be implemented without some other kind of change. That's what my understanding was from the limitations of the current statutory and regulatory authority that CMS was saying in terms of the CLIA lab. I think it's a good example.

DR. MANSFIELD: And would these apply just to direct-to-consumer tests or would there be gaps that would be larger?

MS. AU: Under this report, they would only apply to direct-to-consumer genetic testing.

DR. FERREIRA-GONZALEZ: I think we said it very

clearly in the report, that if there are issues, gaps, they go to all of genetic testing, not only DTC but also all types of services. So here, we're just bringing up specifications with direct-to-consumer testing, like this gap between managing the data versus the laboratory actually doing the test as an example.

MS. AU: So I think for us in the preamble, we clearly identified that these are not issues only specific to direct-to-consumer genetic testing, but in the action steps, we really are trying to focus on direct-to-consumer genetic testing just because that is the subject of this paper.

As I said, we are hoping on the wisdom of the Secretary's Office that if they're looking at this, they say, well, if we're doing this, we might as well look at all genetic tests or a broader range of genetic tests than direct-to-consumer genetic testing. If they did that, that would be a bonus for our committee. If they only look at direct-to-consumer genetic testing, then that would be a start.

So seeing that everybody looks like they want to have lunch, this is perfect. I can hold them captive.

Does the committee -- do we take a vote on advancing this or do we just -- Steve, do we take a vote on advancing this?

DR. TEUTSCH: Yes. I mean, I'm not sure I can cite all of the changes that we have just gone over, but --

MS. AU: We've noted them all.

DR. TEUTSCH: -- we have all of the comments. What we would like to do is to have the approval of the committee to finalize the report. I would suggest that it will go out to you one more time so that you'll see it and then that it can go forward to the Secretary.

MS. AU: And that would be, Cathy, going out to them in what?

DR. TEUTSCH: I don't know that we need a date

MS. FOMOUS: We had initially asked for --

DR. TEUTSCH: You want to go ahead and if you have -- let me ask first. Beyond the conversation we had here, do you all feel that you need to put in specific edits that you want to see? Will we get any if we do that? I can assume that most of the work is going to be done by staff, and why don't we aim then to incorporate

all of that and get it out the third or fourth week of the month? No? When? Okay. When can you have it?

MS. FOMOUS: Before Thanksgiving.

DR. TEUTSCH: Before Thanksgiving with a due date before Christmas, aim to get it back before Christmas, probably mid December with any final changes, and then it can go out.

MS. AU: And the Secretary will have it for New Year's.

DR. TEUTSCH: A New Year's present for the Secretary. All right. So all in favor of approval of this report and the process going forward, please raise your hands.

[Show of hands.]

DR. TEUTSCH: Paul said yes already. 14. All opposed. Abstain. Congratulations, Sylvia.

MS. AU: Thank you.

DR. GUTTMACHER: Mr. Chairman, one technical suggestion. We would suggest instead of Thanksgiving being the target, it should be National Family History Day which happens to be on Thanksgiving.

[Laughter.]

DR. TEUTSCH: I can tell you some stories about what happened with turkeys in Los Angeles but that's another story.

So, why don't we go ahead and take a break. I know we're going to start losing people. Plan to be back at 1:00. That gives you about 50 minutes. We're going to start promptly at 1:00 and go back over the recommendations from the Patents Report.

Thanks, all. Thanks.

[Lunch recess taken at 12:10 p.m.]

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AFTERNOON SESSION

[Reconvened at 1:07 p.m.]

Final Draft Recommendations and Draft Report

DR. TEUTSCH: All right. Folks, we finally have a quorum and we're going to begin. Let me give you the agenda for the afternoon. We are going to go through the Patents Report recommendations and make sure we're happy with those. We are going to get any other last comments.

We have a few things we should talk about about the drafting of the final report, and then we have a few other miscellaneous items, largely from the conversation I had with Francis Collins. So maybe get a couple of ideas at the very end of the meeting. I hope to get us out of here at 2:30 or so, because some of us, I know, are going to leave, including me. So we will try to move that part along. We need to give the patents part fair hearing.

I'm going to repeat this when we have more people here, but a couple things about the report. It is obvious to everybody that there were very strongly held opinions about some of the materials that were in here in

our final recommendations. That, I think, makes it incumbent upon us to do two things: make sure that the issues that are raised by those who have perspectives different than the final recommendations would suggest, we need to have those comments in here.

I'm going to say it now, and I'll say it again. We need comments from those people in writing. We've tried to get them in the past and have not received them. We need them in writing so they can be incorporated into our final draft.

Then the other thing, because clearly some of these recommendations will not be universally welcomed, we need to make sure that we have laid out the rationale for these recommendations and why these were made rather than any other alternatives, because we need to not only be receptive to all of those differences of opinion but be clear how we reached the conclusions that we did. So I know we've got a challenging agenda.

Jim, you're on.

DR. EVANS: All right, great. I was really pleased with the deliberations yesterday, in spite of the controversy. I think that we made tremendous progress in

both content and stylistic features of the recommendations.

What we're going to do here is we're going to march through them. Ones that were voted and approved, we don't need to discuss anymore, but we have a few little wordsmithing things that do need to be discussed.

Essentially what you're seeing now represents the distillation of the comments made yesterday that changes the wordsmithing that we did on the fly and now incorporated into a final form.

There were no changes to Recommendation 1, so we don't need to go over that again.

Recommendation 2. The issue came up, this is the research exemption, do we need the last sentence. The creation of an exemption from patent infringement liability for those who use patent-protected genes in the pursuit of research, period. It could stop there.

What we had yesterday was related healthcare and research entities also should be covered by this exemption.

I actually don't think that last sentence is needed, but do people agree, disagree, have alternate

suggestions?

Rochelle.

MS. DREYFUSS: The reason there's something similar to that in Ganski-Frist is because it's possible to sue the hospital for aiding and abetting essentially the infringement and so that's why those things are there.

DR. EVANS: Do you think from a legal standpoint it's safest to leave it then because you would not want that to occur. We obviously don't want to just --

MS. DREYFUSS: This reads a little different from Ganski-Frist because there, it's an insulation from the remedy rather than an exemption from liability. So it would be harder to make a contributory infringement case here. So maybe we could take it out and just put something in the --

DR. EVANS: That's a great idea. That's a great idea. All right.

So what I'm going to do here, going, going, gone, is we will now fold that into the rationale. That's a great idea.

All right. We will include this statement -- oh, I'm sorry. And this is just the rationale that we had taken out before that deals with association patents. So remember originally Recommendation 3 was this and we decided that there isn't a lot the Secretary really has to do with it. It's more we want to be on the record. So what we're going to do is we're going to fold this into the discussion and the text. People okay with that? All right.

Now between those recommendations and the remaining recommendations, we feel some explanation is required and we have the following. Although the committee believes the changes described in Recommendation 1 offer the most effective means -- and that should be 1 and 2, shouldn't it? Yes. Oh, I see. Gotcha. Those are Sub 1. All right.

Offer the most effective means of addressing the identified problems and promoting ongoing access by patients to the fruits of emerging genetic advances, the steps outlined in the following recommendations should be undertaken in the interim to help address identified problems.

