DEPARTMENT OF HEALTH AND HUMAN SERVICES

SECRETARY'S ADVISORY COMMITTEE ON GENETICS, HEALTH, AND SOCIETY (SACGHS)

- Sixteenth Meeting -

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Monday

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Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC

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C O N T E N T S

P R O C E E D I N G S

[8:35 a.m.]

Opening Remarks

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

DR. TEUTSCH: Good morning, everyone, and welcome to an early Monday morning here in Washington. I hope everybody had a good holiday. Thanks to everybody for making the extra effort to travel here. I'm sure many of you had to give up part of your weekend to make it and battle the weather last night. So, many thanks to everyone.

This is the 16th meeting of the Secretary's Advisory Committee on Genetics, Health, and Society. I'm Steve Teutsch.

The public was made aware of this meeting through notices in the Federal Register as well as announcements on the SACGHS website and listserv. I want to welcome members of the public in attendance as well as any viewers tuning in via Webcast. Thank you for your interest in our work. As you will hear later from Paul Wise, many of you have provided important comments which have been informing our work. We certainly appreciate

that.

Tomorrow we will have a public comment session at 1:15. We encourage any of the public who wish to address the Committee to sign up at the registration desk, if you haven't let us know already.

I would now like to welcome Rochelle Cooper Dreyfuss, who is a new member of the Committee and is attending her first meeting. Professor Dreyfuss is the Pauline Newman Professor of Law at the New York University School of Law and has also served as a member of two National Academy of Sciences committees investigating intellectual property issues and is past chair of the American Association of Law Schools' Intellectual Property Committee.

Before earning a law degree from Columbia Professor Dreyfuss earned a master's degree in chemistry and worked as a research chemist. So, welcome, Rochelle.

I want you also to know that last summer we had the pleasure of welcoming Judge Pauline Newman here. She shared her perspectives on patent reform legislation as part of our International Patents Roundtable. That was terrific.

A couple of our members are unable to be here in person today. Andrea Ferreira-Gonzalez is, I believe, in Europe, and Marc Williams won't be in attendance though Marc is hoping to join us later by teleconference. I believe he had his daughter's wedding this weekend, so I guess he gets some dispensation for that.

We are also welcoming Charles Keckler, deputy assistant secretary for policy in the Administration for Children and Families, ACF, as the new ACF ex officio. Martin Dannenfelser left ACF in May to become staff director of the U.S. Commission on Civil Rights. We wish Martin the best in his new position, and Charles, we look forward to working with you as well.

We have also had a change in representation from the Office of Public Health and Science. Dr. Inyang Isong left this month for Harvard, where she is pursuing post doctoral training in genomics and primary care through a pediatric health services research fellowship. Hopefully she will be carrying flag in that field as well.

Until an ex officio is named, Dr. Mike Carome, who we know well, will be serving as ex officio from OPHS

as well as OHRP. Mike, thanks very much for filling both those roles.

I think this has actually been a rather momentous few months since we last met. Before we go any further, I want to at least take a moment to identify a few of those things.

First, as I think all of you know, we need to salute the enactment on May 21, 2008, of the Genetics Information Non-Discrimination Act, GINA. Really, we need to sincerely commend all of the many advocates who worked so hard and for so long to bring this law to fruition. I know a large number of you are actually in the room today. Thank you very much.

Our nation now has a federal law to protect consumers from discrimination in health insurance and employment on the basis of genetic information.

We know from our own work on this issue, which included analysis of current law and a compendium of public comments documenting the public fears and concerns about the misuse of genetic information, that federal legislation is needed, and we made the legislation our highest priority.

At the same time we know that there is still much work to be done to implement the protections afforded by the law which do not actually take effect until June 2009 for the health insurance provisions and December of next year for the employment provisions. We also know that, as important as GINA is, it does not cover all types of insurance, including life, disability, and long-term care, or prevent all possible misuses.

For today we will celebrate this achievement, salute the President and Congress, and laud everyone who played a role in making GINA a reality. So, congratulations to all of you who played a role in bringing this to fruition.

We have a large agenda. In the interest of time and given our focus this morning on the development of future priorities, I won't review the status of our other current priority issues except to say that in April and May our reports on oversight and pharmacogenomics were formally transmitted to Secretary Leavitt, I'm sure to the relief of many of us who have labored overtime on those reports.

We are aware that careful consideration is

being given to both reports and the recommendations that we put forward.

In April, Dr. Gonzalez, Dr. Williams, and I had a very productive conversation with Greg Downing on the Secretary's staff about the oversight report. We know from the discussion that our recommendations in that area were much anticipated -- probably more than much anticipated. They had asked us to deliver them -- and appreciated, and are now being actively reviewed and discussed.

The Secretary's office has also undertaken a close assessment of the 14 recommendations that we made on pharmacogenomics. In your table folders you will find a list of HHS actions provided to us by the Secretary's staff that relate to some of those recommendations. We look forward to receiving additional reports in the future on the Department's progress and in addressing policy and programmatic gaps in these two areas.

Mara, you look puzzled.

MS. ASPINALL: Thank you. I'm just trying to understand the next steps in terms of comments on the report.

DR. TEUTSCH: We are of course waiting to hear back a bit more from the Secretary's office, but I think we will make it a point, too, to do follow-up with them along the way to see what the progress is, what additional things they could use from us, and to try and make sure that there is an orderly transition in these recommendations over the next few months as we get a new administration.

MS. ASPINALL: Thank you. Because there was, I think, at least one recommendation that had a time sensitivity to it where we talked about convening a group of people within HHS sometime in the fall.

DR. TEUTSCH: That was basically to help shape the registry.

MS. ASPINALL: Yes, yes.

DR. TEUTSCH: I am not aware if that has been scheduled. As you know, one of the things that probably could happen here is to bring the agencies together not only for that issue but to look at implementation. I think those are the kind of discussions we need to continue to have with Greg and the Secretary. Obviously, they wanted these. Hopefully they will take action on

them and carefully consider each of them.

MS. ASPINALL: Yes. It is super how they acknowledged the report and spent so much time going through it. Thank you.

DR. TEUTSCH: There are three main agenda items for us to cover over the next two days: deliberation on our new study priorities, an exploration of marketing of personal genome information and services directly to consumers, and third, our proposed action plan for issues associated with genetics education and training of health professionals.

Our morning will be focused on a discussion of the highest priority issues that were identified in the scoring process that took place in June. Paul Wise, who has been chairing the Priority Setting Taskforce, will present background information on the work and then lead our discussion concerning those priorities.

Our goal for this session is really to develop a shorter and more refined list of issues that can be researched further. Then we will look to finalizing that list at our meeting in December.

Tomorrow we will focus on personal genome

services, including the state of the science, consumer perspectives, and public policy considerations. Representatives from several companies have agreed to come and talk with us and are going to participate in a roundtable that will explore the information provided by these services as well as the companies' plans for helping consumers interpret and use the results in healthcare decision-making.

As part of our exploration of personal genome services we have a great opportunity. We will be participating in a workshop this afternoon sponsored by Secretary Leavitt's Personalized Healthcare Initiative on understanding the needs of consumers in the use of genomic-based health information services.

The workshop will focus on three topics: what is known about consumer interest in consumer-oriented, genome-based health information services, CGHIS, and the consumer's understanding of what is being offered; what information is needed by consumers to make use of these services to maximize health benefits and minimize harms; and what consideration should be made by the CGHIS organizations for privacy protections and informed

consent procedures.

We really do appreciate the Office of the Secretary providing us this opportunity to coordinate these two meetings. As you might expect, it has been a major effort on both parts, and we sincerely appreciate all their efforts to accommodate us.

A bus will be waiting outside this building at 11:30 to take us to, it says Reagan Building here but I think it is the World Trade Center, for the workshop. If you ordered a boxed lunch, please pick it up from Abbe and go directly to the bus. If you haven't, you can go to the cafeteria in the Reagan Trade Center and bring your lunch into the workshop.

Tomorrow afternoon we will be hearing from Barbara Burns McGrath, chair of the Genetics Education and Training Taskforce that was created in November. Barbara will provide an update on two taskforce products: the revised taskforce charge that was modified based on our discussions in February, and a proposed action plan for this group.

There are two SACGHS staffing developments that I want to mention. I think many of you are aware Suzanne

Goodwin left the SACGHS staff in May to pursue her doctoral degree on a full-time basis. She was a pivotal member of the SACGHS team and served on the staff of our predecessor committee, so she had a lot of perspective on the work of what we are doing and part of the historical memory of our group.

She was tremendously dedicated to her work. Her writing and analytic skills were exceptional. She was the lead staff person for our Coverage and Reimbursement Taskforce Report and the Pharmacogenomics Report, and played an important cross-cutting role in issue identification and helping plan and manage the Committee's work.

It is really gratifying to see that her interest in genetics policy goes very deep. She will be focusing on that in her doctoral work. So we hope and expect that we will see her again, putting her talents to work in the genomics area. I guess she is done next year, right? She hopes. Maybe we can recruit her back.

Anyway, recruitment is underway to fill Suzanne's position. Hopefully that will be done soon.

I would also like to introduce David Slade, who

I think is here somewhere. Over here at the table. David has been interning on the SACGHS staff this summer. He is an M.D., J.D. candidate at Southern Illinois University. His studies are focused on health law, bioethics, and administrative law, and he has been working very closely with Paul Wise and the Priority Setting Taskforce. You will see the results of some of his labors this morning.

David, we thank you for spending your summer and helping us with our work. Clearly, we need all your assistance.

Now for the highlight of the morning. Sarah helps us understand the rules of the road.

MS. CARR: Right. Good morning, everybody. As you know, you have been appointed as a special government employee to serve on this Committee. You are subject to rules of conduct that apply to regular government employees. These rules are outlined in a document called Standards of Ethical Conduct for Employees of the Executive Branch that each of you received when you were appointed to the Committee. I'm going to highlight two of the rules that we expect you to follow.

One is on conflicts of interest. Before every meeting you provide us with information about your personal, professional, and financial interests, information that we use to determine whether you have any real, potential, or apparent conflicts of interest that could compromise your ability to be objective in giving advice during our meetings.

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

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

Government employees are prohibited from lobbying, and thus we may not lobby, not as individuals

or as a Committee. If you lobby in your professional capacity or as a private citizen, it is important that you keep that activity separate from the activities associated with this Committee. Just keep in mind that we are advisory to the Secretary of Health and Human Services. The Committee does not advise the Congress.

As always, we thank you for being so attentive to these rules and all the others that you are obliged to follow. We appreciate your conscientiousness very much.

DR. TEUTSCH: Thank you, Sarah. Wise words.

Before I turn the agenda over to Paul Wise, any items of a general nature?

[No response.]

DR. TEUTSCH: If not, then we are on to the focal point of this morning's discussion, which is the work that's been going on by the Priority Setting Committee which Paul has so ably led.

Overview of Priority-Setting Process and Outcomes to Date

Paul Wise, M.D., M.P.H.

[PowerPoint presentation.]

DR. WISE: Thanks so much, Steve.

Basically, you remember that back in the

February meeting the committee for setting priorities was established with a primary goal of facilitating and guiding the process of identifying new priorities for this Committee for the coming several years.

The Committee is made up of these individuals, as you can see.

The goals for this morning, particularly for the discussion. Number one, to review the priority-setting process that we have employed. Second, is to review and to discuss the issue items that you all voted on and an exploration of the results, and how to best put together and digest those results. To reach preliminary consensus on the high-priority issues, or categories of issues, worthy of developing a further issue brief over the subsequent few months, and to review and agree on the next steps in the process.

[This is] just a timeline to remind everybody. Beginning in February at our meeting and then in subsequent activities that I will go into greater detail in a moment, 73 issues were identified for assessment by the taskforce. The items were listed and sent out to the members and ex officios for voting and for scoring in

June. The results were then tabulated. The hope for today is that we come to some approval of the process and some general consensus on categories of the 73 issues that merit further exploration by the full Committee.

From July through November the issue briefs will be developed and sent out to the full Committee for review and deliberation. In the December meeting, final decisions will be made on the study priorities.

Now, the process for identifying the issues for consideration had several different elements. The first was the discussion that we had back in the February meeting. Careful notes were taken and issues that were brought up were put together as part of the general list of issue items.

We then solicited additional items for consideration from the full Committee, particularly the members, and then a conference call with the ex officios to explore even further potential issues that should be considered by the Committee. A request for public comments also went out that generated a large number of very helpful suggested items. Also, conversations with people that we called horizon scanners, people who are

thinking about the future of how genetics will interact with societal forces.

