Continued Discussion of Plan for Next Steps in Priority Setting Process
Paul Wise, M.D., M.P.H.

DR. TEUTSCH: Now we return to yesterday morning's discussion on the priorities and, obviously, a bit of the discussion that we didn't have this morning on the personalized genomic services. We will have Paul lead this. Sylvia will chip in as we need to. Paul.

DR. WISE: Thank you very much. The first thing to recognize is that we have already achieved what we had set out for this Committee to achieve for this session, which, number one, is to review and approve the process that we have been using to set priorities, and number two, general consensus and some very helpful suggested revisions to the categories worthy of further exploration as issue briefs as part of the priority-setting activities for this Committee in the fall, setting up decisions that will have to be made at the December meeting.

There are obviously some time rearrangements that were required in shifting gears a bit for this discussion, but in fact it makes quite good sense to collapse the discussion of these priority setting activities with the discussion of the personalized medicine and direct-to-consumer genetic testing issues basically because they have tended to converge in the sense that our discussions yesterday clearly identified these areas, personalized medicine and DTC, as very important issues for this Committee to address and perhaps to address in a very focused way in the years to come.

Also, there was very much the sense yesterday that we want to make sure that we act quickly on at least one, perhaps more, of these central issues to address during a time of transition these kinds of issues, that converging with the obvious need to discuss in some detail the presentations that were made today.

My suggestion is that as we move forward with the discussion we clearly address the issues that were presented as part of the conversation in today's sessions but we do so with an eye on how we should address personalized medicine and direct-to-consumer genetic testing as a Committee. We [should] address it, consider it, and discuss it with an eye on how it should fit into our priority setting activities over the next few months to ensure that we have a voice at a critical time of transition but also that we have a thoughtful, aggressive voice in setting that agenda at a time that is particularly important and that our voice is strategic in nature.

Let me just open the conversation up at this point to any comments or guidance. Yes, please.

DR. AMOS: Yes. This is my question from before. Actually, it is a comment. I want to talk about standards a little bit. I think Secretary Leavitt made a very important point as to the competence in the science. I think that what I'm struggling with, and I think most people would be too, is the different companies that are offering different things and the rigor of the science.

The general public doesn't understand that just because you repeat something 16,000 times, your precision of your assay may be really great but it may have no relevance to what is really there. With genomic testing it is a little different. It is a little cleaner than proteomics or something like that.

But at the same time, these methods have not been rigorously evaluated. I will give you an example. In just a "simple" diagnostic test for troponin for MI, we ran a round robin of all the different companies to determine what was the absolute value that each of these diagnostic tests that were FDA-cleared, marketed, and being used in the clinic all the time. I think it was about 10 companies that we ran. There was about a 130 percent CV in the results.

The AACC saw that. They asked us to develop a standard for troponin. We developed a complex troponin-C standard that brought the CV down considerably to something a little better because the companies were able to recalibrate.

That has not been done for most diagnostic tests. It was done for cholesterol. It was done for calcium. NIST has about 30 clinical chemistry standards that are out there and we work with the Joint Committee on Traceability of Laboratory Medicine, part of the International Bureau of Weights and Measurements, to try to develop ways to harmonize results across diagnostic testing.

I think there are about 140 or so standards that are available internationally for different diagnostic tests, but there are thousands of different diagnostic tests that are run. So from one standpoint, what is going on with this technology is fairly consistent with what is going on in the rest of the field of diagnostics.

So, how do we, as a Committee, try to interject some sound science in this to enable people to make good decisions?

I will make one personal comment with regard to what Kathy Hudson said about making sure that people who are competent and know how to use the information have the test and can take action. To Kevin's point about the father whose kid with cancer was given 44 different drugs, I have had firsthand experience in that. I'm all for information. I was able to use information off the Internet to save the life of my daughter, after having gone to all the great medical institutions in the State of Maryland [where] they couldn't figure out what it was.

I'm all for information, but I guarantee you that if it wasn't for the fact that I could not prescribe medicines myself I might have killed her. When your kid is in a situation like that, be it genetic or anything else, you are just absolutely grasping for information to try to do something to help your kid.

A person who has that information should not be their own physician. That is my personal statement.

DR. TEUTSCH: Thank you. Comments or questions? Kevin.

DR. FITZGERALD: I'm curious. I understand the process and all. Have you already gotten a sense of different categories you are going to put some of these topics in, considering whether they are going to be large-scale reports or more targeted kinds of, I don't know, white papers or letters to the Secretary or something? Is that still open?