In other words, if those two were immediately enacted, okay, you wouldn't need most of these, but we all know that's not going to happen. All right.

Is that Mara? Okay.

Next one. "Promoting adherence to norms designed to ensure access." I would have to say that it's really been nice to get a lot of this folded into the text. It makes the recommendations much simpler and pithier.

All right. "Using relevant authorities and resources as necessary, the Secretary should explore, identify, and implement mechanisms that will promote more than mere voluntary adherence to current guidelines that promote non-exclusivity in licensing of diagnostic genetic/genomic technologies.

"The Secretary should convene stakeholders, for example, industry, academic institutions, researchers, patients, to develop a code of conduct that will further encourage broad access to such technologies.

We took out a variety of things, and now we'll fold it into the rationale. Oh, yes. Let me blow this up. Sorry. Okay.

"The Committee supports guidelines that encourage broad licensing and broad access to diagnostic genetic tests," and I think we should have "genetic/genomic." I don't want there to be confusion about, well, you just said "genetic" because nobody really quite knows the difference.

DR. WILLIAMS: I would just say, from a clarity perspective, you articulate in the report that you're using the same definition.

DR. EVANS: We don't need to do that.

DR. WILLIAMS: Use it, and just say this is how we're defining it.

DR. EVANS: All right. That sounds good. We'll go through and make sure that's consistent. I think that's a good point.

MS. DREYFUSS: Can you go back to the recommendation itself?

DR. EVANS: Yes.

MS. DREYFUSS: You have industry, academic institution, researchers. The problem with academic institutions is you get technology transfer offices and although it says researchers, researchers could be

industry researchers or academic researchers. If we have TTOs, I would like to see some academic researchers.

So I don't know whether you could explain that in the notes or put it in there to make sure that TTOs don't come in and say they represent academic institutions.

DR. EVANS: Perhaps the easiest way to do that is make a note of that in the explanatory stuff. By academic institutions, we mean this in a broad sense, including researchers as well as technology transfer. Okay.

The Committee -- so that asterisk refers to, obviously, the Nine Points, OECD Guidelines, et cetera, and we didn't feel like we needed to clutter up the entire thing with reiterating those.

NIH's Best Practices and OECD Guidelines encourage limited use of exclusive licensing for genetic/genomic inventions. Points 2 and 9 of the Nine Points to Consider included in their explanatory text are also relevant for genetic tests.

In particular, the explanatory text under Point 2 recognizes that "licenses should not hinder clinical

research, professional education and training used by public health authorities, independent validation of test results for quality verification."

MS. DREYFUSS: I really don't like “encourage limited use.” It sounds like you're encouraging exclusive licenses.

DR. EVANS: Oh, wait. Where?

MS. DREYFUSS: I would rather see it say “discourage use of exclusive licensing.”

DR. EVANS: Okay. Let's see now, where are we?

DR. WILLIAMS: It's encouraging limited use.

MS. DREYFUSS: I understand what it says, but you see the word "encourage" next to exclusive license.

DR. EVANS: Oh, I think it's basically --

MS. DREYFUSS: I think it's a very hard phrase to parse.

DR. EVANS: What if we say “discourage exclusive licensing”?

DR. WILLIAMS: That's what we had previously, and then we had with the exception that there may be rationale under --

DR. EVANS: That's in here.

DR. WILLIAMS: Okay.

DR. EVANS: You'll see that.

DR. WILLIAMS: That may be clearer.

DR. EVANS: That's very important, that when warranted, exclusive licensing, yes. All right, good.

To be added to the rationale:

"In identifying mechanisms that will promote adherence to the guidelines, the Department may need to initially determine the scope of its authorities. For example, because it is unclear whether the Bayh-Dole Act gives agencies authority to influence how grantees license patented inventions, the Department should seek clarification about this legal question."

Then two possibilities. If it is determined that the Secretary has the authority, one way the Secretary could promote adherence to the above guidelines would be to direct NIH to make compliance with the above guidelines an important consideration in future grant awards.

Alternatively, the Secretary could promulgate regulations that enable the department's agencies to

limit the ability of grantees to exclusively license inventions resulting from government funding when they are licensed for the genetic diagnostic field of use. Exceptions could be considered if a grantee can show that an exclusive license is more appropriate in a particular case, for example, because of the high cost of developing the test.

All right, “enhancing transparency.” Yes.

DR. WILLIAMS: Related to this, in the public comment this morning and in a couple of the others, I think there was a specific position expressed that in fact Bayh-Dole is being applied appropriately in this area.

So I would ask that, as part of our revision of the report, to reflect that we specifically articulate that and then we would then -- obviously, it would be incumbent on us to defend why we think that it doesn't quite --

MS. DREYFUSS: I disagree that that's what was said this morning. What was said this morning is that universities are in fact doing what we would like. They didn't say that Bayh-Dole was being applied to do this.

They were saying that universities were voluntarily doing this, and I'm sure there were some that are and we should certainly acknowledge the fact that many do, but I don't think they were saying that this is the current interpretation of Bayh-Dole because NIH doesn't think it's the current interpretation of Bayh-Dole.

DR. WILLIAMS: Well, what I heard clearly from the speaker this morning was we should leave Bayh-Dole out of this and I agree with the statement, I think, that we do need clarification. I think we make a good case for it.

I'm just saying that I'm sensitive to the idea that this report was criticized because we did not adequately reflect other interpretations, positions, and I don't see, since this does not affect the recommendations or the rationale, how it harms us by reflecting the comments that we're receiving as part of this process.

MS. DREYFUSS: The comment was that universities are voluntarily doing that and I think we should reflect that. I think a lot of universities are, but I don't think this is an interpretation that anybody

has made of Bayh-Dole and that's why we need clarification.

DR. EVANS: And I think Rochelle's point is a very good one, that the contention the universities are doing this is demonstrably wrong, that's just incorrect, and I think that we need to point that out. I'm all for being balanced, but we also need to reflect reality.

All right. Enhancing transparency. Using relevant authorities and resources as necessary, the Secretary should explore, identify, and implement mechanisms that will make particular information about patent licenses readily available to the public.

The specific licensing terms that should be made available are those that pertain to the type of license, the field of use, and the scope of technologies, and then in the rationale, as a means to enhance public access to information about the licensing of patents related to gene-based diagnostics, the Secretary could also direct NIH to amend its Best Practices for the Licensing of Genomic Inventions to encourage licensers and licensees to include in their license contracts a provision that allows each party to disclose information

about its licenses, particularly such factors as types of license, field of use, and scope, in order to encourage next generation innovation.

Do we want to say anything in there about the possibility that the Secretary could also use more than just mere encouragement ala the discussion in the previous recommendations about authority and granting, et cetera, or do we want to leave it as is?

Rochelle.

MS. DREYFUSS: I think if the previous one said that they should have the authority to enforce best practices, if this is part of best practices, it goes along with that.

DR. EVANS: Right.

MS. DREYFUSS: A question I would ask is whether we want to put in that allows each party to disclose non-financial information.

DR. EVANS: Well, I think that might go a long way towards placating those who can be placated. In other words, I think that that could be a red flag that we don't need to bring up.

Gwen.

MS. DARIEN: I think if we leave it at encourage, it will end up being just like the clinical trials registry that NCI has, which is so incomplete and not enforceable.