The request for public comments went through the usual mechanisms, including the Federal Register, the website, and the distribution list. However, it was also supplemented by special outreach efforts to reach a variety of different organizations, including consumer organizations, medical associations, groups particularly focused on healthcare disparities, and representative business groups and payers.

The horizon scan activity was basically a prolonged interview with some selected people who travel in this arena. After taking suggestions from members, discussing it, talking with the potential availability of a variety of these people, these five people were interviewed by taskforce members. You can see their names and affiliations here up on this slide.

We then had to make some sense of how we would begin the prioritization process, and that was done through the scoring of the issues. Of the 73 issues, the majority came from the public comments. Sixteen came from the horizon scanners. The Committee, staff, and ex

officios generated 18. Office of the Secretary generated five. One of the articles that was discussed back in February suggested one. This generated the full list of 73 issue items.

These 73 items were then sent to members and ex officios for scoring based on a simple one-through-five scale, one being not important, five being very important.

The criteria for the scoring were the same as had been used in the past that accompanied the request for public comments. [They] accompanied the request for scoring. Just to quickly go through them: the urgency and national importance of the issue; the extent to which the federal government has jurisdiction and authority over the issue; the need for federal guidance or regulation on this issue; whether the issue raises concerns that only the federal government can address; whether the issue raises ethical, legal, social concerns that warrant federal government involvement or leadership; whether the Committee's policy and advice on this issue would significantly benefit society.

Continuing, whether the failure to address this

issue would prolong any negative impact the issue may be having on society; whether there is sufficient data about the issue that exists for the Committee to developed informed policy advice; and whether another body is already addressing the issue or is better equipped to address it. Lastly, whether the issue is within the charter of this Committee.

Basically, the scoring was built on the scorer's general summation of these issues rather than voting on each individual criterion.

This is a histogram of the results. It basically shows here the two lines which point out the top 10 and the next 10 rankings of the issues, where they fall in the general distribution of the scores. These are scores that are the total average scores for the members and ex officios' scores

These are the top 20 items that were scored highest by the Committee members. I'm not going to ask you to memorize this list. We are going to go through it in some detail over the next few minutes. But you can get a sense that some issues scored higher than others and also that many of these issues relate to one another.

There are certain clusters of issues that were identified as high scorers just by the simple one-through-20 ranking.

Now, the taskforce had to come to grips with, okay, how do we begin to make sense of 73 issues, all with individual scores. We could just take the top 10 as they are listed here and just hand them off for the development of issue briefs, more detailed exploration of these issues for consideration by the Committee in voting in December.

However, it was pretty clear that not only just on their face many of these issues relate to one another but also that there were likely to be patterns in the voting that would also help us to assess the clustering of some of these issues into categories worthy of further development.

So what we did was basically employ a mechanism to look at the profile of voting patterns. This is just a heat map.

[Laughter.]

DR. WISE: It shall be explained. The geneticists in the audience will recognize exactly what

this is.

Basically, what this pattern does is the deep red are fives and the very pale, beige-yellow is a one. You can see that this doesn't become totally clear at this point.

[Laughter.]

DR. WISE: But, that you can begin to see that in fact that some of the members, which are arrayed here along the bottom, and the issues over here, voted in very similar ways to other members. In fact, when you look at the voting pattern and how well it matched, it sort of looked like Eharmony.com. It really says something about your personalities as well as the issues that you voted upon.

But these brackets to the left and along the top are actually graphic depictions of how tight the relationship and the voting patterns are between different issues and between different voters.

I will move on and blow up one just randomly selected portion of this graph and magnify it. You can see that a very tight bracket here with a very short distance from the margin implies a very tight fit. A

long distance, like this cluster versus this cluster, with very tall brackets implies not a very good match, in fact dissimilarities between the two.

When we begin to look at the clusters of the issues to see which issues look very much like other issues based on the voting patterns rather than just the face validity of the substance as we would see it from these issues, you begin to see clusters emerge.

What I have done here is put in the red arrows the top 10 issues as they emerged from the voting. The brownish-yellow are the next 10 in the overall voting score. What you can see is that in fact there are clustering of high scores in certain arenas. What it did was it allowed us to not only look at the top 20 list but also begin to see that in fact there was clustering of voting patterns that would also, or should also, inform the way we put these issues together for further consideration.

The red are the top 10, the brownish 11 through 20, and then the next 10 are the yellow. I'm going to go through this in detail, so if you can't see, this is just to show clustering, not to go into the elements of the

clusters.

Basically, of the 10 20 to 30 highest-ranking scores out of the 73, this is the general pattern that began to group these together. I will go through these in detail.

Basically, the names I have chosen are not catchy. In fact, they are supposed to be as boring as possible because, really, we just want them as generic descriptions of the categories. But you can see that genetics and healthcare reform represented a cluster. Ensuring the clinical utility of genetic information was another. Some people might read this as more of a translational set of activities. The public health applications of genomic research, consumer access to genomic information, informed consent for genomic data sharing, coverage and reimbursement for genetic services, education of health professions on genetics, and genetics, minorities, and health disparities.

Now, interestingly and importantly, many of the individual, if not most of the individual, issue items that hit the top 20 as well as the ones that populate these areas were suggested by the public comments.

Now, looking at the genetics and healthcare reform cluster, these are the issues that were rated highest: the role of genetics in healthcare reform, integration of genomic information, clinical decision support, incorporation of genetics into electronic medical records, and implication of structural changes in healthcare delivery.

Now, these are all in the materials. They are all outlined in greater detail in the book that accompanied the scoring for each issue item. But I'm really just putting this up on the screen to get a sense of how the clustering seemed to take place and that it has some face validity. It makes sense; people did not vote randomly. In fact, they elevated things that tended to fit certain patterns.

Ensuring the clinical utility of genetic information. These were all heavy hitters. They all came up in the top 10, except for this last one that fell somewhat below, into the top 20.

Yes?

DR. EVANS: I understand that these ended up being clustered by voting patterns, but I don't think

that necessarily means that they indeed belong together. For example, while I think evidence development is extraordinarily important and the impacts of personalized medicine on health care are extraordinarily important, I don't really see those as being in the same category from a logic standpoint, not from a voting standpoint.

DR. WISE: Right. Ultimately logic will have something to do with the priority setting process.

[Laughter.]

DR. EVANS: We are hoping.

DR. WISE: But we must dissociate the logic from the voting at some level.

The clustering that I'm suggesting is a starting point for the discussion, not an endpoint. In fact, the voting and the clustering that I'm suggesting should provide guidance to the process but nothing more. We have the ability in the discussion today as well as subsequently to rearrange these, to move them, to create new clusters or new categories that are worthy in and of themselves for the development of issue briefs. This is merely a starting point. This is to provide guidance.

But it does provide guidance. The scoring did

result in, definitely, the elevation of certain issues and the devaluation of others. That guidance is important, but it is merely guidance. We will have time to rearrange these.

The public health applications of genomic research.

DR. TEUTSCH: Joseph, did you have something?

DR. TELFAIR: Yes, sir. Dr. Wise, I just have a question.

DR. WISE: Please, Paul. Only my mother calls me Dr. Wise.

[Laughter.]

DR. TELFAIR: Well, you don't live where I live.

The question I have is based on your last statement. Does that mean that the criteria we used that guided the voting would also be part of that consideration when we decide the prioritization of these items as well?

DR. WISE: Yes. The suggestion is that the criteria for voting would also be the guiding force in how we ultimately decide by December on the most pressing

priorities for the Committee's subsequent action steps.

DR. TELFAIR: Thank you.

DR. WISE: Consumer access to genomic information. Again, some heavy hitters in the top 10 can be identified here. Again, some of these we could pull out, some of these people may find are not appropriate because of certain other criteria on the list. Others may be brought in or explored differently, but based on the issue items and their voting pattern and their voting priority this area seemed to be extremely important.

Informed consent for genomic data sharing was another arena. Coverage and reimbursement for genetic services was felt to be important but did not rise to the top 10. It was in the 11 through 20.

Education of health professions on genetics was quite important. In fact, it was among the very highest scorers, and that is good because we have a standing taskforce dedicated to address this issue. I will talk about that in a minute.

Genetics, minorities, and health disparities. Clustered, it was not among the top 20 but was very close to the top 20. It fell between the top 20 and 25.

Next steps. Basically, the next step would be a discussion here to both comment and find consensus and general approval of the process that the taskforce pursued in generating this list of important potential priority items for the Committee and the development of issue briefs: in other words, the clustering or categories of issue items that are worthy of further exploration by the Committee.

This we would coordinate intensely with the Evaluation and Education Taskforces. The Evaluation Taskforce name may undergo some change, but it was clearly recognized that many of the issues that we were identifying as very high priority would likely fall into the purview of what we are calling the Evaluation Taskforce. In speaking with Mara and Steve, the suggestion is that the development of the issue briefs for categories of issues that likely relate to the purview or the charge of the Evaluation Committee and the Education Taskforce will in fact be done in close coordination with these taskforces, taking advantage of their expertise and commitment to explore these issues in greater detail.

DR. TEUTSCH: Just a reminder for those of you who may have forgotten. We did have an agreement about a year and a half ago to create a taskforce based on some issue briefs that dealt with a series of translation, evaluation, and economics issues. That was deferred. It was approved by this group but the committee's work was deferred to get on with the oversight report.

Mara has agreed to lead that effort. She has a group of people that have already been identified. But that work is now beginning, as opposed to the education one, which has already moved nicely along.

DR. WISE: Thanks, Steve. The issue briefs being developed can reject elements that came up high on the list or include others or other things that come up over the course of the conversation and the discussion. The voting to date on these issue items are to provide general guidance to the development of these issue briefs.

These issue briefs will then be distributed to the Committee for review, and we will vote on these issue briefs and ultimately select the priority issues for subsequent action steps. Thanks.

So I expect that my presentation may have generated some questions or points for discussion. We now have some time to explore through open discussion any issues that you may want to raise.

Discussion and Determination of High-Priority Issues

DR. TEUTSCH: This group is rarely shy. I can't believe our work is done.

We have two major things we need to talk about. One is the process. We can't go back but we need to go forward. Is the process that Paul laid out reasonable. The second, of course, is how we organize our thinking and the process going forward.

I saw a couple of hands. Jim, do you want to start?

DR. EVANS: Sure. I think that, using the heat map-generated categories as a start, it might be useful to kind of refine those to come up with, all right, here is a category that clearly we think is important.

I would, for example, bring up that high on the list, no matter how you look at it, is the issue of the impact of personalized medicine on health care, the role of genetics, genomics, and healthcare reform. I would

see those as different from that also very important issue of clinical utility, evidence-based medicine, et cetera.

So I would say that perhaps those should be teased apart into two different but both very important categories.

DR. WISE: I just think that is very important. It was clearly a consideration as we were looking at how best to put together these clusters. I felt somewhat relieved in doing this to know that this is likely going to be an important focus for what we are calling the Evaluation Taskforce to sort through some of these things to see where logically these things may fit and where other arenas of activity for the Committee may be more appropriate.

So my placing them together in this way reflected not only the heat map associations but also the kinds of conversations that came out of the February meeting. But I expect that it will be explored in great detail by the Evaluation Committee and the development of the issue briefs. Please, Paul.

DR. MILLER: Congratulations on your work,

first of all. It looks like it took a tremendous amount of time. I don't understand it, but it looks like it is very impressive.

[Laughter.]

DR. MILLER: I particularly like the colors.

A couple of thoughts about it, comments, and then, I guess, a question. One is, when I was filling it out it struck me, and I raise this to test it rather than anything, is that at the end of the day we really have about, at most, five things that we are going to do.

So at some point all of this detail and the [list of] 73 really comes down to identifying five things. That was how I thought about it. These are the things that I would really like to do and these are the things that are all very interesting and good but I think should fall off the list ultimately.

It struck me from your presentation that as you cluster these things around, and you could see that in the back of your head as you were going through it, one way of approaching it is to create these issue areas to come up with these five issues.

The details of it almost can kick start the

process of priority setting within the particular committee to say, gee, here are some things that are potential things that you should look at within the context of healthcare reform, or something. These are some ideas but really it is up to the Committee to tease that out. That might be a way of capturing all that information, making sense of it, and moving it into the next process.