DR. WISE: That is still open. Our approach was not to define what would be the most appropriate, effective action steps but rather to define what areas of content were likely to be of greatest importance to the Committee's work over the next few years.

I'm pretty confident that our general sense was that personalized medicine and direct-to-consumer issues should be part of that deliberation and would be included.

Now, how we approach that I think is really the focal point for this conversation now. We don't have a lot of time, but the hope is to provide some guidance to the various members of the various taskforces, particularly ours, to what would be the most appropriate way to address these issues.

Now, it may be that the most appropriate focus of the work for our group and related groups over the next few months is merely to articulate what in fact are the central questions that are likely to be most important to this group moving forward. That may in fact be bringing in the best science. There are other tensions that we have heard.

For example, we have heard quite a bit about the push in modern medicine for greater and greater standardization in clinical decision-making, getting clinical discretion out of the encounter. But we have greater and greater standardization coming, smacking head on with what we are calling personalized medicine, which implies a grave departure from standardization. Everything is personalized.

We have a clash between a culture of regulation in health care and a culture of regulation in IT. What we heard today is really IT.

So I could see our work would be, over the next few months, really articulating what the central strategic questions are for this Committee, not in general but for this Committee, and bringing it quickly back to the Committee for further work. Paul.

DR. BILLINGS: Paul, one of the themes that has seemed to me to come up in the last two days more clearly than before, and was certainly being made earlier in this discussion, was around the issue of standard setting.

Now, we have talked about standard setting specifically in the direct-to-consumer motif, but actually, standard setting of course is broad and goes for all aspects of the genomic and genetic enterprise. It could go for the translation of evidence from association studies into clinical practice. It could go for standards for how you evaluate when a methodology like sequencing is appropriate in the clinical setting. It could go quite broadly. It is a theme.

I was thinking particularly of what the Secretary said about things that are valuable to him. A committee like ours talking about standard setting, even as we instructed FDA in our last meeting, we could also help them with their standard setting.

I wonder whether that is a theme somehow that we ought to incorporate more broadly in one or more of these topic areas.

DR. AMOS: Paul, I just want to comment on that. You said that personalized medicine is not conducive to standardization, but you have to define what you mean by that. What I'm talking about is actually standardizing the measurements, and there are ways to do that. These measurements could be used universally.

I'm talking about establishing measurement infrastructure, standard reference materials, standard reference data, standard reference methods, that will enable people to actually do direct comparisons over time and space of their measurements. Those are critical.

DR. WISE: I would agree. I would just point out that many people talk about standardization [not as] standards used in the laboratory but rather standards of use in the clinical encounter. So it is very helpful that you point out these distinctions. It may be that we need to address both or pick and choose. But again, articulating what the central strategic questions for this Committee really are I see as some of the work that will need to get done over the next few months.

Muin, do you have a comment?

DR. KHOURY: Since we don't have that much time, Steve, do you want to say something?

DR. TEUTSCH: It seems to me that some of this is going to get fleshed out in the issue briefs as we get through each of them. I think our task for the next half hour is, we basically had clusters that we agreed to. Are there any that we need to move on? Some of them are going to move to the Education Group that they can begin to act on.

Are there others here that we feel we can tease out that should move separately from the overall priority process, [while] obviously integrated with it, because we believe that they deserve, if you will, a more rapid, more in-depth look between now and December?

I see Mara and then Kevin. Muin, I'm sorry. Do you want to integrate that first?

DR. KHOURY: No, it's okay.

DR. TEUTSCH: So Mara and then Kevin. I'm sorry.

MS. ASPINALL: I'm going to suggest, consistent with the discussion yesterday, that the DTC personal genomics issues are ones that we should move on immediately. They came up high in all of the voting relevant to a lot of people, [as evidenced by the] standing room only [audience] today, and are, I think, a very relevant issue.

I would separate those DTC issues from personalized medicine more broadly and really would suggest that the personalized medicine and personal genomics continuation of what we started today would be one of the issues that is a priority moving forward consistent with the process -- I guess I'm going out on a limb here -- that we would prioritize as one of the issues to discuss.

DR. FITZGERALD: Just following up on that, I agree DTC is obviously going to be very, very important. Maybe we need to break that out from personalized medicine. My sense was there are a lot of issues embedded in DTC, and that may require a larger, more broad, comprehensive report.