DR. EVANS: I agree. So taking both of those things into account, if we disclose non-financial information, that would avoid a lot of problems with proprietary information, and then we also will use in the discussion, we will use the same wording about authority in this as in that, the previous recommendation. Does that make sense?

DR. DALE: In Line 3, --

DR. EVANS: Line 3 of which one?

DR. DALE: To be added to rationale text.

DR. EVANS: Gotcha. Okay.

DR. DALE: Is the word "should" or "could?" If it's put encourage, it's pretty soft.

DR. EVANS: I know.

DR. DALE: I would say should encourage would be more in the spirit of what we're doing.

DR. EVANS: I would agree with that. Do other people agree? Okay. All right. Okay.

Then, Darren, you'll get the language in parallel. Okay.

All right. 4. Advisory board to assess impact of gene patenting and licensing practices. The Secretary should establish an advisory body to provide ongoing advice about the public health impact of gene patenting and licensing practices.

The advisory body could also provide input on the implementation of any future policy changes, including the other proposed recommendations in this report.

My only problem, as I read it now, with this is public health has perhaps almost a more narrow meaning than we really want here. We aren't really talking here about just public health. We're talking about patient access, the whole bit. Health impact. Yes, yes. Not trying to dis public health, Mr. Chairman.

Okay. All right. To be added to that rationale. This advisory body would be available to receive information about problems in patient access to genetic tests from the public and medical community and could review new data collected on patient access and

assess the extent to which access problems are occurring.

One of the advisory board's missions would also be to recommend what additional information should be systematically collected through iEdison so that iEdison can be used to determine whether grantees are complying with the guidelines mentioned in Recommendation 2, and the only thing I wonder, you know, this is a presumption in a way of access problems.

We could say data collected on patient access and assess whether and the extent to or assess whether access problems are occurring to make it a little less pejorative. Whether access problems are occurring and to what extent, if that's even needed, I don't know.

MS. DREYFUSS: Monitor access problems.

DR. EVANS: There you go. And monitor access problems. To monitor access problems and if any are occurring --

MS. DREYFUSS: To monitor access and --

DR. EVANS: Oh, to monitor access, yes, collected on patient access. Okay. Let me start over.

This advisory body would be available to receive information about problems in patient access to

genetic tests from the public and medical community and could review new data collected on patient access and monitor access. That seems awfully awkward. And identify whether problems are occurring and to what extent.

DR. McGRATH: So maybe to address the issue of pejorative language, in the first sentence take out the word "problem." The advisory board available to receive information about patient access.

DR. EVANS: About patient access. That's good. From the public and medical community and could review new data collected on patient access and identify whether problems are occurring, and maybe we could make that two sentences, public and medical community, the body.

Okay. All right. One of the advisory board's missions -- oh, we already went through that. Everybody okay with this?

To be added to the rationale, the advisory -- oh, we went through that. Okay.

All right. The advisory body should consist of federal employees and outside experts from a broad array of areas. For example, the body could be made up of

clinical geneticists, patent law experts, representatives from the diagnostic kit industry, commercial laboratory directors, technology transfer professionals, laboratorians, and federal employees from the USPTO and NIH.

The advisory body could also explore whether approaches to addressing patent thickets, including patent pools, clearinghouses, and cross licensing agreements, could facilitate the development of multiplex tests or whole genome sequencing.

One option to avoid the creation of another committee would be to create a standing subcommittee of SACGHS to serve as this body. SACGHS already has much of the necessary expertise and by its charter focuses on highly relevant issues.

MS. DARIEN: Can you add in consumer to the list?

DR. EVANS: Yes.

MS. DREYFUSS: Also researchers?

DR. EVANS: Yes. Okay. Clinical geneticist. Let's put --

DR. TEUTSCH: Jim, I think we have some

concerns about expanding the mission of this committee. We do not have standing subcommittees at the moment. We could, but we don't at the moment. It is an option. I don't know why we want to necessarily suggest that we want to expand our mission that way.

DR. EVANS: I guess the reason it came out was not in a self-serving sense, right. It was more because we had some reticence to say you need to create a new body and we wanted to say to the Secretary, hey, we already do this kind of thing. If you want us to do it, we will. Now, again, I'm agnostic about it.

DR. TEUTSCH: Or you can leave it more general. You could establish this function within an existing committee.

DR. EVANS: We could. Okay. Yes. So you're saying get rid of that, right, and instead say such an advisory body could be established within a relevant existing committee. Great. Okay. And then we need consumers up here who should be fairly -- let's put researchers, consumers. Say what?

MS. DREYFUSS: Research geneticists.

DR. EVANS: We've got, let's see, clinical

geneticists here and researchers. So I think that would cover it. Yes, and the advisory body should have a variety of federal employees. Could we just say the advisory body should consist of a variety of experts from a broad array? I mean, I'm okay with it as this.

DR. WILLIAMS: You're never going to get -- I mean, the solution to these never-ending lists that could be drawn from but not limited to or something like that.

The only other point I would make, though, on this and this is another structural thing is that the last sentence of this particular paragraph is a non-sequitur because it's not talking about the composition. It's talking about work of the committee which actually should go back to the previous slide.

DR. EVANS: So now you're talking about this last --

DR. WILLIAMS: The advisory board could also explore whether approaches to addressing. That's a task. That's not a composition.

DR. EVANS: Okay.

DR. WILLIAMS: And so I'm saying move that to the -- doesn't the previous slide talk about things that

the committee should be addressing?

DR. EVANS: It does.

DR. WILLIAMS: That's where I think it should go.

DR. EVANS: Very nice, Marc. Very nice. All right. I like it. We'll have to clean up the formatting. Okay. All right. Nice. All right.

All right. Two more. Providing needed expertise to USPTO. The Secretary, working with the Secretary of Commerce, should designate a liaison between this committee and the USPTO. This liaison, along with technical advisors the SACGHS could recommend, would provide input to the USPTO about scientific and technological developments related to genetic testing and technologies. This input would help inform the USPTO's examination of patent applications in the realm of human genes.

Marc.

DR. WILLIAMS: So which this committee are we referring to? SACGHS or this committee that we're proposing in the previous recommendation?

DR. EVANS: Okay. So we're talking about a

liaison. This is --

DR. WILLIAMS: Liaison between -- we've referring to this committee.

DR. EVANS: Provide input to the USPTO, and where are you saying?

DR. WILLIAMS: So I'm saying in the first sentence, designate a liaison between this committee.

DR. EVANS: Oh, okay. We're talking about --

DR. WILLIAMS: Is that SACGHS or is that another committee? So we need to say the other committee.

DR. EVANS: Wait a minute. This committee is SACGHS.

DR. WILLIAMS: Then we should just say that.

DR. EVANS: You're right. There we go. Now, the reason we have -- oh, I'm sorry. Rochelle.

MS. DREYFUSS: I don't know that this committee, SACGHS, is always going to have the information that the PTO is going to need. I would like for it to be able to advise the PTO on who relevant experts are for new issues that arise.

DR. EVANS: We have that here, right, along

with technical advisors that SACGHS could recommend?

DR. BILLINGS: Do advisory committees to the Secretary play this role in other aspects of the world, recommending experts, blah-blah-blah? Is that something that is novel that we're asking for, something that's kind of commonplace?