Here is my question regarding your analysis. I was struck in terms of the member scoring and the ex officio scoring. In other words, if you can walk us through either the great deviations or the great similarities between what the ex officios thought this Committee should be all about going into the future vis-a-vis what the members thought this Committee should be all about, I think that would be helpful.

DR. WISE: As you can see from the heat map -- I'm kidding.

[Laughter.]

DR. WISE: I have stared at it way too long, but you actually can see differences. We did analyses and correlations between the ex officios and the members.

In fact, there were some differences.

The ex officios seem to focus, not surprisingly, on areas that represented their arena of activity and tended overall to score everything lower. So when it was normalized, it fit pretty well.

Yes, Gurvaneet knows exactly what I'm talking about.

[Laughter.]

DR. WISE: But the point was that the ex officios generally conformed to the same kind of hierarchy of priorities as did the members. It shifted things slightly but not significantly in moving things from the bottom to the top.

So we felt comfortable after looking at that that the total average score for members and ex officios was probably the best reflection of the best wisdom that was available to the Committee.

I should just point out that we received a member's voting extremely recently and it has not yet been integrated into the scoring. However, looking at the results this morning, basically it conforms very nicely to the scoring priorities that the rest of the

Committee already did. So we don't expect any changes to take place.

DR. TEUTSCH: In your folder you have the most recent version and you can do the discrepancy scoring yourself. I found it interesting but I couldn't figure out the overarching message myself.

DR. MILLER: That is what I was trying to see. But it strikes me that after going through the numerical discrepancies, really, the ex officios and the members more or less line up globally in terms of priorities.

DR. TEUTSCH: The scores that Paul showed you were the scores of both the ex officios and the members.

DR. MILLER: I think that is telling. That is important.

DR. WISE: Yes, please.

DR. FITZGERALD: Paul, I want to thank you. I thought that was just obviously clear from what you presented.

[Laughter.]

DR. FITZGERALD: I think we just need more education in cladistics for the lawyers.

DR. TEUTSCH: What is cladistics?

[Laughter.]

DR. FITZGERALD: Paul will explain that to you.

Just one question. When you came up with your categories, there seemed to me to be a difference that we might want to take into consideration as we go forward in deciding these things. Not to say that things aren't important, but for instance, when Jim talked about personalized medicine being an issue we obviously have to address, I would say yes, personalized medicine is what we have been working at over the last three reports for sure and certainly what we are working at now with the education and the efficacy reports.

So in one sense, personalized medicine would be pulling it all together and that would be the global kind of approach, whereas something like the effectiveness or the need to ensure clinical utility would be a piece in each of the reports that we have done. So it is kind of an intersection but not a combination of everything.

So it seems to me some of the topics that we have discussed would be relatively focused, which might be easier in a sense to get at, whereas others may be important but we are going to run into the same issue we

have run into before with the oversight of genetic testing and everything. What is a genetic test. It became the oversight of the testing.

I'm not saying we shouldn't do it, but if we really go for the broad, global thing, I think we need to know that ahead of time and then set our goals accordingly.

DR. WISE: Thank you. Basically, what you are identifying now and the refinements of your thinking and suggestion would be precisely what should be captured in the issue briefs that are the next step. In other words, to refine this, identify what does this really mean, what in fact has been already done by this Committee, what in fact is ongoing by other committees that are advisory to the federal government, so that the Committee members can then have a far more detailed understanding of what this issue would involve and the best way perhaps to approach it. This is my expectation from the next step.

As Paul pointed out, what I was basically trying to do was to take 73 individual items and turn it into maybe 10 to 12 categories of high priority items. How they fit together and where they belong we still have

time to move forward with.

The discussion that we are having now will alert our Committee, the Evaluation Taskforce, and the Education Taskforce about how the Committee members feel about certain strategies and certain approaches to take.

DR. TEUTSCH: Kevin, I want to get you to elaborate a little bit more because I almost heard you talking about you can organize this in a whole variety of different ways and which kind of a strategy would provide a better framework for our thinking.

DR. FITZGERALD: I guess the idea is getting back to something that I think we have been wrestling with a little bit explicitly but also perhaps more so implicitly.

As the Committee goes forward, how does the Committee wish to focus its resources. Does it see itself as the group that provides the 50,000-foot overview which is going to, of course, set a certain dynamic for how you approach things and what kind of topics you take on, or is this a group that also needs to get more detailed and fine-grained and look at issues like clinical utility, which are going to be incredibly

important issues across the board but aren't going to be addressing everything.

It is a general kind of criterion but one that one could apply in looking at whatever topic that you pick up. It is another way of kind of looking at your heat map.

DR. EVANS: I don't think those are mutually exclusive.

DR. FITZGERALD: No, no, no. They are not exclusive at all.

DR. EVANS: There isn't any reason why one thing that is tackled can't be very broad and one is very narrow.

DR. FITZGERALD: No, exactly. I'm just saying it sets two new large categories that one could look at and see where your topics fall into.

DR. TEUTSCH: Joseph.

DR. TELFAIR: I just have two things. One is just a comment and the other one is a question. It seems to me that if part of the decision that we as a Committee have to make is related to the criteria, then what we have to think about is some kind of mapping done with the

final 20 priorities. In other words, it is more of either a straight map or a grid map. I don't know if you know, but in social statistics you always have interrelationships, which is what I think you are talking about.

One of the ways you get around that is that you also then look at how those things are related to that, to get away from the idea that everything is related to everything, which is part of what we are saying. A grid map would actually work, and that would be a suggestion to the next committee.

The other question that I have is, do you see, as we think about these priorities and you have two taskforces that are related to this, that there would be some kind of demarcation of the areas between the two taskforces. That would make logical sense in that the Education [Taskforce], for example, would focus on most of the issues, and then you have the other taskforce, Evaluation.

I was wondering whether or not that was something that you were thinking about or not.

DR. WISE: Yes. How our taskforce, the

Priority Setting Taskforce, related to the other standing taskforces was very much a consideration. The highest priority for us in the Priority Setting Taskforce was respecting the process that we have embraced for setting priorities. We felt that the process of voting needed to be respected, the process of the way we try to capture as many items as possible needed to be respected.

So the requirement for respecting the process is that the other taskforces also respect the process. It just so happens that education of professionals and in different arenas came out among the very highest priorities in our scoring. So it was a full embrace of the taskforce education activities and the expectation would be that that taskforce would very much be involved, if not take the lead, on developing the issue briefs related to education that would then come to the full Committee for consideration.

The Evaluation Taskforce is still in development, but clearly, based on the interest, the commitment, and the expertise of the members on that taskforce and the general mandates of that taskforce, we would expect that many of these issues or a few of these

categories of issues would fall to that taskforce for exploration, for doing precisely what Kevin is suggesting, and that the Priority Setting Taskforce will in fact rely on the Evaluation Taskforce for guidance and assistance in this arena.

The categories begin to break out pretty well. Clearly, the education falls squarely with your taskforce. The other we are going to have to see how best to approach it in terms of coordinating with the Evaluation Taskforce.

So we see this as a highly integrative process but respecting the priority setting process that was set forward in the February meeting.

DR. TEUTSCH: Gurvaneet.

DR. RANDHAWA: I want to start a discussion on a slightly different thing. We haven't really discussed if the products of the new topics will all be the same as what we had in the past. So we are talking about these things as large topics requiring exhaustive factfinding and large reports at the end of that.

Is there any enthusiasm for smaller topics and shorter turnaround? For example, having some white

papers or thought pieces which wouldn't require the same timeline and same resources. Are there going to be different categories or topics and different products that we can think of or are we thinking of only large, substantial topics?

DR. WISE: Well, this may fall outside the work of the Priority Setting Taskforce, but my general sense would be that among the very highest priorities there may be different appropriate action steps taken. Some might be best served by a quick white paper kind of thing. Others may require a much more involved, full report generation. But, the full Committee and its standing taskforces would then be able to begin to chew on these priorities that have been identified in ways that would make the most sense for the Committee to have the most effective results.

I see my charge and the charge of our taskforce as the development of the highest priority issues for the Committee. How best to address them may be the work of the taskforces and the chair.

MS. ASPINALL: Can I comment on that? Gurvaneet, I think that is a key issue. We have started

to discuss that. I personally very much agree. I think we need to be action-oriented. There are some issues that require the extensive time that we have had on some recent reports. There are other issues that both because of their timeliness and work that has already been done that may be very easy to do in a relatively short time frame and articulate the issues and the concerns of the Committee.

So, at least from the Evaluation Taskforce, I very much want to be both proactive, action-oriented, and have the ability -- and Steve, I think it is fair to say you are comfortable with this -- to parse through them in a way that is most personalized and most specific to each issue. So when we were looking at it, they all did not need to be the same extensive, year-long process but that was part of the prioritization from the groups.

I'm quite taken by the fact that so many important issues came from all of us but particularly the public comment period. To get to even the top 10, if we do them in that serial, very long process, we won't be able to get to them. I think, at least personally, it is very important to get to them. So we will need to both

prioritize and figure out a way to get effective comment on it, quite frankly, in the shortest period of time.

DR. TEUTSCH: Barbara.

DR. McGRATH: I hope we don't lose track of some of the ones that fell down for the 11 to 20 as well because some of them didn't exactly fit as a separate category but would be, maybe, part of the others. I'm thinking particularly of the globalization and international. It doesn't necessarily stand on its own but it fits into other ones.

The idea of increasing communication and coordination with bodies just like this one that are in Europe and Asia seems like one to not just forget but infuse into some of the other ones, like informed consent. It fits into a lot of them, not necessarily the healthcare reform in the U.S. but some of the others.

DR. WISE: I should just take this opportunity to say that that actually was one that I voted high on.

[Laughter.]

DR. WISE: There is a little red spot up there.

But it did not come out high in the voting. It came out near the bottom. The ex officios hated it even

more than the members.

However, we always have the opportunity, particularly within the taskforces and the development of the issue briefs, to elevate and to pick certain things, recognizing that it scored low but that it just made so much sense. Things change over the course of six months, but also that it just fit so squarely into the exploration of items that did score high that it warrants inclusion.

Again, this is guidance. It is not divine law. I think points like this need to be continually brought up because this is just guidance. But it is guidance. It does tell us something about the relative importance of these issues by the Committee members, but it does not preclude ongoing exploration or inclusion into one of these other categories.

Please.

DR. HANS: I just wanted to add to Gurvaneet's comment, or lead off from there to suggest that the Committee may want to think about doing something a little bit different, or entirely different, during this period of time. Those of us who are in the executive

branch are already updating our presidential transition briefing books. Whatever happens in November, we know that new leadership will be in charge in all the departments.

It is an opportunity for this Committee if you want to tell the new incoming administration these are the three priorities or the five priorities that you should have over the next four years. It is an opportunity if you get your timing right to be able to put those ideas forward during this transition period. Then you have an opportunity over the rest of the tenure of the Committee to delve more deeply into those issues.

But you may want to think about is there something you want to say to the new administration as they are coming in, and the new leadership as they are thinking about their priorities.

DR. TEUTSCH: Yes. I tend to agree with you. Mara captured some of the concerns that we want to be action-oriented and we want to do things that are relevant. I do think we need to engage the new administration, whatever it is, effectively. There is a lot of work that this administration, even if it moves as

fast as it can, won't even get to that is of our older work. The reports that we just talked about on pharmacogenomics, oversight, and reimbursement are going to be ongoing issues that aren't going to be solved quickly.

I do believe that, to the extent we can, that we are informing them and responsive to them so that we are going to show some results of our work, not just talking to ourselves.

DR. AMOS: I'm just wondering; in the Evaluation Committee, Mara, is there going to be a list of criteria for priority setting that will be agreed upon? I'm hearing a lot of different perspectives.

MS. ASPINALL: Yes, there will be, but my sense is we are not going to rewrite the prioritization that we have for the whole Committee. A lot of work has gone into putting the overall 73 issues together. It is really taking the short list and reprioritizing them, to Sherrie's point. We did talk a little bit about how to do that vis-a-vis the new administration, particularly in light of healthcare reform and several of these issues. If that becomes an issue with the new administration, it

is very relevant.

My sense of it is that the eight issues that Paul went through in terms of priorities will remain mostly in stake. We are not going to restart that process because everyone voted on them in that light. But [we will] take two or three of them at the top and say, okay, those are the key priorities, how do we then move forward with a smaller number from there.