Maybe we could break out some of the issues that were highlighted, ones I think we have already addressed in previous reports which will obviously be a part of any larger reports that come down the pike on personalized medicine or DTC: issues like informed consent, privacy and confidentiality; issues like coverage and reimbursement; and issues like clinical utility. Set some kind of clear delineation of what we are talking about in those areas in response to questions that have come up or issues that have arisen since the latest rounds of reports even just a month ago.

That I think we could do in a brief, focused period of time. DTC itself, in at least my sense from today, is fairly complex. That may require a more in-depth kind of stroll.

DR. BILLINGS: I would second what Mara said about separating topics of personalized medicine from DTC. Personalized medicine is, in my view, quite a different kettle of fish than all the issues that are brought up by DTC. That is one thing I would want you to do.

DTC, by the way, isn't just one thing. We had several models of DTC up at the podium there today. Aside from reviewing what currently are the controls and standards of the activity, I'm not sure we can get anything done in six months on DTC, actually.

DR. WISE: Muin. I'm sorry. Gurvaneet.

DR. RANDHAWA: This is a process question because I think we are coming up with topics without having a list of the topics we agree we will be working on. Are we thinking of collapsing some topics together for issue briefs. Are we going to separate some things for higher priorities. That might be useful for us as a starting point.

DR. WISE: We could put up the slides. Basically, the comments and suggestions from yesterday have been attached to the different categories so that when the issue briefs are put together those are part of the consideration.

I don't think there was a sense that we should be collapsing a lot into what really started off as a relatively small group of potential issue briefs but that there may be some rearranging or inclusion of some issues that were suggested yesterday that were not on the original clusters that I presented. But it didn't appear to be anything major. Clearly, we will make it available to everybody so you can see.

DR. RANDHAWA: The reason I'm raising that point is, if we wait for the issue briefs, we will be waiting for the next meeting. I think part of the discussion we had yesterday was shall we act in the interim on one or two high priority topics or issues. If we have a sense from the group in terms of what are those more or less central issues that we should immediately move on, then that might help us and we don't have to spend time making issue briefs on them.

DR. WISE: If it is the sense of this group, then we will do that. It sounds like a suggestion has been made that we see direct-to-consumer genetic testing, at least initially, as somewhat distinct from use of genetic testing in personalized medicine. We can certainly conform to that.

Then we would move very quickly, as best as possible, to articulate some proposed approaches and get it to the Committee long before December so that we could begin to make some headway on these issues that we expect will be voted as high priority issues in the December meeting and we don't just wait around to do that. Muin.

DR. KHOURY: I guess December would be post-election. Essentially, this is our last meeting before the new administration, or maybe it will be in limbo for a while. Coming back to the list of eight clusters -- and I wish you could put them up -- genetics, healthcare reform, ensuring the clinical utility of genetic information, public health applications, consumer access to genetic information -- that is where DTC fits in -- informed consent, coverage and reimbursement, education, then genetics, minorities, and health disparities, we have already one taskforce that is doing its work on education. Another one is Evaluation. What will happen?

MS. ASPINALL: We have to figure it out.

DR. KHOURY: We have to figure out what to do with that. Then our job is finished, essentially.

So, are we just buying time between now and December so that the issue briefs can be developed and then we formulate our point of attack for the next administration? Is that what I'm hearing?

If that is the case, then I think we may be missing a couple of opportunities for more immediate action. I don't think the last couple of days' worth of discussion should go unnoticed by this Committee. If anything, at the minimum the Committee could, or should, consider writing a letter of some sort to the Secretary expressing some kind of issue with these personal genomics, if you want to.

The other thing is, three years ago a group of feds, like FDA, CDC, and the FTC, put together some consumer alerts. That was prompted by discussions of this Committee as to what the federal government should do.

In other words, you guys can decide what you want to do. You can bide time while the issue briefs are being developed and we can discuss things in subcommittees and/or act on a couple of things. They don't have to be big things but more placeholders at the end of the administration.

Now, mind you, there is the Oversight Report, the Pharmacogenomics Report, and a whole bunch of other products that this Committee has put in front of the federal government, which is pondering what to do with it. I'm trying to push us to do more rather than less.

DR. WISE: Let me just respond. I have Robinsue next and a few others. Obviously, Steve can talk whenever he wants.

I would not characterize what we are suggesting or what we would like to do as buying time. It is quite the opposite. Number one, we have an arena of past activities, past proposals, and past work that has not been acted upon by this administration. There may be elements of those things that we want to push in a variety of different ways in the very near term. That is being discussed.