DR. EVANS: Is it novel? Sarah would know.

MS. CARR: I think it is a little bit. I'm not aware of another committee that does that, and I was initially a little concerned about this in that it's having a member, an SGE, in discussions with PTO, I think, not in a public way, but we conferred with PTO this morning, John LaGaider, and I don't think he was interested in -- he was neutral on the matter of whether a PTO would want to actually establish a FACA committee.

So I think we -- I don't think they're necessarily interested in such a formal body, but I think there would be some issues to work out with us.

DR. BILLINGS: That's my guess.

DR. EVANS: The question is because of the questions that arise about this, is it feasible, et cetera? Are there modifications that might help it? If

not, it would be one that we would put out there and if it can be worked out, fine. If not. All right.

And then to be added to the rationale, the committee believes experts in the field could help USPTO in its development of guidelines on determinations of non-obviousness and subject matter eligibility in this field, once pending court decisions, such as Bilski v. Kappos, are decided.

Would we want to say in its development of guidelines on determinations of such matters as non-obviousness so not to confine it?

MS. DREYFUSS: I would also get rid of once pending decisions are decided because in six months, this will already be dated.

DR. EVANS: Yes. There you go. Pending court decisions.

MS. DREYFUSS: No. Just the patent matter eligibility, period.

DR. EVANS: Okay.

MS. DREYFUSS: There will always be pending court decisions.

DR. EVANS: Well, yes.

DR. WILLIAMS: Period after field.

DR. EVANS: Okay. All right. Okay.

DR. TEUTSCH: Can we go back? I still have some trouble with the previous one.

DR. EVANS: This one?

DR. TEUTSCH: About the liaison with PTO. I think we want to -- this is really about them getting technical expertise. We don't really have to deal with the mechanism --

DR. EVANS: That's true.

DR. TEUTSCH: -- by which they do that.

DR. EVANS: That's true.

DR. TEUTSCH: And I think if we -- I mean, I haven't wordsmithed this, but I think the Secretary should work with the Secretary to assure that PTO has the necessary scientific expertise available to blah-blah-blah, and they can figure out the mechanism, whether it's across an agency --

DR. EVANS: Okay.

DR. TEUTSCH: -- or whomever.

DR. EVANS: So this would be something, like we can erase what is above. We could say something like,

"The Secretary should work with the Secretary of Commerce in order to ensure that the USPTO is kept apprised."

Is kept apprised of technical and legal developments? Okay. "Technical and scientific developments related to genetic testing and technology."

How does that look now?

"In order to ensure that the USPTO is kept apprised of technical and scientific," okay.

So that gets away from the whole, can a liaison even work, et cetera. Now, does this still make sense?

The Committee believes experts in the field could help -- so in there, do you want to leave it like this, or do you want to say in the rationale that one such mechanism, if permitted -- Rochelle is shaking her head. Just leave it like this. Great. An honest woman, I love it.

DR. WILLIAMS: The secret of a true leader is getting others to do their dirty work for them.

DR. EVANS: Such leadership, right? When I shake my head, other people nod, and vice versa.

DR. WILLIAMS: It's the rattling that distracts us.

DR. EVANS: That's right. I didn't hear anything. I see. That's right.

"Ensuring equal access to clinically useful genetic tests. Given that genetic tests will be increasingly incorporated into medical care, the Secretary should ensure that those tests shown to have clinical utility are uniformly covered by governmental and non-governmental payers."

Then to get to Paul's comment in the rationale, "Such uniformity in coverage would ensure that all insured patients, regardless of geographic location or economic status, obtain access. Our advocacy for such equal access is merely one component of this committee's longstanding concern about ensuring equity in the provision of genetically related tests and services." That should be plural.

Earlier reports and recommendations have called attention to the importance of equitable access to genetic testing.

So does that, Paul, address what you had brought up?

DR. WISE: It does, although looking over the

report, we were really focusing on the recommendations yesterday. It's whether that belongs in the beginning. So I'm a little bit more substantially away, because the document does not say why you are compelled to spend five years of your life doing this study.

In other words, it jumps right into scope and definitions, but it doesn't say, at all, why this came to our attention and why it's so important, that this rose to the surface and demanded amelioration.

DR. BILLINGS: I want to completely support that sentiment by Paul, not only because he has a great name but because it's a great thought.

DR. WISE: I'll take great name.

DR. BILLINGS: This goes to what Steve said at the beginning of this discussion, which is that the document currently does not make the argument for this particular remedy, the primary remedy that we've proposed, and why it's important at all, or at least not adequately from my point of view. What Paul is suggesting is in part changing the document to do that.

DR. EVANS: So, Paul, are you talking about this type of thing at the start of the report? You're

really talking about something quite different?

DR. WISE: It's the same point that I'm trying to make, but just it's really a question of format. I think it's fine to keep this in here as a reminder. Sam mentioned this as part of the recommendation, just to make sure that this is a good place to remind.

DR. EVANS: Again.

DR. WISE: It could be smaller, and you may not want to go into all the prior things, but put something up, because when you look at the introduction, it's very hard to see what the goal of this whole exercise was.

It also doesn't make any case. It looks almost gratuitous, and I think you're basically putting up your dukes a little bit when you do that, because it puts a huge burden on the specifics of your recommendations by not having the initial frame being, look, there is a potential problem here; this field is exploding.

DR. EVANS: There is controversy, right.

DR. WISE: Right. And as a committee, we have long been concerned about the rapid evidence-based implementation of equitable provision of genetic and genomic capabilities, and then reference the prior

reports and say it's time that we looked at this. It's a complicated issue. We know it's controversial, but we have been forced into doing our best to address this in a fair and open way.

DR. EVANS: That's good. We can couch it in terms, for example, as we do, but I don't think we do it upfront in this obvious way that you're advocating, that other bodies have looked at this but have not focused on the patient access problem, and try to get that front and center at the very start.

DR. WISE: I mean, the second paragraph, page 3, in the middle, it's buried. The lead has been buried, and it may be to elevate the goal of this study, or this exercise was boom-boom-boom. And then why, the justification for why this came to this committee at this time.

One paragraph, and then do some referencing to prior things, but it's a very different framing than just saying we sort of have an axe to grind here and we're going after this issue, regardless of whether anybody thought there was a real problem. It puts the burden on the critics somewhat differently.

DR. EVANS: That makes sense, that's good advice. All right, we'll work on that. Good.

Rochelle.

MS. DREYFUSS: I've always thought that, too, actually, that the beginning just doesn't say what this is about, and I think we should also add "reduction of healthcare costs," because it's not just about equal access, it's also about the problems of patent thickets, multiplex testing.

DR. EVANS: Which, all in the end relate back to our basic charge.

MS. DREYFUSS: So I do think that needs to be in paragraph 1 or 2.

DR. EVANS: Good, good. All right.

DR. WILLIAMS: I was just reflecting on this and it shouldn't be in the recommendation, because I don't think it's something that the Secretary can specifically take ownership of. The one piece, as I re-read that first paragraph over and over again, the idea about "ensure patients," I think it doesn't reflect the idea of the disparity issues that one of our commenters today mentioned, that there are issues beyond insurance

that impact access.