Paul mentioned logic. I think about it as logic and logistics. We need to use the logic that says which are the ones that are most relevant and logistics to understand how we can do something that is important, action-oriented, and quite frankly, can be staffed from SACGHS as well. [That] means that we probably can't take on six new issues and hope to get them done in some reasonable period of time.

It is that balancing act between priorities, action, and resources to get it done. But the focus, on a brief look at the issues, is that several of them can be done relatively efficiently given what is already out there and the strong views of the Committee.

DR. WISE: Joseph.

DR. TELFAIR: Yes. The direction the conversation [is interesting] because a fact that was pointed out was the choice and prioritization of the categories via the public comment, which is something that, as a criterion, seems to me that is going to have to be thought about given what has been said.

The second thing is that there are categories and areas that have been in play as far as discussion goes for quite a long period of time that really haven't been addressed at the level of that. It seems to me that if we are going to look at using both the criteria we have and look at what has been said that we also need to think about historically what we have not actually paid attention to that keeps coming up over and over again pretty much through public comment and other means as well.

I think that is consistent with what we are saying, and I would say that if we take what was suggested in terms of the top five or whatever that are actionable and that we probably need a lot of play from, it makes sense to think about those other aspects of it as well. From a consumer advocacy aspect I think it is

pretty critical.

MS. ASPINALL: Can I say one quick thing? If you look at what the Committee voted as the top 20, I believe 14 of them came from public comment. So I think while we are quite creative here it really says that the comments we got in from the public were critical not only in the 73 and just creating a long list but creating what we all saw as the top priorities.

DR. WISE: Scott.

COL. McLEAN: Any observations or comments on the degree to which we are looking at topics that are novel versus a rehash of things that we actually have done before and are pretty well addressed but people just aren't aware of that?

DR. WISE: Theoretically, that was one of the criteria that was used for the voting. However, in the development of the issue briefs that are the next step some effort, I expect, should and will be made to identify the opportunity in front of us on this issue which has already been covered by this Committee or others, or has this issue really been ignored despite its importance.

That should be part of the issue brief development, to guide and form the Committee's judgments about ultimately setting the highest priorities. I think that is going to be crucial. It certainly will be crucial in how I think about it, and I expect that that will be part of the issue brief process.

Can I just say a couple things? It looks like we have a hiatus or lull in the conversation. One is to thank the staff for putting this all together. I get the easy task of presenting it. They had the very hard job of putting this all together. So, David, Sarah, Betsy, Cathy, thank you very much. David, particularly as a rookie, did a spectacular job on keeping track of all the scores, almost on an hourly basis there for a while, and supporting the taskforce's activities.

Can I just ask very specifically [are there] any questions or concerns about the process that we used?

[No response.]

DR. WISE: Thank you. We do have more time; is that correct, Steve?

DR. TEUTSCH: I would suggest one of the things that we do is look at the clusters that you did and make

sure that we have not only gotten a sense of what other things folks are high priority clusters, what do we call them, and how do we get to a list that we can tackle in a reasonably organized fashion.

DR. WISE: Could I suggest that we not go through perhaps each one of these but start with the one that tends to generate the most conversation? There are a couple of them that do. One had the highest number of elements that rose to the top.

This was not one of those, but this was. It may be that this set of topics is dispersed or then becomes an element of other arenas, but the elements of personalized medicine and genetics, and personalized and direct-to-consumer provision of genetic testing clearly became a cluster not only in the conversations in February but showed up in all the cluster analysis of the voting patterns. This not only got very high ratings but people clustered all of these issues together in the way that they voted.

So, could we begin, perhaps, by seeing if there are comments or guidance that people could provide us in thinking through this arena? Sherrie.

DR. HANS: I'm sure this will come out in the issue briefs that are developed, but I was struck that this particular area is one where I'm not aware that there is a lot of work being done in HHS, in the public forum, or committee work by other groups.

So I think, particularly as the issue brief is developed for this particular area, [we need to look] very carefully both within government and outside at who is dealing with this set of issues. To me, it doesn't seem to be one that is getting a lot of attention and focus at this time and could be a real opportunity for this Committee.

DR. EVANS: As, actually, the heat map suggests, I see the top one as perhaps a difficult topic to distill down. Maybe it is not very actionable but it is extremely important. That is, the affordable sequence is going to have huge effects on so many different things that to put it into a category that, to me, hangs together really well in those remaining four things seems a little illogical.

I really like the broad list that you came up with that you showed a few minutes ago. I'm not sure

those were together in that, but it does seem like the bulk of those issues can be subsumed under one category, and that is consumer impact, the impact on consumers and the access by consumers.

So I would suggest that perhaps that top one be teased out [but] not thrown away because I think it is an incredibly important issue. Do you see what I'm saying?

DR. WISE: I do. I think the way that [people] voted, and actually the way that I thought of it as being relevant to this cluster, is basically because making it affordable does do a lot of things. What was of greatest concern in the way people looked like they were voting was that it basically would mean the consumers would have high access directly to genetic testing.

DR. EVANS: Again, I think the heat map is important, but we have to remember how the heat map groups things. It groups things as to similarities in what you voted for. It doesn't mean that because you rated two things with great similarity and that they overlapped that people even thought of those as related. I would say this is one of those instances.

DR. MILLER: I would add, combined with Mara's

comment, that possibly what Jim's concern is, or certainly the way that I'm thinking about it, is that the outcomes are very different between the two groups. One way to think about some of these issues is the bottom four lend themselves quite nicely to product or to activity, to stuff that this Committee can do.

The top one is a more global think piece. It is important, granted, but it is harder to envision what the deliverable might be other than maybe descriptive or something. So matching that and focusing on what are going to be the core deliverables that come out of this Committee, that have come out before, and that we can envision coming out of the Committee is also a good way to winnow down and to focus this Committee. We are not saying that other issues are not important, but to really begin to zero in on where can this Committee add value with product and activity.

DR. TEUTSCH: Could I suggest, as we go into this, we have to make sure we have the clusters correct, either as Paul laid them out or with some modification. Are there important things that are missing or need to be reframed. What we have here is guidance and one way to

do it. I suggest if we have comments on whether the clusters are right, that would be helpful.

The second thing is, if we can get to reasonable agreement on these or some modification of them, then I think it is helpful to go through the specifics within here and look at specific pieces within there and specific issues. If you think they belong in separate clusters or whatever, that will be important to bring out so that we have as good guidance as we can for how to go forward between now and the next meeting.

Before I get quiet again, Marc, are you on the phone?

DR. WILLIAMS: Yes, I'm here.

DR. TEUTSCH: Good. Congratulations on the wedding. We are in the midst of a discussion on priorities.

DR. WILLIAMS: I'm enjoying it very much.

DR. TELFAIR: To be consistent with what the chair just recommended and also what our colleagues just said, I would agree that the first one does not fit into this grouping. But I would also argue that the one that is scoring the 3.88 is actually driving the other three.

So, with a slight modification, comprehensive consumer strategies would drive everything else if you looked at it in terms of a group and a category and in terms of a deliverable.

So if we decided to look at comprehensive and predictive strategies and then, below that, what are some of the tasks that would come under that, this list would fit that way. Again, the way I look at things is I map out outcomes and then steps that we need to get to the outcome.

So the outcome is developing a model that this Committee could come up with that is a comprehensive strategy that has elements to that including these areas independent of the very first one. There are some other bits that fit in, but these bits right here fit together that way.

I would just suggest, given what was just said, a way to look at this would be to keep this category. I would clearly define access. What access are you speaking about. Are you speaking about access in terms of whether something exists or doesn't exist. Are you talking about access in terms of whether something is

utilized or not utilized. There is more than one element to that, and that is argued in the health services literature.

But I think you would look at it that way. That would be my recommendation, particularly for this one. Keep it but define those groupings and categories. I think that that is something to do and that, hopefully, fits in with what you just suggested.

DR. WISE: That is really helpful. Thank you. Kevin?

DR. FITZGERALD: I would like to build on what Joe said, but first, I just want to say I disagree with Marc. Just so we can get that clear.

[Laughter.]

DR. FITZGERALD: I think there is a question here that needs to be clarified in order to figure out exactly how we are going to group this. What is it consumers are purchasing. What is it we are protecting them from. Is this something where they are purchasing their sequence?

DR. TELFAIR: No, not to protect. I would drop the protection.

DR. FITZGERALD: I'm just saying, what is the target. What is it they are supposedly purchasing. Is it something that is actually supposed to have clinical utility? If so, I think that gives us a much different question than consumers just purchasing something for the heck of it, because it is fun to have your 3 billion-plus sequences up on your wall, or whatever.

I think that is one of the things, for me anyway, that would make a huge difference in how this area gets circumscribed. Again, if it is supposed to provide clinical utility, that raises a whole different series of questions than if this is just something that there needs to be truth in advertising, or whatever.

DR. EVANS: Perhaps one way of getting around that is to drop the protection aspect and just say implications of genetics as a consumer product. Then that could address or one could subsume into that consumer interest, protection strategies, medical and legal implications, standards, et cetera.

DR. WISE: Paul.

DR. BILLINGS: I don't mean to return to more tactical considerations, but it concerns me that these

topic areas, because of their breadth, may exceed past the sweet spot, let's say, of this Committee. So I'm thinking about how the resources are going to be used for these briefs that are going to be created as we make this discussion and how we are going to prioritize that time as well, since that is obviously an essential activity.

What I'm really thinking about is the role of other committees and other large bodies of work that might be done, let's say on healthcare reform. Let's take that as a topic. I suspect there are some resources out there in the government that have been done on healthcare reform. Maybe I'm wrong. Certainly it hasn't been effective, but that is a separate story.

So, how will we limit the briefs, in a sense, so that we focus the briefs on things that we can then do something about going forward.

DR. WISE: Do you want to comment?

MS. CARR: It seems to me that is part of the role of the group that is working on the development of the brief, to help propose back to the Committee what specific issues within the cluster should have the highest priority. I'm not sure I'm answering your

question, but I do think that is one of the most important things. Then, also suggest perhaps what specific strategies or an action plan for addressing the issue.

That gets to Gurvaneet's point, I think, and Mara also, that we don't need to do an in-depth study on every matter. Even on one of the highest priority issues the Committee might decide that it simply needs to write a letter to the Secretary urgently to make the point. I think that would be another aspect of what comes back to the Committee in December to actually operationalize all these issues.

DR. TEUTSCH: Paul, to your point, I think the other thing that we are doing and we will need to do between now and December is to look at what is going on elsewhere in the government so that we do have a better understanding of where we could actually make a contribution that would be substantive. That will be part of the process between now and December so that we can be clearer with the whole Committee as to where we think the issues are that we could inform.

DR. BILLINGS: Yes. Six months in the life of

this Committee seems like a long time. If we could pull the plug on some of it and focus it earlier, that would probably be a good idea.

DR. WISE: Julio, did you have a comment?

DR. LICINIO: I have two comments. One is about the carbon footprint of this meeting, which is very high. It is not good for the environment.

The other one is that I think it is very important because, as you said, people may just have the sequence for their own sake. That is one thing. But some of these companies that we are going to be hearing about tomorrow, they say, "Oh, you are at risk for cardiovascular disease" or "You are at risk for that." So if the sequencing comes with some kind of an interpretation that places people at supposedly higher risk for this or that, then it is a very specific story that we have to address.

DR. WISE: I think you are right. I think this is going to be a central consideration as the process moves forward.

Other comments on this category? We can come back to different issues as they come up. Let me move on

to the second category, then, perhaps the most complicated.

MS. ASPINALL: Actually, Paul, can I make one comment? I think this category is a good one to get back to Kevin's issue, which I think about as horizontal and vertical. The first one, implications of an affordable genome sequence, to me is a classic horizontal. Maybe like clinical utility. It is broad. You could imagine a thought piece. Whether that is a high priority or not is a separate issue, but it has a lot of implications and there is no answer. There are just a lot of thoughts.

Some of the other specifics, though, I think about in my simple terms as verticals. The second one, standards for monitoring DTC genetic tests, is not easy but it is much more straightforward than implications of a genome. So we could look at standards for monitoring in a very action-oriented way, Paul, from what you said, to say we think there should be standards, somebody should come up with them, this is the person or group to come up with them over this period of time, and these are what we think are the five standards that should be core to that.

That is how I think through this horizontal and vertical. I would probably need a balance. There are some things that are important enough that we need the thought piece across, but at the same time, my priority is not having them all that way and having at least a few that are time-sensitive, action-oriented, and relevant, given Joe's comment about the public.