We also have our issue briefs in the eight general areas that we are going to work to move ahead on. But again, there may be a few, probably one or two, like what you suggest and we have been hearing about the last couple of days, that deserve closer, more intense attention. We would then utilize the education ones by the Education Committee and perhaps the personalized medicine and/or the direct-to-consumer genetic testing by the Evaluation Committee or a new group that might be put together to take on one of these, depending on what decisions would need to get made.

But the idea is that we would utilize whatever infrastructure already exists or create whatever new infrastructure exists, to move these issues forward quickly connected to this priority setting process. We would never buy time.

DR. TEUTSCH: A couple things. One is I think we are trying to get ourselves positioned for the next administration. One of the things that I have asked staff to do, and hopefully we can get agreement from all of you that we should actually do that, is to pull together all the recommendations that we have made historically so that we can have them in front of the new administration. You will get to see a letter in December to make sure that we have the right issues highlighted so that we can move forward with that.

I'm hearing that there is a desire to move reasonably expeditiously on at least a couple of the other issues that we have heard about here: the personalized genomic services and probably DTC. We are already pretty well positioned to take on that. The Evaluation Taskforce we already know has a good name. That can begin to take on that issue. We could form another taskforce if people would like to deal with the DTC issues, if that is a priority that we think we need to get in a more concrete way more than we can do in just an issue brief before the December meeting.

That is one way we could proceed if people would like. If they have other priorities, we can do that, too. But that is one suggestion about how we might begin to move this so we are a little bit more prepared to actually take action at least beginning in December.

DR. WISE: Robinsue, do you have a comment?

DR. FROHBOESE: Thank you. The comment I was going to make has already been made, so I pass. Thank you.

DR. WISE: Paul.

MR. MILLER: I just want to reiterate Steve's idea and go one step further. I think we can have staff pull together the pending recommendations from the other reports and put it together in an annual report or in a memo from the Committee that goes both to the internal HHS transition committee and that is part of the process.

Not that I'm giving out jobs, but I think it would be helpful not just to pull out the pending recommendations but to somehow prioritize them. Group them in a way that they become really useful and helpful. We heard from the Secretary today about the executive summary. If it is going to be a four-page memo of nothing but bullets that this little Committee sitting in the corner of HHS wants the new Secretary to go through, it is going to go in the pile.

But to the extent that we can really shape those recommendations [by] prioritizing them in terms of short-term and long-term goals, low-hanging fruit, however we do it, but to really present those recommendations in a way that will become particularly useful for the transition team for the incoming administration, I think that would be really valuable.

DR. WISE: Mara.

MS. ASPINALL: I would also agree. To go back to the comments about doing DTC in six months, prioritizing it now and setting the priorities for the next administration to focus on may not be the be all and end all that we do on DTC. It is not easy, so it would be some real work. But I do believe we can, between now and then, prioritize the issues within DTC to be able to identify what we believe HHS should be looking at going forward.

That doesn't say that after that we don't have a fuller report on other issues. I think it is very consistent with what Steve said about going back. We are giving them, as Paul said, the executive summary. This is what we have done in the past and this is what we think your high priorities are that haven't been resolved that we still think are out there.

In terms of new issues, here are the new issues you see, but we don't have all the answers now. We just want to make sure in the first 30 days of the new administration that it is on the radar [of the transition team] and SACGHS is looked at as a proactive, up-to-date, current organization that can help them look at it. So it also forms the ability to say come to us, we would like to participate.

DR. TEUTSCH: Listening to what Paul just said about putting together a report, it is not just a compendium. It is going to be structured and focused so that it has impact. There is a lot on your plate already. Is that something that we should be incorporating into this, or do we need to tease that out?

MR. MILLER: I thought it made sense given the clustering.

DR. TEUTSCH: Yes. You said as a basis it needs to be coordinated. We could form another group to actually take on the task because it is taking the historical stuff and moving it. What is your sense of that?
DR. WISE: My sense is that I think it is appropriate for our committee to do it, and I will do my best. However, it will require significant staff support since I haven't been here for any history.

[Laughter.]

DR. TEUTSCH: We will get revisionist history.

DR. WISE: That's right. I could make it really interesting.

[Laughter.]

DR. WISE: I think that it is precisely the kind of aggressive, strategic voice that needs to come from this Committee during the transition period. I think our committee will work with the other committees and certainly with Steve and the staff to put that type of voice together in the short term. Thank you, Paul.