It's not to say that we should go overboard, but I would like to see something in the rationale that does reflect the fact that we're not trying to solve the healthcare system.

DR. EVANS: Yes. I think that's important, and I think that we can say, and hear, that we recognize that problems in access have many drivers.

DR. TEUTSCH: Jim, what we're missing here is what Mara said yesterday, which was that we need a process whereby those who do not have coverage have access, and the Secretary should be taking steps to identify and remove obstacles.

A simple process can be used between patients, providers, and the industry, that can facilitate, because that is part of this access issue.

DR. WILLIAMS: That's true. So that should be added to the recommendation.

DR. EVANS: That's good.

DR. WILLIAMS: Previous slide, because I had forgotten that. So that should be in the recommendation.

DR. EVANS: "To ensure that those tests shall

have clinical utility and that processes be explored which would facilitate" --

DR. TEUTSCH: "Remove barriers to securing access to those who do not have insurance coverage or access, or are unable to afford it."

DR. EVANS: "The mechanisms."

DR. TEUTSCH: "Unable to afford them."

DR. EVANS: "Explored to enable those who cannot afford" -- wait a minute. "Those who do not have adequate coverage." In a way, what we're really saying here is we need to reform the healthcare system. I mean, isn't this a little out of sight of our --

DR. BILLINGS: Isn't the point here, then, that we need to say what we think we can affect and what we can't?

DR. EVANS: Yes. I'm not --

DR. BILLINGS: Can I just finish? Then shouldn't we also, then, suggest that we have some way of measuring the impact of our remedy, including potential adverse outcomes from our remedy?

DR. EVANS: Yes. Again, so take it as one at a time, I really worry about having something like this in

here. It's like, okay, thanks, we're supposed to reform the healthcare system. I mean, yes, that's true, but this is a little outside of the scope of patents.

DR. TEUTSCH: No. She was talking about specific barriers to access.

DR. EVANS: What Mara has talked about a lot are enabling the programs that companies have, be they diagnostic or therapeutic to cover, provide free testing. We've had a lot of conversations about this. I'm far more skeptical than she is that this is even a viable way of really having an impact on much in the way of testing.

So I don't want to really, at the 11th hour, add a recommendation that the whole Committee hasn't really thought out and discussed.

DR. WILLIAMS: Well, that is what we are doing, isn't it? The point I would make here is that I think the criticism, inasmuch as we criticized the commenter yesterday, relating to the Warfarin story, about the fact that they were attributing lack of pharmacogenetic testing for Warfarin is attributable to the fact that there was not exclusive licensing.

By the same token, I think the point that was

being reflected was that there may be solutions, other than alterations to patent law, that could affect this. So I think it is germane to put this in here at this point.

DR. TEUTSCH: Jim, here is my suggestion, that you reframe this so that it's about getting access to tests, period, and then you can talk about uniform insurance policy, removing barriers as part of the text.

DR. EVANS: Isn't that what this says?

DR. TEUTSCH: No.

MS. DARIEN: No, it says for people that are covered; it's not for people who are under-covered.

DR. WILLIAMS: "Uniformly covered by governmental and non-governmental payers."

DR. EVANS: All right.

DR. WILLIAMS: So in some ways, it is. I mean, I think what this is really saying is that, because remember, the purpose of these recommendations is to effect changes that are within the Secretary's purview that could ameliorate some of the problems, independent of the statutory changes that have been recommended.

DR. EVANS: Right, right.

DR. WILLIAMS: So this germane.

DR. EVANS: So give me some wording here that is narrow enough so it's not "reform the healthcare system." I'm all for reforming the healthcare system, believe me, but that would be jarringly inconsistent to throw that in in a recommendation. Give me some defined language again.

DR. WILLIAMS: I think we have that.

DR. EVANS: Say that again.

DR. TEUTSCH: At the end, you say, given that genetic tests will be increasingly incorporated in medical care, the Secretary should ensure that those tests shown to have clinical utility are available and accessible to patients, period.

DR. WILLIAMS: The rationale.

DR. TEUTSCH: Then the rationale, you can talk about the issue of uniformity of coverage and that sort of thing. You can talk about how that can be done.

MS. DARIEN: I would put "equally accessible to patients."

DR. EVANS: "Are equally available and accessible." "Equitably available"? Then in the

discussion, we would talk about --

MS. DARIEN: "Uniformity in access would ensure" instead of "uniformity in coverage."

DR. EVANS: Okay. Discuss uniformity, uniformity of coverage, alternative mechanisms.

DR. WILLIAMS: The specific point that Mara mentioned was reduction of administrative burden.

DR. EVANS: Right. We could say "alternative mechanisms, reduction," and we can ask Mara for some wording. I don't want to put words in her mouth. "Administrative burden when implementing plans." I don't want to say "coverage plans." "Payment plans for those uncovered," something like that. "Those without coverage." We can wordsmith this. All right, yes.

MS. DARIEN: I mean, I don't know how you're going to end up wordsmithing it. I think some of the pushback the man from Athena got was that he was talking about having co-payment coverage. We were speaking about this later, but a test that is $5,000, somebody can't afford. I mean, if they're going to pay 80 percent, somebody can't afford a thousand dollars.

DR. EVANS: Actually, it's $11,000 or something

like that.

MS. DARIEN: Or, whatever it is, but so that it it ends not being that solution, that solution is not put forward as the solution.

DR. EVANS: Right. "Reduction," and "preventing undue burdens" or something like that, "financial burdens on patients."

DR. TEUTSCH: All right. So it sounds to me like we've worked our way through the recommendations. There will be a few tweaks, but I think we're there.

Before we vote on this, I want to reiterate, because not everybody was here in the beginning, at least the process that I would like to see going forward is we know this is going to be a report that gets a lot of attention, and some of it is not going to be wholeheartedly endorsing it.

It is incumbent upon us to make it really clear why we think the solutions we are recommending are the best ones. So there will be some wordsmithing in here, more than wordsmithing, making sure that our arguments are as cogent as they can be, and also we acknowledge all of the other perspectives that need to be in here, and

the positions, many of which we heard about in the last day or so.

What we absolutely have to have are words from the people who felt that their ideas were not fully captured in here. We need some words from you, paragraphs, so that they can get incorporated into the next draft.

DR. EVANS: Suggestions of where they go.

DR. TEUTSCH: Where they go. We need them and, unfortunately, I know Jim's been trying to get this throughout the process but has not received them. This is our last chance. We need to get those so that they can be incorporated, and I would like to see them here by the end of next week, so that we can complete the draft and get it back out to this committee for one more look-see by e-mail.

DR. BILLINGS: Steve, are you including the long response we got yesterday?

DR. TEUTSCH: The long response?

DR. BILLINGS: From the ex-officio who wrote us a very long response, Brian.

DR. TEUTSCH: We'll look and see if -- I mean,

he's been there.

DR. BILLINGS: I'm saying that that was a response by a member.

DR. TEUTSCH: We'll go back through that and pull some of the things in, although it wasn't necessarily very specific exactly where that all goes.

MS. WALCOFF: We're voting before we see all these changes?

DR. TEUTSCH: Well, you've seen the recommendations. That would not really change.

MS. WALCOFF: To the whole report.