So we can say the standards for monitoring DTC, just as an example, are so important right now. This is how we think it should go forward. We can do this in three months from our perspective, and we think the timeline of the relevant bodies that should implement it is another six months.

So that is how I think about it. It maybe even gets to Michael's questions in terms of priorities. Having that balance for things that really are relevant and timely. Let's get to them. Here are the issues. It might be a 10-page letter. It might be a five-page letter. Well, I can only hope. But other ones will probably take or suggest to this group that there are one or two that are big enough that we take over a longer period of time. But, not to have that stop doing a few

other vertical stripes.

DR. AMOS: I just think that the Committee has a real opportunity to, at this stage of deciding what the priorities are, really make an impact with the transition in the government coming up. There are a lot of very cool topics to talk about and things that are very neat to consider. We run the risk of spending a lot of time on stating and worrying about things that we really may or may not have any impact on.

If we take a deep look at what these topics are, there are some really important issues that could be addressed if we delve a little bit deeper and not just take the first pass of voting as the final. There are things that I think about a lot, like are the tests really even accurate or not. There are some very basic, basic issues that we could potentially have an impact on that we should consider further.

DR. WISE: I think everybody would agree with your suggestion and your strong support for moving forward strategically, quickly, and smartly. That is always a good reminder when you get committees and taskforces coming together.

I saw my job basically as, number one, recognizing that not everybody agreed on which were the cool issues but to try to identify clusters of issues that were generally felt as being cool and to whittle down 73 to something we can really get a handle on. It may be that we want to move more quickly than putting issue briefs together and then voting in December. I would hope that the other taskforces could help push this more quickly to seize opportunities as they arise in ways that would make the full Committee more useful and more effective on a larger stage.

DR. AMOS: I guess I'm also saying don't get hung up on the "cool" things unless you can really make an impact.

DR. WISE: By "cool things" I meant my 15-year-old definition of "cool," the things that are going to make the biggest impact in the real world. I think that that is right.

Could I move on to a second area that also generated interest and conversation?

DR. TEUTSCH: Paul, before you go too far, I want to make sure I understood what you said.

DR. BILLINGS: That would be a first.

[Laughter.]

DR. TEUTSCH: Clearly, the world is moving quickly. Perhaps one of the things we should do as we listen to this discussion and begin to hone it down is to actually focus on a subset of these clusters or issues right now and say let's work on those. It is a process thing. Later on we can come back as we take on other topics.

DR. BILLINGS: That is exactly it. Frankly, I would like to pull the plug on some of the clusters right away.

DR. TEUTSCH: I think that is an important discussion to have: A) what is missing; B) which of these things should be dropped and which ones should we grab onto. We all agree that we want to be impactful and that sort of thing. To the extent that you all have clear notions as to where the meat is right now, we need to hear it. We need to discuss that.

DR. EVANS: I completely agree with what you are saying, but I think that we first have to define what are the logical categories that people thought were

important. Then the next step is to triage and say, yes, that is cool but we are not going to get any traction on it, we are not going to do it in a timely fashion, so it moves down. But I think first we have to go through and we have to forge these categories.

DR. TEUTSCH: But then we can maybe triage in the discussion.

DR. EVANS: And triage.

DR. LICINIO: I have a question. We also have to be a little realistic not only in what we can do but also what the Secretary realistically do. Just hypothetically, if the Secretary said that evidence-based guidelines for genetic technologies is really the highest priority and that became the highest priority for the Committee, what is the Secretary going to do about it? He basically has the report or recommendations. What impact would a recommendation from the Secretary have on the issue?

Even let's say if we do our job in a timely fashion and we do the best possible [work], the Secretary agrees and makes the strongest recommendation, if that is not going to impact on the issue very much should we go

that direction. I think we should try to triage also thinking of things not only as a Committee.

I think the best outcome of the Committee would be for the recommendation to be endorsed by the Secretary and then for something to be done. If that something that could be done would have a real impact, then those are the things we should do. If everything goes okay and then the Secretary agrees and does everything in the best of all possible worlds and then it doesn't impact on reality, I don't see very much of a point.

There are things that the Secretary can have an impact on but there are things he or she, whoever the new one is, cannot impact very much on. We just have to try to understand that.

DR. WISE: That is an important reminder. It underscores certain of the evaluation criteria that were listed.

DR. AMOS: I just am wondering from the Committee, after seeing the topics and seeing everything that has been submitted, are there any new ideas that came out of your thinking after seeing these things? For me, I think a broad topic might be federal investment in

technology because there are major technology gaps that are missing that are going to allow these things to come to fruition. That is one idea.

DR. WISE: There is always opportunity to insert new ideas into the considerations of the Committee. If people have other ideas or things they want to suggest, we can bring that into the process through the development of the issue briefs and subsequent deliberation. This does not preclude bringing in new things in any way.

Any comments specifically on this set of issues? Kevin.

DR. FITZGERALD: I'm not surprised that it showed up as clearly as it did on the heat map because in certainly the last three reports that we put out one of the back stops that we constantly came up against was this idea of is it going to do any good. How, in the end, do we measure the good that is supposedly going to be done by large population studies or by oversight of genetic testing or by pharmacogenomics.

So again, I think it might be important how we delineate it, but it is something that we have seen over

and over again. It is something that I think just has to be addressed because this ultimately, from what I understand, would be the gold standard everybody would like to apply.

DR. WISE: Joseph.

DR. TELFAIR: A question again on just the way that you grouped these. From the way I'm looking at it, you have what your operational definition of utility is. You have outcomes, then you have that leading to outcomes here. So there are two groupings. The latter three fall together, and the other two would fall together. I don't know what the committee said, but it falls in that category again, particularly from all the discussion that we have had about cutting to the chase on what are the priorities and how you would group these.

So it is both a question and an observation. Sorry about being confusing on that, but I'm just trying to make sense of this grouping that you have here.

DR. WISE: I have Rochelle first.

DR. DREYFUSS: I'm new to the Committee, so partly this is a question that you all probably know the answer to. I'm a little confused about the difference

between "consumer" and "patient." This one seems mostly directed to questions of how a doctor would actually treat a patient and use of personalized medicine, and yet that direct-to-consumer category is in there. It seems to me those are really different things. Maybe I'm wrong about that, but personalized medicine, I thought, was about how doctors use genetic information to treat patients and not about how consumers might wish to do that. I wonder if that third one belongs there.

If I'm right that personalized medicine is actually about treating patients rather than consumers buying products, then questions of access to it, the costs of personalized medicine, the costs of personalizing medicine and the effect on class 2 drugs, all of those seem to fit into that category.

DR. WISE: I think that is important. It has been raised as we went through this as whether it belonged there. But as a clinician I can tell you that when consumers have direct-to-consumer genetic information it quickly becomes a clinical issue because they walk in with a piece of paper or "Please check this website. This is my genome. Tell me what to do." It

crosses some of these boundaries.

DR. DREYFUSS: But that seems to me to be incorporated in the previous question of how do consumers understand this, how do you explain it to consumers. It doesn't seem to me to be quite the same and is actually how do you operationalize genetic information clinically.

DR. WISE: I'm sorry. Go ahead. Joseph, and then I have Joe.

DR. TELFAIR: I think we concur because that is what I was referring to when I said how do you operationalize the word "access." There are more than two elements to this. Access is structural and access is personal.

So you have to think about this that way. I think the definition just used in terms of someone walking into your office with information is where it moves from a structural part to a personal part. But then there is overlap, so you have to make a distinction between the two.

I'm sorry to jump in.

DR. WISE: No, it is helpful. Jim.

DR. EVANS: In my mind, I feel like three of

these items, the first one and the last two, very clearly hang together in a logical fashion. I think most of us who ranked these things were very enthusiastic about efforts to address and apply evidence-based medicine in the genomic field. I think those get to that. I agree the third one falls into the last category. I think the second one is extremely important but is one of these very broad things that goes far beyond just the issue of clinical utility.

So I would move that the second and the third be placed in different categories, but the other three seem to me to hang together very well.

DR. WISE: Steve.

DR. TEUTSCH: To build on what Kevin said, in fact a lot of this was addressed in both the Pharmacogenomics and the Oversight Report. We had a whole chapter in that report on clinical utility guidelines and outcomes research.

So at least a substantial part of this seems to me to have been recently addressed. I think it will be important, if we want to take this on, to figure out then what is new here. What do we have that we didn't say in

May. Maybe there is.

The other part is, as Paul says, perhaps what we need to do is assure that the recommendations we have already made happen rather than revisit them. That leaves us with a subset of these that make fit in one of those other categories where we can actually do some rearranging and emphasize what is now called the impact of personalized medicine on health care and those sorts of issues.

DR. EVANS: Right, but I think that is part of the triage issue. It is fine if we get some logical categories and then say, okay, this was addressed in large part by this committee or that committee, so therefore it obviously falls low on the list going forward. But it seems to me, again, before we get to triage we have to figure out a rational way of thinking.

DR. WISE: Gurvaneet.

DR. RANDHAWA: Before we go to the triage step for this category, I was hoping we could consider maybe adding one or two related categories or topics that did not get the highest votes.

One which I think overlaps with the last topic

here is the research priorities for pharmacogenomics. To me, that was one actionable thing that is not there in the Pharmacogenomics Report that was done. It goes into the whole issue of what kind of research topics are we funding. So here we are specifically saying outcomes research, but maybe within that also what categories of drugs, genes, disorders, and how to go about funding them or prioritizing the funding. That might be one.

In the other pharmacogenomics category, there was Topic No. 20 on the use of pharmacogenomics for improving the safety and efficacy of existing medicine. That again may be triaged out but it does seem to fit squarely in the clinical utility aspect of genomic information.

DR. WISE: Comments, suggestions in this area?

[No response.]

DR. WISE: We will go on to the next. Comments on this issue?

DR. EVANS: I came up with the same clustering you did here when I was going through it.

[Laughter.]

DR. EVANS: This is a really interesting topic,

but I don't know where else it fits. I just want to [make] an editorial comment. The reason I think it is a really interesting and important topic is that many of the implications of pharmacogenomics are really going to be not so much in the individual doctor's office as often hyped but in the realm of public health. I have no idea where it goes in the rest of this thing.

DR. WISE: Muin is going to tell us.

DR. KHOURY: It is funny. When we were trying to rank the topics, we are in the National Office of Public Health Genomics and I did not give this as a high priority because all of the elements are somewhere else. If you look at the issues of health disparities, that is a public health issue.

If you look at the issue of clinical utility or if you look at [any of] the other issues, the public health implications of genomics research is all what we are trying to do. The mere fact that you ended up with a cluster that has only one line to me says that all the other issues are part of this.

It is kind of funny that we ended up this way, but a lot of the other issues are encapsulated under the

public health implications of genomics research, including screening, including consumer awareness, including education of providers, including policy, including oversight. This is all public health genomics.

DR. TEUTSCH: True confessions. I spent 20 years at CDC, so I'm a public health guy. But I did one of the interviews with Kathy Bosley from Dow as part of the horizon scanning and I found it particularly interesting. Her perspective on some of the these topics was really very different than the conversation we tend to have.

Some of the things that she brought up were about the work site. She is a chemical manufacturer, but it is equally applicable, I think. You actually brought up some of these things when we talked with the ex officios. You are dealing with a whole variety of exposures. How do you realistically approach the testing issue from an ethical, from an employment, and from other kinds of perspectives. That was one side.

The other side that she talked about was the toxicologic environment in which we all live and all of the ethics in terms of how should public health engage in

understanding exposures and genetic susceptibility at a public and community level. Very different issues. Much of it is ethical but practical as well that, within the broad scope of the Committee, fits in here.

What was really interesting is how low that scored in the process that we went through. So it seemed to me that there were at least some things that fit broadly into this. Some of my colleagues have heard me talk about this. I had a portfolio management issue of figuring out do we want to do that and make sure we cover all of those bases. Is that the kind of thing that we should be in. I agree with Paul; we need to be guided by what we have done here.

But there are things that fit into this kind of a category, it seems to me, that are really rather different than the specific things that we talk about more in terms of clinical utility and more in terms of public health utility and management.

DR. WISE: Scott.

COL. McLEAN: I thought that the concept of environmental or occupational genomics was really one of the few topics that struck me as being one that was

relatively novel and out of the purview of what we have talked about again and again and maybe bears a little bit more attention. Certainly, my organization would be very interested in occupational genomics and the implications.