Kevin and Michael.

DR. FITZGERALD: Just quickly, following up on what Mara just said, I don't think it is going to be onerous to at least raise certain issues like we heard today. Again, much of this is already indicated in earlier reports. In order not to reinvent the wheel, what I would recommend, too, is talk to Andrea and talk to Marc and other people on the other reports so that we can potentially pull out succinct pieces.

We are talking about standards in the Oversight Report. We are talking about clinical utility in all of the reports. We are talking about direct-to-consumer advertising in the Oversight Report. All these things are already there. All we need to do is, if we are going to put a letter together, just probably boil them all down and focus on raising them.

MS. ASPINALL: I think that is right, but I'm talking about a slightly different tweak on that. Do exactly as you said and highlight the issues. The new administration is going to have tons to read and lots to do. We just want to get to the top of the list and remind them of what we have done so they don't ask us to redo it, et cetera. There is a lot of overlap in people, so it is not as if we are starting completely fresh.

I would still suggest DTC consumer genomics wasn't fully raised in the past reports and that we add that to at least the priority list so it includes some of the key issues from the past -- we talked about reimbursement and oversight today -- with maybe at least one new issue at the same time.

DR. WISE: Thank you. Michael.

DR. AMOS: The thing that impressed me over the last couple days is Muin's comments and Jim's comments. All the geneticists around the table have specific comments about the science that is being used for the direct-to-consumer testing. I would think a short statement from the Committee stating the validity of the science that is being used. Compare it to good science or bad science, whatever you want to say.

But [talk about] is this good science and what are the issues. We heard from Teri today about the whole genome analysis overall. What can people believe based on good science.

DR. WISE: Jim.

DR. EVANS: Believe it or not, I think there is one thing that the whole Committee can probably agree on. I think that says something very powerful about where our priorities are. That is that over and over during the last two days what we have heard is there is a lot of excitement among the Committee for issues related to personal genomics and DTC. Let's just say what some of these outfits are doing.

But there is also great concern that a bedrock principle of all of ours, which is clinical utility and evidence-based medicine, could get lost in the shuffle. I think that if we are going to highlight something, it is very worthwhile, in an enthusiastic way. Say this has great promise [while] highlighting adherence to evidence-based medicine and not putting the cart before the horse.

I would just throw that in there as perhaps something that deserves a very high priority in a brief letter.

DR. TEUTSCH: It seems to me that, based on this discussion, there is obviously a need to pull together the information we have heard the last few days. Obviously, the Secretary is interested and we can get that to him at least in a form of what we think are some of the core issues, highlighting some of what Jim said.

Maybe what we could do is draft Sylvia into pulling that together, as she pulled together the last session, for us to look at. It would be good to get something to this Secretary, since it is of keen interest. Then that will hopefully begin to set some of the framing for some of the work that we are going to need to do in more detail later.

DR. EVANS: Not to sound too iconoclastic, but does it make sense to send something more to this Secretary?

MS. DREYFUSS: He could be the Secretary continuing.

DR. EVANS: The whole purpose of this conversation is to get pertinent things ready for the next Secretary.

DR. TEUTSCH: Those would not be mutually exclusive.

MR. MILLER: There may be things that this particular Secretary, if there is something really easy and low-hanging fruit, might want to do on the way out. He might be able to shake one or two other things out.

DR. TEUTSCH: Particularly if there are things that we have already recommended that we can remind him of. Sylvia.

MS. AU: I definitely need volunteers to help me. All those people I helped write reports for.

[Laughter.]

MS. AU: I volunteer Marc.

DR. WILLIAMS: I'm listening.

[Laughter.]

MS. AU: You just volunteered, Marc. Kevin? Kevin just volunteered.

DR. WISE: Steve, are there other issues?

DR. TEUTSCH: Are you good?

DR. WISE: I'm good if you are good. I just wanted to thank everybody for all your help over the last few months.

DR. TEUTSCH: Those are the clusters. You have them behind you now. You are framed by them, Paul.

DR. WISE: Yes. For the rest of my life.

DR. TEUTSCH: The Committee will be fleshing out the details of what is in them.

DR. BILLINGS: Steve?

DR. TEUTSCH: Yes, Paul.

DR. BILLINGS: If I heard the process that just went on properly, we are going to maybe draft something like a letter on DTC that Sylvia is going to do, right?

DR. TEUTSCH: Right.

DR. BILLINGS: Paul is going to continue in his wise way to do his thing.