DR. TEUTSCH: Pardon?

MS. WALCOFF: To the whole report. I mean, we're not going to have a look at it as all of these things have gone in, because I think that was such a contentious report. I hate to say that, because I know it means a little bit of delay.

DR. TEUTSCH: If we don't do that, it means that it would be delayed until February.

DR. WILLIAMS: From my perspective, and I've been thinking about this, I've heard the comments, I've read the comments, I know where they go, I know what

they're reflecting. It doesn't change the substantive recommendations that we will potentially be voting on and approving.

I personally don't need to sign off on the full report, which I think most of us around here have agreed probably is not going to be read anyway.

DR. EVANS: Thanks.

DR. WILLIAMS: If we set that snarky comment aside, to me, I am comfortable with the rationale that has been presented, the fact that we're going to be reflecting the perspectives, but the recommendations that we have here are the ones that I think are reflected. I think we can vote on it.

DR. EVANS: Yes.

MS. WALCOFF: I was going to say that, since it is so contentious, I think we might get more favorable votes if we give the people who -- I mean, you know who is going to vote for it because of everyone who has been voting for all of them all the way along. I think the whole point is, I think you're trying to address some of the dissent, and perhaps if you do, it may become more of a full committee report.

DR. EVANS: I think we have a pretty good full committee report. The dissent was by three individuals.

MS. WALCOFF: I'm one of those three.

DR. EVANS: I know.

DR. TEUTSCH: Sheila, what is it you would like to see in here that isn't in here now that would change your vote?

MS. WALCOFF: I think that I would want to see how everything has fit in, because I do feel like we've made some substantial changes to it, and I think --

DR. EVANS: Since yesterday?

MS. WALCOFF: -- the tone in the report -- well, it's hard to really keep track of every single one that everyone has been making.

DR. EVANS: They really have not been substantial.

MS. WALCOFF: But I can support the report today.

DR. EVANS: I mean, there have not been substantial changes from yesterday. As I said at the start, these were the changes that we decided upon and voted upon. It's just that they have been now

incorporated into the right place and formatted.

The changes we made today, I would argue strongly, are not substantial changes to the report.

MS. WALCOFF: But I think they do go to tone, and I think that is something that people pay attention to.

DR. EVANS: But is tone worth four months of preparation?

MS. WALCOFF: Better than five years.

DR. EVANS: Gwen, and then Paul.

MS. DARIEN: So can I just ask a process question, so I understand what you're saying? So you are -- since the vast majority of this committee accepted the report, has read the report, has studied the report, Paul, and Marc says he knows where things are, and so you are asking that -- the suggestion is that we accept the report as it is and the people that dissent look at the report carefully and give you words that describe their dissent and indicate the places where that dissent goes so that dissent is reflected in the final report.

So is that the process you're --

DR. TEUTSCH: Right. That's what we're

discussing.

MS. DARIEN: It seems like an eminently fair process.

DR. EVANS: I would add that this goes on in almost every report we do, that on the last day, there are always some changes that occur.

MS. WALCOFF: Not every report is as contentious as this one, though.

DR. EVANS: Not every report.

MS. WALCOFF: I think everyone agrees with that.

DR. EVANS: But again, to delay what has already been a long process, four months, for very minor changes, would be nuts.

DR. BILLINGS: Jim, first of all, I'm going to speak for my vote. I could very easily vote for this report and vote in favor of its adoption, depending on how the argument is made and the options for the particular remedy, which is the primary recommendation of this. We're recommending a change in the patent enforcement around health-related testing, right? That's the primary recommendation we've adopted.

How that argument is made, what the balance of risk and benefits of adopting that, how that's portrayed in the report, that's all essential in my view to making a good report, and, frankly, I feel that it's deficient currently.

DR. EVANS: As you expressed yesterday.

DR. BILLINGS: As I did. So the changes that Steve has suggested as the chairman of this committee might actually change my vote.

DR. EVANS: The question is, is it worth changing?

DR. TEUTSCH: Jim, let me make this suggestion. One of the things that we could do offline, we could go through the process, approve generally the recommendations today, do the revisions that we were just talking about and have, once sort of the final draft is available to all of you, we could actually have a teleconference and vote. It would not take us until February. It would have to be public, but we could do some such thing and you could get -- with the purpose of just taking a final vote.

DR. EVANS: Sylvia, you had a comment.

MS. AU: I think I agree with Steve. I think it's going to be kind of like what's happening with my report, where we have a chance to -- you're going to get the comments from the people who don't think their voices were incorporated adequately in the report, give people one more chance to look at it with a very defined timeline, but I think we can go ahead and approve the recommendations because I don't think that's going to substantially change. It's the argument about the --

DR. EVANS: So I think we voted on the recommendations and now what we're talking about is the body of the report, whether there need to be --

DR. TEUTSCH: What we would do is vote on the recommendations.

MS. WALCOFF: Even if you did do that same process, it is delaying it, I guess.

MS. AU: It won't delay it to the next meeting. I mean, it's going to be the same process as ours.

DR. EVANS: We can do it in some kind of time-reasonable way. I'm all for getting more buy-in from people.

DR. TEUTSCH: All right. So let's restate

what's going to happen. We need comments on specific issues by the end of next week. You'll get recrafted a complete report with recommendations, time frame to be exactly decided. You'll have a chance to see that. We will vote on that report at that time and today we're basically going to say that we're generally correct. The recommendations are okay, so that we have that buy-in.

DR. FERREIRA-GONZALEZ: So let's say this language is incorporated into this report and the majority doesn't agree with some of the changes in the report. So what do you do? I mean, the recommendations have already been approved.

DR. TEUTSCH: That's why you get to review it and if you feel like we've gone overboard the other way, then we'll have to deal with that, too.

DR. LICINIO: That's exactly my point. If you agree with the report as it is, absolutely fine, and you don't have anything, and then it's changed in a way to reflect the minority view, can you do a dissent from the dissent?

DR. TEUTSCH: Gwen.

DR. EVANS: Again, I will just put in one more

plug for this idea. We went over this for eight hours yesterday. We voted on every recommendation. We have made a few changes. I would move that we approve or not approve this report. As we have done with many other reports, there can be wordsmithing to the report to try to change some of the text, but it would not be in substantial ways. It wouldn't affect the recommendations.

I don't know, Steve, if you're listening.

MS. DARIEN: I guess, just as a point of clarification, isn't the dissent going to be clearly marked as dissent?

DR. TEUTSCH: No. We're just going to identify those issues as part of the considerations in coming to conclusions.

MS. DARIEN: That there wasn't agreement around these issues, are we going to say there wasn't agreement around these issues?

DR. EVANS: No. As we say in the report now, there is dissent, that there is dissent about some of these points. That, I'm sorry, guys, is not going to change. We could change this report so that people from

Bio would absolutely love it. Then there would still be dissent. They would just be from other people. I'm not sure what we're going to accomplish by dragging this out.

Paul.

DR. WISE: I'm sorry, Steve. As somebody who was not identified as one of the dissenters, I'm actually quite worried of pushing this through without adequate time.

One [reason] is, I'm not sure what the rush is. Is there any particular reason, after five years or so, that a few weeks or a month, one way or the other, is going to make a difference?