DR. WISE: The reports are most effective by mapping the landscape rather than documenting individual trees. It may be that if we come to a point where the issues like minority health and some of the others, as Muin points out, that are already identified in other clusters may be most effectively addressed through a singular framing like this.

That I still think is an option for us based on what we think would be the most effective use of the Committee's expertise and energy, particularly our strategic role. It may be that the report on this takes into consideration some of the other clusters. That may be the most effective use of time.

DR. AMOS: So, is it possible to set a list of really near-term quick hits along with some major product output goals that may take longer to develop and [where] more extensive research needs to be done as to the background. But in consideration of the timing with the

government changing and everything, get a high priority list of quick hits that we can really go after that are high impact and then look for the broader issues to tackle.

DR. WISE: That would probably not conform well to the process we have identified. The whole process is supposed to be a process of identifying priorities in December. However, the taskforces would be able to pick up the ball and run with some of these things prior to that if it comes through in these discussions and certainly through the voting as meriting direct attention.

But right now, the next step would be to develop these issue briefs on a select group or categories of issues. Part of the issue brief will be to identify what kinds of long-term and short-term impact and what kinds of action steps would be required.

DR. AMOS: But, getting back to Sherrie's point, timing is of the essence now. At NIST we are preparing our strategic plan that is going to be ready the first week of December. It is going to be an executive summary of a bigger strategic planning process.

But it will be available and ready for the transition teams because they are going to hit the agencies right after the election. That is when you have the biggest opportunity.

DR. WISE: I hear you and respect your judgment. I have Gurvaneet and then Mara.

DR. RANDHAWA: I think it would be useful to have this category. I definitely support having it so long as we make it more explicit as to what is it adding on beyond the clinical utility aspect. Given my experience with the discussion of the U.S. Preventive Services Taskforce, a couple of the areas that were not tackled by them, one was occupational medicine, absolutely, but another one would be, for example, areas such as obesity and interventions. Some of them occur in the clinical settings, some of them occur in community settings which don't have direct interface with clinicians.

So if you can map these out as to the other areas where the other topics won't be impacted, it will be useful.

DR. WISE: Thank you. Mara.

MS. ASPINALL: I'm going back a little to the priority issue. We have some time on the agenda tomorrow and a pretty full discussion today. In the interest of time, because if we pick all the issues in December the new administration is already clear and then it takes it a while to get started. So maybe either at the end of this discussion today I would suggest, or tomorrow, that there is an identification of one, two, or three -- so, a relatively small number -- of issues that the group believes are time-sensitive.

I know it is a little bit different from the process, but I'm pretty comfortable because they are all, I think, most likely going to be part of the top 20. So they are already part of the process that we identified as a high priority. Maybe we pick one or two and say they are high priorities and use the time between now and December to go a little bit further than the issue brief.

My bias is it can't be one of the "implications of" topics because it can't be done in this short period of time. But if there are some things that we know are going to be part of healthcare reform, which is likely to be part of somebody new's administration, or if there are

some issues that are time-sensitive, and many of the ex officio members are aware of those, why don't we identify them and get a small subset of the Evaluation Committee or some other group to start to look at them to get into a little bit more detail by the December meeting.

So, at the December meeting we will have some issue briefs on some and we will have some early position statements on one or two time-sensitive issues.

I guess I would like to formally suggest that to deal with this issue of losing six months, or five months, between now and December but, on the other hand, not losing the very important relevance of this Committee right out of the block with the new administration.

Michael, does that get to your issues, and Sherrie, your issues? Then, right at the beginning of the new administration we are seen as action-oriented with clear thought and direction.

DR. WISE: I think that is very helpful. I'm working at the suggestion of the whole Committee, and I would be very open to moving this discussion forward particularly tomorrow. If we are all comfortable with the identification of one or two quicker-moving issues

that could be taken up by the taskforces we already have or other things, I think that would be all right. We should consider that.

Some of us have been involved with presidential transitions and administration transitions and know the ins and outs of opportunities and doors opening and windows closing and the illusion of doors opening and windows closing.

[Laughter.]

DR. WISE: We need to consider that but also consider the requirements for formal decision-making that would require a separate vote at a meeting. Paul.

DR. MILLER: One thing in light of this conversation that I'm not quite clear on is to what extent does this Committee's recommendations fit within the overall governmental transition planning. Maybe some of the ex officios can alert me. Does this Committee end up being like one paragraph in the HHS transition report? What are we, in a sense, talking about?

I have been involved in transitions, too, from not inside the government but outside the government. I'm trying to get a sense of where this Committee, as an

outside advisory board, fits in in terms of both HHS and this overall government transition so that I have a better sense of what the product should look like to be most helpful, influential, and valuable over the next six months.

I think regardless of what happens in November the horse is out of the barn come the second week of November, if not before. That is when it is that December things are setting up. By January the first wave is all ready to come in. We need to be thinking about that timeline. It is a process issue.

DR. WISE: Comments or thoughts? Yes, Sherrie.

DR. HANS: There is the inside-the-government and the outside-the-government transition process. I wasn't suggesting that this Committee should be speaking to the outside-the-government transition.

DR. MILLER: No, I'm worried about the inside.

DR. HANS: We don't really have a mechanism to engage that process.

DR. MILLER: That wouldn't be appropriate. No.

DR. HANS: But as to the inside-the-government transition process, and certainly the other ex officios

can comment, from a staffperson's perspective, having a committee like this of learned experts say this issue and this problem need to be solved under your administration doesn't necessarily need to have the answer. It is something that I can put in a briefing book that supports my arguments with leadership.

So it is something that I'm already working on, Muin is already working on, Gurvaneet is already working on, that you bring forward and say "I have been telling you for six years this is important and now, look, the Committee agrees with me. You guys really need to invest resources here. Come on board with this and move in this direction."

So, something that staff can use as evidence of support that there is a knowledgeable group who has been charged with addressing these issues, believes this is an important priority, and they are important problems that need to be addressed by government.

DR. TEUTSCH: Sherrie, I just wanted to at least remind us all that we have a set of recommendations that are out there: pharmacogenomics, oversight, reimbursement and coverage. We will soon have patents,

right, Jim? He left just as I said that.

[Laughter.]

DR. TEUTSCH: So we have a number of things, regardless of how quickly we can get this process together, which hopefully will inform the processes in each of the agencies. As we said in the beginning, this administration is only going to be able to get so much accomplished in the next six months and those issues are going to continue to be there. As far as I know, we still think they are important to move forward.

I hope, Sherrie, that those at least happen. Anything we can do in addition would be helpful.

MS. ASPINALL: It sounds to me that there are two things going on. One is we already have issues out there and making sure those are articulated for the new administration. Obviously, there are a lot of people in HHS that continue. So it is clear, but maybe rearticulating those issues that we already have outstanding would be useful.

I think, secondly, the discussion is should we, maybe before the next meeting or right at the next meeting, because it is only two weeks after the election,

be very clear on the one, two, or three highest priority issues even before we get into depth on them.

I guess that is what I suggested before. I'm hearing that there is some agreement on doing that. I think, Steve, to your point, there are probably two of those. But, to make sure that we are clear about what exists and we add to what should be the priority going forward.

DR. WISE: Kevin.

DR. FITZGERALD: To that end, perhaps we don't need to see this in a completely either/or approach. I don't think we have to say that some issues should be addressed in a more succinct fashion and in a time-sensitive fashion and then considered to be completed.

One thing we could take into consideration would be the possibility of looking at what we have already done, as we have mentioned. Take clinical utility as an example. It is in the reports. In the Pharmacogenomics Report we have Recommendation Nos. 5A, 5B, 5C, and 5D that all look at clinical utility. In the Genetic Oversight Report I don't recall exactly what the recommendations were.

But the idea would be to build on that. Maybe it could lead to a letter to the Secretary saying considering the fact that we have addressed this now in three separate reports from three different perspectives one could say globally this is an issue that should cut across all of personalized medicine however we end up describing that. Then say we will then, as a Committee, consider how we might go forward looking at this. But in the interim, as the new administration comes in, this is something that this Committee has, obviously, identified but would like to broaden that identification. Then say regardless of what area of personalized medicine we look at this should be something that needs to be concretely addressed.

DR. WISE: Moving forward in this way would require some convergence, some consensus emerging from our conversations today. If there is no convergence, no coherent consensus, then it would in many ways preclude moving forward more quickly on certain items. The fact that there has not been enormous chaotic discussion here makes me more comfortable with the idea of entertaining this kind of not mutually exclusive approach.

I think that we should keep this as a framing principle for the rest of the discussion this morning and also for the later discussion. But in many ways, it is going to have to respond to the general consensus that comes out of going through these categories.

Let me put out another category, as we move forward. Comments, concerns, enthusiasm? Joseph.

DR. TELFAIR: Not to continue to say the same thing, but again, you have structural changes and recommendations, and you have specific changes and recommendations. The recommendation would be that genetics and healthcare reform in terms of this Committee may be broader, may be bigger. If we are talking about what we can do that is actionable within a reasonable period of time, some of this may be recommendations to another committee on this.

I say that just to be cautious about it. We can make recommendations, but healthcare reform in and of itself is actually a very large structural activity that requires way more than what this group can have. We can make a contribution to it in terms of recommendations.

I think the simple part of the letter aspect of

that would put that in context, but there is also a structural element. Changing structure, which is the first one of the roles of this, and then the last one, which is actually the healthcare delivery system itself, if we could do that then, wow, we would be sitting much higher than what we are in different ways, if you know what I mean, Kevin. I'm kidding.

[Laughter.]

DR. TELFAIR: I would just say there are structural elements to this and then there are the specific elements to this. If we can make recommendations, this would be one where it just simply would be a set of recommendations and a very short thing. It fits into these other groupings because this is a very broad area. It is like health disparities, which is a very broad area that you can only make right now recommendations to because it requires significant structural changes to really do something like that. There are a lot of other groups working together on it.

Maybe that would be the glue: what other groups working together we could recommend for that. That is my thought.

DR. WISE: Yes, please.

DR. KECKLER: I realize I'm novel to this, but when I was voting on it I certainly interpreted the issue of the incorporation of genetics into public health records and electronic health records a little bit differently outside of this broad topic. I interpreted it actually in my own mental clustering with something like the informed consent, which ended up in a separate cluster of its own.

Just coming to it afresh after several years apart from these types of topics, it seemed to me that there had been, obviously, due to the affordability issues and so on, a vast increase in the amount of data that is being generated on individual genomes. The data was obviously of varied quality -- that is an issue -- but from various sources without any particular standardization or integration.

So it seems like there is now a lot of data and in the near future there is going to be a continuing acceleration of the increase in data generated, but unless this data achieves some kind of integration and comparability and so on, it is not going to be used

effectively.

It seemed to me a very initial, up-front issue was to figure out how this data can be combined. It even goes back to that separate cluster that you talked about with public health issues. With all of these people generating their genomes, is there going to be a way to take this data from different consumer types of tests and just from different consumers and somehow combine it so that we can do population studies.

I just interpreted the cluster a little bit differently and saw a theme that you haven't articulated necessarily as a cluster here.

DR. WISE: That is very helpful. Again, we have the opportunity to both insert issues into a cluster like this but to rearrange different elements of these clusters and put them into other places if it makes more sense as the issue brief begins to get put together.

Your confession about how you voted on this is very helpful because it actually mimics, I think, the way we all did a bit of a Rorschach activity for some of these. This discussion is very helpful in identifying best ways to recluster or reinsert.

Other comments?

[No response.]

DR. WISE: I should point out that several comments have been made about linking this to other clusters. We are attentive to that, and we certainly can integrate that into one or more of the categories. Kevin.

DR. FITZGERALD: Just again for clarification purposes, I know this can be more broadly conceived. So even as we go forward it might be important just to make it clear that this would probably also have to include things like privacy and confidentiality. The whole idea of when your private information gets into these databases and all, how is that presented to the consumer or the patient, however we are going to delineate that, as to what sort of security might be there and who is going to have access.

When you start doing these large population databases, obviously as the information is pulled together the ability to parse out an individual becomes greatly enhanced. All those issues fall into this.

MS. ASPINALL: Just a quick question. Did any

of the past reports deal with this issue?

DR. WISE: Yes.

MS. ASPINALL: That is what I thought. The Pharmacogenomics one did quite extensively.

DR. WISE: Please, Scott.

COL. McLEAN: I loved the Coverage and Reimbursement Report. It is, I think, one of my favorites.