There is another topic on this, that being coverage and reimbursement, which has been the focus of a good deal of work by this Committee already again. That is an area which we may want to also make. The Committee has generally been in agreement that reform of the coverage and reimbursement system is a good idea. Might we want to draft something instructive to this Secretary and the next Secretary about that as well?

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

DR. TEUTSCH: Sure.

DR. WILLIAMS: Okay. Related to the topic, actually, that was just brought up and from what Sylvia was tasked to do and which I have now apparently volunteered to do, it seems to me that we could take the recommendations from the various reports that have been done over the tenure of this Secretary and essentially do a progress report, which is to say where are we on each of these recommendations. Are they still relevant; are they being continued in another workgroup; are there issues that still need to be resolved; or are there things that are carrying forward.

It seems to me that that would be a very pragmatic document to develop that could be valuable not only for our current Secretary in terms of things that might be attainable within the short time

frame remaining but would also be valuable to the incoming Secretary to say here is the work that has been done, what are the things that we want to target going forward.

That is Point No. 1. Point No. 2 relates to a comment that was made earlier that I think is important to address and not let stand. That is the issue relating to standardization versus personalization. These are not incompatible, and they are not antipode. In quality improvement, the idea is to use techniques of standardization called mass customization, where basically you use evidence-based information to customize care to the individual but do it in a very standardized fashion. There are a number of institutions, including ours, that have done this very effectively.

But what this relates to in terms of our current discussion is having the evidence base, as Jim Evans has just said. So really, I think that the key to personalized medicine will be to use informatically based mass customization approaches that are going to take advantage of robust evidence bases that really let us know what it is we need to do.

DR. WISE: Thank you, Marc. It sounds like we have some good guidance.

DR. TEUTSCH: We have some guidance and we have some of the people on the workgroup. Paul, I think that some of the things that you are talking about, to the extent that they relate to this, we can certainly pull in on reimbursement. There are all the issues that we have discussed on reimbursement for genetic counseling and things like that which are clearly not resolved.

But beyond that, it seems to me we roll it into the larger document that we are talking about next time because, clearly, those are salient issues that are going to be on the table.

Other thoughts and guidance before we wrap up? Just to be clear, Sarah is saying "How many do we have here?"

[Laughter.]

DR. TEUTSCH: We have two letters. One Sylvia is going to begin to draft that is going to try to pull together what we have heard over the last couple of days on personal genomic services. We will try and link that to some of the things that this Secretary can do with the six months he has remaining.

Then we are going to, in a broader sense, go back over all of our recommendations that we have made and begin to look at framing those in a way that we could present them to the new administration. Paul is going to be working on that, along with some of the things that we need to highlight as being new priorities that we believe should be the focal point for them and will hopefully be the focal point for our work going forward.

DR. WISE: Right. Both would have to attend to what Paul Miller suggested in that it is not a whiny laundry list of things.

[Laughter.]

DR. WISE: But the idea is that we have a strong, aggressive, thoughtful, coherent voice at a time that is likely to be highly chaotic.

So I'm done. Do you want to close the meeting?

DR. AMOS: I just have one quick question. Is somebody from the Committee or the staff going to try to probe and find out what would be the best avenue to communicate with the next administration? I think that would be useful.

DR. TEUTSCH: It would be helpful, particularly if we knew what the new administration was going to be before November. But I do think we have to figure out how to best communicate with them as the time gets closer and we have a better understanding of who they are and what their real interests are.

That is in fact why we have tried to delay this process for making final decisions today. Paul Wise could have taken us to the point of casting things in concrete, but we thought we really should be informed by our best knowledge about what the new administration is likely to be interested in and how we might cast things.

DR. AMOS: Because there are people sitting around the table that have some history.

DR. TEUTSCH: Those of you with history, if you could let us know so we can capitalize on that history later on.

What would you like to say, Mara?

MS. ASPINALL: Maybe not today, but just to clarify what, if anything, in the midst of this discussion is necessary from the Evaluation Taskforce.

DR. TEUTSCH: Clearly, in two minutes we are not going to be able to do that. But there are a lot of items that are on Paul's list that we need to revisit and have that discussion.

MS. ASPINALL: We will do that.

DR. TEUTSCH: Genetics and the healthcare system is a large part of that.

MS. ASPINALL: Right. That is consistent with what we have said in the past. I just want to clarify that. We will have the issue brief and the description for the December meeting.

DR. TEUTSCH: Yes, that's fair enough.