DR. EVANS: Right, if it can really be done. What I'm talking about is, we could go from meeting to meeting every four months and have this same discussion.

DR. WISE: I understand.

DR. EVANS: If we really have a mechanism where we can deal with some of this stuff, remote control, then I'm fine with that. I would ask, though, pursuant to, for example -- it was either Julio or Gwen -- do we really have that mechanism to do this?

DR. WISE: Let me just finish my point, [which]

is that this is not only controversial; we've dealt with other controversial issues, but this is potentially lethal to the Committee at a time when things are very unstable, I would say, in terms of how the Committee fits into very active policy considerations and new mechanisms, coming up all the time, for advisory roles.

So my sense would be to be attentive to the requirement to get this done, get it done efficiently, respect the hard work that has already been done to make this work. At the same time, if there isn't some critically pressing reason to do it immediately, like today, that we respect these requests, which I think are actually quite worthwhile and legitimate, do the best.

Or, you'll do the best you can to integrate the wording that will definitely come, within the next week, to you about this, put out the report so we can all look at it again, and then get the true feeling of the Committee, given the conversation we've just had.

Unless there is a really compelling, time-focused reason why we can't do that, my suggestion is that we do this right.

DR. EVANS: I am all for doing it right, as

long as we have a mechanism by which we can do that.

DR. TEUTSCH: Marc, and then David.

DR. WILLIAMS: So what I would propose is that [since] we're obviously going to be getting comments in to do the revision of the report, that that report can be sent out for review and then final comments, and that then when we meet, it is essentially a non-discussion, thumbs-up/thumbs-down.

DR. EVANS: Whoa. You're saying meet?

DR. WILLIAMS: Steve is actually running this part of the meeting, if I'm not mistaken.

The problem that I see is that, again, this could be a beach ball. This could hit back and forth, ad infinitum. We do need to have some closure. We do have recommendations that the Committee has agreed on.

I am in favor, if we can present this information in a better way -- I advocated for that yesterday -- but we have to have a defined process with an endpoint.

DR. TEUTSCH: I think I agree with what Paul is saying, that the deadlines are ours and we need to bring it to closure.

What I would like to see, having gone through the review process, which we just described, we will have a public teleconference to vote up or down on that final report, because I agree we owe it to ourselves and to everyone else to make sure that this report reflects, as broadly as we can, as completely as we can, our rationale so it is clear, and the different perspectives that we had to consider in getting to that decision.

I'm sorry. David.

DR. DALE: I agree with that position, Steve. And we would do this before Christmas, and we would have a mechanism, if anyone could not participate, that they could vote, cast their vote without being on the phone, a proxy?

DR. TEUTSCH: That's a challenge. That's a challenge. I don't know, we would need to look into that. I don't know whether you could give a proxy. I hope it's going to be an up-or-down vote.

DR. DALE: We need to be prepared for that. It's awfully hard to get everybody on a call, unless you have multiple calls, because you don't want to have the option of eight votes.

DR. TEUTSCH: Let us go back, because this gets to be a technical issue with the FACA Committee.

DR. DALE: We have these two pieces on parallel track. They both need to be reviewed.

DR. TEUTSCH: Two pieces? That's approved.

DR. DALE: That's approved, okay.

DR. TEUTSCH: We are talking just about the Patents Report.

DR. DALE: Well, I would advocate for us trying to do it before Christmas.

DR. TEUTSCH: Yes, we will do that. We'll find out what can be done. I understand people have other commitments. We will try and find out what mechanism you have to cast your vote if you can't be on the phone, but hopefully, we will be able to have that conversation.

What I need now is some agreement that the recommendations are agreed to and that, directionally, we're on track so that we can proceed with that.

All in favor?

DR. WILLIAMS: So, just to be clear, this is not a vote to approve?

DR. TEUTSCH: This is not a vote. This is a

vote --

DR. WILLIAMS: This is an endorsement of what we currently have, and the procedure that has been outlined?

DR. TEUTSCH: The recommendations and the process.

DR. WILLIAMS: Yes.

DR. EVANS: So this is a vote on the recommendations?

DR. TEUTSCH: All right, you want me to split them up? Let's first vote on the recommendations. We're going to vote on the final report. What you want is some assurance that the recommendations are the ones we just did this afternoon.

DR. EVANS: We went through all of them.

DR. TEUTSCH: All in favor of approving the recommendations.

[Show of hands.]

DR. TEUTSCH: Twelve. Opposed?

[Show of hands.]

DR. TEUTSCH: One. Abstentions?

[Show of hands.]

DR. TEUTSCH: One. If there is not approval, you will still get to vote on the final report.

Mara, are you on the phone?

[No response.]

DR. TEUTSCH: I'm sorry, and then the process.

All in favor of the process we outlined, whereby the revisions will occur. We'll have a teleconference to approve the final report, presumably in December sometime. All in favor.

[Show of hands.]

DR. TEUTSCH: Fourteen. All opposed?

[No response.]

DR. TEUTSCH: Abstentions?

[No response.]

DR. TEUTSCH: Who said we couldn't get to an agreement on this report? Okay, thank you, all. I know it's been a long slog.

Jim, thank you. What do we have to do? Jim, thank you for all your leadership on this. I know it's been challenging.

DR. EVANS: My pleasure.

DR. TEUTSCH: Before we break up, there are several issues that Francis raised to us, and I would just be interested in getting some of your suggestions.

There were three issues. One is incorporating the value, economic value, of technological innovations in the Cost-Utility/Cost-Effectiveness Task Force activities. The second one was about considering addressing the implications of an affordable genome as a discrete topic. The third was about publishing a paper highlighting prior SACGHS recommendations.

I'm going to take them in a different order. How do people feel about us trying to get some more visibility for our recommendations by writing a paper highlighting recommendations, something like a commentary in JAMA, or something of that ilk?

I'm seeing several nods. I'm seeing nods here. Are there any people who feel that is not a good idea? The people who are going to write it may feel it is not a good idea.

Okay, so given that we want to move in that direction, do I have volunteers who will help write such a paper? Dr. Dale, Dr. Evans.

I'll work on it, Julio, and I know we'll count on staff. Okay, Andrea?

DR. McGRATH: I am not volunteering exactly, but I would just like to put in a plea to think carefully about who we aim it at and where we do it, and not necessarily a clinical medical journal, because then we get too narrow with just one discipline.

DR. TEUTSCH: I think we could think about a variety of journals, but I think what was being suggested was we need to get to a very broad audience, a policy audience. So it could be in "Health Affairs," it could be "New England Journal [of Medicine]", JAMA, but that type of a journal as opposed to specialty journals.

Gwen.

MS. DARIEN: So after we finish doing the more scientific version, I will help you do a lay version.

DR. TEUTSCH: It would be great. I mean, if we could get the kind of manuscript that could be adapted for different audiences that would be great.

MS. DARIEN: I will help do that.

DR. TEUTSCH: The second issue is, and this is talking towards Marc -- and he has not been forewarned --

about incorporating the economic value of technological innovations in your Cost-Utility Task Force. Or, is it already there?

DR. WILLIAMS: Well, I think that we are certainly not ruling out that the cost-effectiveness legislation, at least for some of the monies, as I read it, indicated that there are certain places where research would have to exclude consideration of costs from the effectiveness.