[Laughter.]

COL. McLEAN: It is really, I think, very, very central to the work the group has done. But because I think it is so excellent I sorted these lower because I thought this was water under the bridge. But the fact that they are coming up again, are we missing something with that? Is there something we haven't followed on with? The fact that these have come up as recurring topics, [is] someone trying to tell us [something]?

DR. WISE: It may be telling us that people did not read the original report. But clearly, one of the criteria was, is this an urgent issue that has not been covered. It came through anyway, so your question to the group is still worthy of some discussion. Sherrie.

DR. HANS: I think of it as like GINA. The predecessor to this Committee recommended that GINA be developed and passed, and then this Committee just continued to revisit the issue: have testimony, pull together information, send and collect that information to the Secretary, continue to support that movement occur. This may fall in that kind of category.

There is already the report out there. It may just be an issue of follow-up and continuing to raise it as an important issue and getting public input in a variety of ways and putting that forward to the decision-makers.

DR. WISE: Mara.

MS. ASPINALL: I wondered about the same thing. I actually voted it high, partly because we haven't seen any major changes as a result of our report and other reports. Maybe one of the things, again back to what I said before, is that I would definitely recommend that with the change in administration we have a very clear list or letter or something that articulates what we have done and what we think are the continuing issues that need continuing focus. A lot has happened in the current

administration and HHS has been so cooperative with us in many ways, but not all of the work has been done.

To me, I put this, as it sounds like you do, at the top of the list. We have had some progress. Where are we now. Don't lose track of it just because we did the report in '06.

DR. WISE: Marc, are you still with us?

DR. WILLIAMS: Yes, I am.

DR. WISE: Do you have any comments about this conversation about how to think about how to approach issues of coverage and reimbursement, particularly in light of the prior report?

DR. WILLIAMS: I think it is important to recognize that we did have a conversation with representatives of the Secretary earlier this year to discuss several aspects of the Coverage and Reimbursement Report.

I guess the question as I'm listening to this is, as we think about the role of SACGHS, when we produce a report such as the Coverage and Reimbursement Report do we have an obligation in some ways to continue to engage and follow up and have regular report-backs.

I agree with some of the other people that have been talking to say it doesn't make much sense to redo it. It sounds like we may need to think about, and perhaps this would be something that would be worth an hour or two of discussion, how we maintain engagement around a report or some other thing that we have generated so that we can really see what is happening. That, in many ways, would inform us about are there specific pieces of information or other things we need to do to advance the movement of the report going forward.

DR. TEUTSCH: Marc, thanks. I would remind folks we did write a letter to the Secretary about this in February, which you saw at the meeting.

Clearly, it is still important. There is clearly a lot in that recommendation that didn't happen that we need to do. But one of the things of course we can do, and it gets back to what do our products look like, is monitor these things and make sure that we move them along, identify salient issues, and so forth, so it can remain a priority. Not necessarily generate a large report but make sure that it remains on the agenda. My sense is that it was important.

DR. FITZGERALD: Steve, a possible approach would be to, in our monitoring, try to discern what it is that may still be an obstacle to the fulfillment of the recommendations and then see if there is something specific that we could then address in sending forth yet again another letter and saying here is a recommendation to look at that.

DR. WISE: Sure. Sylvia.

MS. AU: Steve, I think this keeps coming up because I think this is one of the biggest stumbling blocks of doing any of the other things that we have recommended: education, access, health disparities. This is the biggest stumbling block, and I don't know how we can impress upon the administration to put this as a very important thing in the transition plan. If we can get the reimbursement part done, then we can do so much more in everything else we have recommended.

DR. TELFAIR: I have a question again. I know that we have recommendations and we have a letter or we have some way of following up. I'm just wondering whether or not one of the strategies to use in terms of the development of the recommendation itself but also a

development of the strategy or the tasks related to getting specific information back.

For example, with this issue and some of the other ones, they do keep coming up because there are other groups besides this one that are working on the very same issue. Then everyone is drawing the same conclusions, that it is constantly something that we have to push. PHA is working on this, and other kinds of groups and organizations are working on this.

One of the recommendations would be whether or not we could task or make a recommendations for some kind of task like we have done before which is a multi-committee or a multi-organizational group that is out of the Secretary's office that can report on these clusters of issues.

I agree; if we put together the list of here is what we have accomplished related to priorities that we have recommended, the next question of course would be what other groups and organizations are also working on this. Even the list we have is, are they still out there, are people still identifying them.

We assume we know why there is group

interaction, but now can we also be part of whatever the ongoing work would be. Can we get reports back on that as part of our function. I'm wondering, as a Committee, can we put that as part of what it is that we do. It seems to me that there is the short-term and there is the long-term follow-up on these things to reach conclusion.

I think the GINA situation is a clear example of something where there is a short-term and a long-term follow-up that may, because of the climate we are in, take longer to actually actualize over time.

I don't know if that was clear or not.

DR. WISE: Any questions about this, or comments? Any other comments or questions on this? I think you provided some very good guidance.

[No response.]

DR. WISE: This clearly falls into the domain of the Taskforce on Education, and it was very nice to see this come to the top as a very highly ranked set of issues. Comments, suggestions for the taskforce?

[No response.]

DR. WISE: Good. We will move on, then. The fact that these are in yellow is because they did not

rank within the top 20 but were pretty close to the top 20 and clustered in this way.

DR. LICINIO: Could those three become one topic and then be moved up?

[Laughter.]

DR. WISE: We put this together, one, because the top 20 is totally arbitrary. The other thing is that the distance between No. 20 and No. 25 was extremely small. But also, it was because this in many ways was generated by our conversations in February and was deemed important [enough] in other contexts that we grouped this cluster to give us more substrate for issue briefs. Sylvia.

MS. AU: But I think this is the third list of all the things that need to be woven through any of the priority topics that we address. So we have priority topics and then we have a list that says you must address these things, and one is the healthcare disparities in minority populations.

I think that as a cluster it might not rank in the top 20, but it definitely is something that you have to address in anything that you write.

DR. WISE: Kevin.

DR. FITZGERALD: Again, this might be one where we can acknowledge the broad concern for the general issues, as Sylvia has pointed out, that are just there and then maybe say, obviously, genetics is another area that could play a role in either concretely addressing these issues or exacerbating them.

I don't know how we have to do too much more than that because, again, a lot of these are also mentioned in the previous reports, perhaps in a little more cursory fashion, but still they were mentioned. These are things that have to always be kept in mind.

So again, this might be a relatively easy one to address.

DR. WISE: Barbara.

DR. McGRATH: The only question I have with that is when we do overarching they tend to disappear like clouds. I remember the conversation in February and, actually, some of the public comments. Maybe there is a more pointed question: is genomics decreasing health disparities in our country. Just more of a pointed question rather than of course we need to attend

to these issues with all of the other ones. It would be a really hard question to answer, but it keeps coming up. This seems like a good body to really address that question with maybe some data.

DR. LICINIO: Or maybe the opposite. Could genomics increase health disparities?

DR. WISE: Paul.

DR. MILLER: It comes back to my earlier question or comment that I have been thinking about through this conversation. I agree this is an important issue, and I agree with Sylvia it is a thread issue maybe more so than a stand-alone issue. But with this and some of the other things I'm having trouble, and maybe this is a lack of creativity on my part, wrapping my head around what it is at this point given the other reports that is going to be our deliverable.

So, all of these issues are important in some ways. Some of them lend themselves, and that is what I was focusing on as I was doing my marking it. What are the things that this Committee can deliver and add value to and create a product to, and those are the things I think that we should be focusing on, rather than saying

these things are important, don't forget about that.

Maybe some of those are the details that are best left for the individual groups to come up with some of those priorities, but with some of these topics I'm having a hard time thinking about what it is that at the end of the day we say.

Not to be disparaging but yet another letter to either this Secretary or another Secretary to say don't forget this is important and so on, as opposed to here is a learned body that says here are some informed consent standards that we think are really important. Here are some [things] that we do that you should change regs on reimbursement with respect to genetic tests. Concrete kind of things that a new administration, regardless who it is, is going to say, "Wow, that is a good idea. Let me run that through our process and say either yea or nay, that fits or not."

I'm having a hard time saying, yes, of course, health disparities are bad. Do you know what I mean?

DR. WISE: I know exactly what you mean.

DR. MILLER: That is the struggle that I'm having in a sense with this conversation. The reality is

that we have maybe, at best, five things or three things that this Committee can do. I think we should focus on three or five things that we within the next 12 months can deliver and put on the table and say, "Here it is."

We take the pieces, as I think Kevin had said a number of times, that are already contained in the other reports, pull those out, and say here are the things that are still left to do, here are five new things that we have delivered, that is, in a sense, our agenda.

DR. WISE: I think you articulate extremely well the challenge to the group in sorting these things out. In large measure, the issue briefs are supposed to make the case for each of these clusters so that we have more time and more detail to make these judgments in this way.

I think, Marc, you had your hand up?

[Laughter.]

DR. WILLIAMS: Actually, that was for the previous comment that I made. You anticipated the little Email that I sent to Sarah.

DR. WISE: Joseph.

DR. TELFAIR: I agree with what was said. I

think that one of the other considerations is the ownership question. Do we have to do that. Can we also be looking at the factfinding part of this. There are clearly others that are working on these issues and probably are doing either a better job or moving in that direction. Just simply say that there is another group that really should get supported because they are dealing with these issues without us having to go through what was just recommended.

We could make that as part of our recommendation. If you know that there is a group of organizations and individuals working on this, more power to them. Let's recommend that that should be supported, and let's focus on what it is we have. I would recommend that.

I recommend that these are critical issues but we don't have to take ownership to have to deal with all of them. I would put that forth with that because the issue here is what can we best recommend to be most effective in terms of actionable things to do. We could consider that working participatorily with others or even recommend others who are doing it as one of our

strategies.

DR. WISE: That is a burden that any of the clusters or any of the issues that we adopt will have to meet. The suggestion is that the issue brief will have to make the case, including identifying which groups are doing what as far as we can tell. Then the Committee can make judgment in that way.

Other comments specifically on this? What I would like to put up is the summary of the groupings that we have just run through. Yes.

DR. AMOS: I just want to say one thing for practical consideration. I think historically, as I best remember, most administrations do most of the things that they are going to do with the highest impact within the first six months of the administration. When the Democrats got Congress, the first 120 days. They always set these timelines as priorities. They try to get a lot done in that first time, and there is a honeymoon period in a new government oftentimes. So the quicker the better we can move on these things.

DR. WISE: Other comments or questions about this list? We would like to move to try to gauge the

general consensus about these categories as the basis for creating the issue briefs. Paul.

DR. BILLINGS: Before we codify this in some further way, it does seem to me that we ought to map this back on the work that has been done by the Committee so far. That seems to be something everyone is saying. I can't right off the top of my head, as Steve, you seem to be able to do, pull out the chapter and the little verse of where it appears in the last four years of work. That is fantastic. It is why you are the chair.

But it would be, I think, quite useful to really do a mapping back so that we can say something intelligent about the brief we want to do.

Next Steps

DR. WISE: Mara.

MS. ASPINALL: I would agree. I'm trying to think about [this] timing-wise [and] whether that is a real time issue or that is a between-meeting issue. But I think it would be helpful and will have to be done anyway to move forward so we are not repeating things unnecessarily.

I guess I'm going to go back to the comments

about time sensitivity. How do we want to deal with that issue to, as we have heard a lot of times, take advantage given some challenges, but to be able to prioritize some of these issues separate from what we have done in the past.

What I have heard from this discussion maybe, then, is two key things. One is reviving in some way what we have done in the past to ensure that it continues to be a priority with the next administration in an action-oriented way and not just for the sake of listing it.

Secondly, the potential of fasttracking a couple of issues so that when the administration is coming in and maybe immediately post the December meeting, hence work between now and December, that we have some prioritization of issues that can go to the administration. Given that may have to happen right after the December meeting, I think we need to discuss it today so that we can do the work between the meetings and get it approved by this group so it is ready in December.

DR. WISE: Comments or suggestions on what Mara is proposing? Really it is part of Next Steps.

MS. ASPINALL: It is basically an additional next step that would be required between meetings. To me, it doesn't change the fundamentals of the processes you outlined, which I think are the right ones for our long-term priorities, but ensuring that as a group we hit the ground running with the new administration on summarizing the existing issues and prioritizing one, two, or three new issues.

I have heard a lot of consensus about that, but I just want to clarify that. Whether it is the Evaluation Taskforce or another taskforce, there is some additional work to be done that can be presented in more specifics at this meeting in December.

DR. WISE: Kevin.

DR. FITZGERALD: Just to build onto that some of the issues that Paul brought up, again, when we identify the things that we have already addressed, perhaps with some comprehension, it might be helpful to also identify, if we can, why we think these things have perhaps not yet been fulfilled or our recommendations have not yet received the kind of traction we thought they should.

Maybe then [we could] come up with further specific recommendations to say on this issue, then, we recommend in addition XYZ. That, I think, could be done in a relatively succinct way without perhaps having to garner a great deal more information or expert opinion, although we probably have to make sure there is public consultation.

DR. WISE: Other comments, questions, or concerns? I should just remind everybody that the last time the Committee went through the priority setting process I believe there were 12 issue briefs created. So in fact, we have identified a smaller number of candidate issue briefs right from the get go. It may be, given that we have two standing taskforces already up and running, that, clearly, one would have direct relevance to some of these topics. [As to] the other, it would be more engagement with the taskforce to identify specifically which of these arenas it might capture.

But there is an infrastructure already in place that could fasttrack some of these issues to move it forward more quickly as opposed to relying strictly on creating a new structure. So I think we are well

situated to respond to what Mara is suggesting.

Sarah, do you want to make any comments on fasttracking certain selected issues that we can identify here today?

MS. CARR: I think that is a decision for the Committee to make. If the consensus is that you want to do that, we want to honor this process but not to the point where you are not comfortable with the process and you think there are some things that need to take precedence. So I think we should be open to that.

DR. WISE: Other comments?

DR. EVANS: I think we should do that. What is the available time during this meeting to hammer out what we would think should be fasttracked?

DR. TEUTSCH: We have time until 11:30 today, but then we have time again tomorrow to have further discussion. What I would suggest is that, without talking about exactly what we are going to do or what the priorities are, we get some consensus that these are the right clusters. If we can get there now, I think we will have gotten part of this done.

We can delegate back to the Priorities

Taskforce exactly what these issue briefs look like, and they don't have to look the same for everything. If it is on reimbursement and coverage it probably is more of an update of what is going on. As Kevin says, what would it take to move us to the next step. Others might have to be more elaborate because they are new.

Then, tomorrow we can deal with the issue that I think Paul Billings brought up and I have heard now coming up in other places: are there some things that we can move forward now that are at the top of the list that we really want to focus on so we can move more aggressively on them.

Particularly, if there is a topic or two that fit in with what we call the Evaluation Taskforce that we can say we actually want to move on even more quickly or move into the Education group, then I think we might be able to meet most of the needs that I have heard here today.

DR. WISE: Paul.

DR. MILLER: Along those lines, maybe I will something concrete. I would recommend that on the cluster issue called informed consent for genomic data

sharing, following up on Kevin's point, I would broaden the title of that. One way of doing that is to add a couple of commas. You might say "Informed consent, privacy, and discrimination." Maybe throw discrimination in there, maybe not. But, to broaden that out to that family of issues that go around genomic data sharing. I think that would more appropriately describe the kinds of issues that that cluster would sift through and do.

DR. WISE: Jim.

DR. EVANS: I would agree with that. I think it addresses the one thing that seemed lacking. I think that is a great general cluster. I think one thing that is lacking at least in any kind of explicit way are two of the issues that were in the top 20 regarding the electronic medical record. It could be the perfect place for that.

The other thing that I would suggest as far as these broad categories is, [instead of] "consumer access to genomic information" perhaps "implications of genetic information as a commodity" or "as a consumer commodity," something along those lines. I'm not sure what is meant by "consumer access to genomic information." We need a

different header for what was addressed by the priorities there.

MS. ASPINALL: Maybe, given the broad issues there, it is consumer issues with future access to genomic information. It is this afternoon and tomorrow.

I didn't want to get into implications, but just what are the issues. The deliverable here may be identifying the myriad of issues firsthand. The second level may be what do we want to do with them. So we are, again, trying to be action-oriented and specific.

DR. WISE: That is really helpful and clearly would fit easily. Gurvaneet.

DR. RANDHAWA: This is just a comment, and I'm sure this can be done when we work on the issues briefs. But on the first one, genetics and healthcare reform, it just seems so broad and daunting. The two things that are discrete within that, which are the electronic medical records and getting the genomic data integrated in that, and then the clinical work flow issues and clinical decision support, are fairly discrete items to work on while this topic by itself is a fairly broad topic. But that could be done in the issues brief.

DR. WISE: Julio.

DR. LICINIO: When I looked at this I thought that healthcare reform is a very political topic and not within the scope that I have to decide if there is going to be healthcare reform and how to put genetics there. If we put "genetics and healthcare reform," then we have to talk about healthcare reform. Are we the best group of people to be discussing healthcare reform.

DR. EVANS: I think that the issue rose because of the specific implications that the rise of genetic medicine has for healthcare delivery and the structure of health care, which of course has a big impact on healthcare reform. My personal feeling is that that is a reasonable thing to have on there.

Now, it is very broad and whether it is something that should be triaged to a high position or not I don't really have an opinion on at this point, but I do think there are very specific aspects of genetic medicine that have a big impact on healthcare delivery.

DR. LICINIO: Why don't we put healthcare delivery in the title? If it's not on the political agenda to do healthcare reform right away, then the whole

thing dies.

DR. MILLER: I would suggest that we do healthcare delivery. Healthcare reform may come with a connotation implied within it that we as a Committee might or might not, or appropriately or not, want to say. Really, what we are talking about is whether we reform the healthcare system or not. We are really talking about the issue of genetics and healthcare delivery or the healthcare system, regardless of whether it stays the same or is reformed.

MS. ASPINALL: I agree. I think "reform" has political implications. I just think about the future of health care. I like "system" more than "delivery" because it may be broader than delivery. It is everything from products to structure to the fundamentals of it. So I would go with system or future. I know I wrote one of those, and what I meant is not necessarily somebody's capital letters, "Healthcare Reform," but rather how health care will be reformed and will be changed by genetics. So, "system" or "future."

DR. EVANS: I vote for "system." "Future" sounds subtle.

MS. ASPINALL: Too big.

DR. EVANS: Yes.

DR. WISE: Steve?

DR. TEUTSCH: I only want to comment that within the write-up were issues of the implications of the innovations in the healthcare system. So much of it is about innovation and the economics, some of which will probably fall to Mara's Evaluation group anyway, that are embodied within this.

DR. WILLIAMS: Can I get in here? This is Marc.

DR. WISE: Hi, Marc.

DR. WILLIAMS: Part of me says the discussion that has gone before is relevant to this idea of healthcare reform. This is a huge topic. Obviously, there are going to be a lot of variables. But I think there is one very specific thing that is very relevant to genetics and genetic testing and the Department of Health and Human Services, and that is how Medicare is going to define this in respect to their preventive medicine exclusion. That is something that is, to some degree at least, under the purview of the Secretary.

I would think that working to try and understand how CMS is going to be interpreting these tests as relates to their preventive medicine exclusion would be extremely important and actually would be doable in a relatively short time frame.

DR. WISE: Thank you, Marc.

DR. TELFAIR: What is not up there, and maybe this is a next step, is what I think has run through the discussion most of the morning. Of these clusters and of the subgroupings within these clusters, what have we already addressed, first of all. Second of all, some recommendations were made when you look at the individual, broad groupings under each one of these. You made recommendations specifically to retooling these as well. Maybe that is the next step, as opposed to what we are doing now.

DR. WISE: Yes, that would be included in the information for the issue brief so that the decisions about priority setting could be made on the basis not only on the importance of the issue and its nature but also its strategic role in this Committee ultimately taking effective action. Have we done it before, are

other groups doing it, what is left to be done, what continues to be undone in the real world.

DR. TELFAIR: I guess my point is that we are walking through agreeing or not agreeing on whether or not these clusters make sense and we want to follow that through, but it seems to me that part of the information is missing from what we have already discussed. We need to include that in this because we will repeat this process again once we follow through with that.

That is the point I'm making. Should we go back to some of that information that we have already agreed to and come back and look at this because it sheds a different light on the list, to me, if we take this other information we have already discussed. Which are the categories, which are the recommendations, and that sort of thing. That is the point I'm trying to make.

DR. WISE: Can you give an example of what you mean?

DR. TELFAIR: Yes. For example, it was brought up earlier, public health applications and genomic research. One of the points that was brought up was also within public health is that several of these categories

-- for example the education and health professionals, consumer access to genetics, the whole issue of genetics and healthcare within the system -- all actually fall under the broad category of public health applications.

DR. WISE: It does fall under it, but it is not coincident. It is not the same thing. There may be other aspects of public health that do not fall under the other categories. The issue brief will try to identify what those are, including occupational and some other things that came up, to see if it should be renamed, if it should raise issues that we haven't yet discussed here, for deliberation by the Committee. If it is felt it just doesn't cut it, then it falls to the wayside.

If the question is, is there sufficient utility in that category as it relates to moving forward with an issue brief, nothing more than that, that is where I would hesitate just chucking the whole thing on the basis of what we have got so far.

DR. TELFAIR: You just made my point. It is not so much chucking the whole thing, it is restructuring it based on the discussion we have had. You just restructured it and said we need to look at it. That is

actually the point I'm making.

DR. WISE: Great.

DR. FITZGERALD: Just for clarification to try and avoid some of what Joe is hinting at here, or clarifying, one of the things we have run into before is this distinction between genetics and genomics. If you look up there, sometimes we say genetics and sometimes we say genomics. I think we just have to be careful when we determine our clustering exactly what we are talking about with regard to that.

Then, to respond to Barb's question before about the minorities and healthcare disparities, one of the issues we ran into was the fact that there isn't good evidence as to the potential exacerbations or the potential positive contributions that genetics and genomics can make to addressing those issues.

So again, that would be an example of a concrete suggestion or recommendation we could make to the Secretary. I think we have actually addressed that in some of the reports perhaps more tangentially, but to say in order to get at this somebody has to come up with this data, not that it is going to be easy to do.

DR. TEUTSCH: Let me see if I can pull some of this together. What I have heard here is that these general topics, and we have heard a lot of suggestions about how they can be somewhat reconfigured, whether they are stand-alone, whether they are cross-cutting. I have not heard a lot of suggestions about topics that have been missing from here. We have gotten a lot of advice about how we can recraft the names, how we can move around some of the subtopics, but people are generally okay with this set of issues.

Before we break, because we have 2.5 minutes, can we get agreement that this is a reasonable set of issues?

DR. EVANS: As long as you get the electronic medical record, since that is such a big topic.

DR. TEUTSCH: It was one of the issues within this that Paul showed us. We have a lot of specific suggestions about what needs to be tweaked and what are likely to be priorities or issues that need highlighting, but I got the sense this is a reasonable set of issues.

MS. ASPINALL: Yes.

DR. FITZGERALD: I think it shows that, perhaps

contrary to past precedent, we voted with some logic.

[Laughter.]

DR. WISE: Don't get carried away. We have to vote again.

DR. TEUTSCH: I got the sense that Eharmony works. There are things like that, too. But we have to be careful.

[Laughter.]

DR. TEUTSCH: Any dissent, though, to that set of issues?

[No response.]

DR. TEUTSCH: If not, then what we will do tomorrow is we have an hour. What I would like to do is deal with some of the things that we heard earlier. Are there things that perhaps aren't even worth our time at this point that we should drop off, and are there a couple of issues that we should highlight that one of our existing committees [could take up], or other kinds of things that we should take up with a greater sense of urgency over the next five months before we reconvene and actually vote on a priority.

Is that a reasonable agenda for tomorrow?

With that, then, first let me thank Paul for his enormous amount of work.

[Applause.]

DR. TEUTSCH: And to the staff for pulling all of this together. It was an enormous effort. We are most appreciative to you, Paul, for leading us through this discussion.

We are going to wrap it up, and we are going to now depart for the Reagan Trade Center. There is a bus that is outside the building on Second Street. For those of you that have lunches, you can pick them up here. For those of you who didn't, you can get them over at the Reagan Building.

[Whereupon, at 11:30 a.m., the meeting was recessed to reconvene the following day.]

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CERTIFICATION

This is to certify that the attached proceedings

BEFORE THE: **Secretary's Advisory Committee on Genetics, Health, and Society**

HELD: **July 7-8, 2008**

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