I think that any rational view of comparative effectiveness has to include issues around costs, including cost-effectiveness in the traditional sense, opportunity costs, doing this versus doing something else, comparative costs, cost minimization, et cetera, et cetera, et cetera.

So we have reviewed what has currently come out from the different agencies that have issued that, and there are a number of other things that people have written on this that I haven't had a chance to review yet with the group, including from RAND and the new NIH studies.

So the intent is that we will definitely try

and capture that as a piece of what it is we are doing.

DR. TEUTSCH: We are going to talk about this in February, as we oversee the charge of the group.

DR. WILLIAMS: Correct.

DR. TEUTSCH: So we will have a chance to get people's perspectives.

DR. WILLIAMS: Right. The thing that we have been waiting on is the one thing that the Secretary has direct control over, the money that was designated to the Office of the Secretary around comparative effectiveness research. From what Sarah was saying earlier, that is still within the Office of Management and Budget, and is still being vetted. I don't know what else they are doing. That was a joke.

I think that will give us a much better direction about how we want to target where we think we need to go, since we're responsive to the Secretary as opposed to AHRQ, or, as Alan reminded me this morning, designating what NIH does with its money. So we want to be responsive to the Secretary's role in the whole realm of comparative effectiveness.

DR. TEUTSCH: The last item was considering the

implications of an affordable genome as a separate topic that we would take up. I think where Francis was coming from, he said we need to be forward-looking. We are really talking about an affordable genome in the foreseeable future; what are the implications for health and healthcare, healthcare systems.

It is not that we have not discussed this. It has come up in other reports, and it will [come up] in some of the ones we are currently doing, but it is a reframing with a focus on that as the, what shall we say, critical technology, the change -- what's the right word? -- disruptive technology that could really change the landscape.

I don't want to get into a decision today, but I would be interested in your thoughts about whether that is something we should be taking up in that frame.

DR. FERREIRA-GONZALEZ: I think this is a very important topic. As we have seen the technology exploding and the bioinformatic tools starting to be developed, when you talk about the foreseeable future, I think it's very real, that in the very near future, we will be able to have these tools for the clinical. We

still don't know what it means to have the whole genome sequence, but we definitely need to have a very indepth look not only at the analytical-clinical validity and utility, but also the ethical issues behind that.

DR. TEUTSCH: Sheila.

MS. WALCOFF: I was just going to add that I do think it's an interesting topic, in particular, related to the work we've just done on DTC, because some of the criticisms, and there was a recent article this week about this, between the testing of two of the most popular DTC companies.

We have the whole genome available quite inexpensively. How does that affect it; is there still a discussion about health versus not; how does that interrelate to the new way we are talking about research, if there is a new legitimate way, and traditional research.

So I would be in favor of it.

DR. TEUTSCH: Sylvia, and then Marc.

MS. AU: I think that this really does need to be addressed, because it's going to throw our whole concept of genetic healthcare upside down, because if

someone is going to have full genome sequencing, then you're going to have to take the family history to help you figure out maybe some of the variants, what is going on with the family.

So instead of it being the way it is now, where you take the family history to see who might be at risk, to do genetic testing, you're going to have the genetic sequence and you might have to take the family history to figure out how that sequence is interpreted.

Also, it's going to have massive impact in the public health arena if we start doing this, if it gets cheap enough, and we're doing this for newborn screening.

DR. FERREIRA-GONZALEZ: Are you talking about the germline whole genome?

MS. AU: Yes.

DR. FERREIRA-GONZALEZ: Remember that you're going to have cancer.

MS. AU: Oh, absolutely. If they know about things that happen later in life.

DR. FERREIRA-GONZALEZ: You can imagine where a chimera of genomes --

MS. AU: Absolutely. And, is it going to make

healthcare disparity even worse? Because we're going to know things about people. People aren't going to have coverage, and they're not going to have treatment.

DR. FERREIRA-GONZALEZ: Different ethical issues before the germline versus the change in the market.

DR. TEUTSCH: Marc.

DR. WILLIAMS: As I'm thinking about the work of the Committee going forward, it seems to me, barring some recommendation or some request from on high, that we will probably have a fair amount of available time at our second meeting in 2010, and I would suggest that we do an educational, probably a full-day educational program, around this particular issue. I think that would be highly useful.

DR. TEUTSCH: Barbara, and then we'll wrap up.

DR. McGRATH: I was thinking of adding a cautionary tone, but I like the idea of an educational session. I think certain technologies come along, like whole-body scans, and they're interesting and intriguing to think about but they may go nowhere. This is a pretty important committee. I think, that we should really

think hard about where we put our priorities.

So, are we looking at tools, perhaps, to the privileged? Are we looking at how genetics can help society and health more generally? I think a great step is to do an educational session but not go full down that road and bump aside other issues.

DR. TEUTSCH: All right. Well, I am hearing enough interest that we will try and put something together, whether it's an educational session or whatever. I think we'll have at least a little more discussion of this in February.

Closing Remarks

Dr. Steven Teutsch, M.D., M.P.H.

DR. TEUTSCH: Well, folks, we have done an enormous amount in the last two days. I don't know about you, but I'm pretty exhausted.

Just to run through a few of the things that we did -- I have to look at all my notes, because there was a lot of stuff -- basically, we heard about how GINA is being implemented from the various federal agencies and what is happening. We heard about some issues which we are going to need to continue to monitor going forward,

some of the unintended consequences of all of this.

Then, of course, we reviewed the Patent Report. We made an enormous number of very thoughtful comments, had a lively discussion, but as you know, we've now made a number of changes. We basically approved the recommendations. We have a report that is going to go through some final revisions, and then we'll review it in December and look forward to getting that out.

We had the report from Charmaine this morning on Genomic Data Sharing, formed a steering committee, and we will be hearing more about that at our meeting in February.

We reviewed the Draft Education and Training Recommendations that Barbara put forward and, I think, got some very useful suggestions. We'll look forward to getting those finalized in February, as well.

We heard a large number of public comments. One I do want to signpost is, Paul brought up we do need to get back to Myriad and let them know about that. So we will be preparing a letter to alert them to these concerns.

We reviewed the DTC Report that Sylvia has been

working on. We're going to clarify that these are, for the most part, health tests. We're going to emphasize some of the oversight and how they relate to CLIA, and basically, get that report completed and out. That will be great, and I think that's a real accomplishment.

Let's see. Then we're going to be preparing a paper highlighting our recommendations. Then we will be moving on to discuss where we want to go with the affordable genome at one of our upcoming meetings.

That is what Marc is incorporating into the Utility Report on Economic Evaluations, but you will hear about that in February, as well.

So I think we have done an enormous amount. Congratulations to everybody, and thanks particularly to Jim on the patents. I think we've come a huge way. To Sylvia, for all the work on getting the DTC completed, and to all, thank you very much and have safe travel.

[Whereupon, at 2:25 p.m., the meeting was adjourned.]

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CERTIFICATION

This is to certify that the attached proceedings

BEFORE THE: **20th Meeting of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS)**

HELD: **October 8-9, 2009**

were convened as herein appears, and that this is the official transcript thereof for the file of the Department or Commission.

SONIA GONZALEZ, Court Reporter