

Determination of Priority Issue Areas and Action Plan
Steven Teutsch, M.D., M.P.H.

DR. TEUTSCH: If not, we will return to our primary task today, which is to review the priorities.

We were in the midst of a discussion on utility. I will turn it back over to Paul. I know that there were a couple questions, I think from Jim and Andrea.

DR. FERREIRA-GONZALEZ: I think we were discussing research dollars for the gathering of this evidence. I want to bring that issue back because I think it is a very, very important issue.

As we continue to move forward in developing the infrastructure for the evidence development, we are going to continue to find out that there are gaps in that knowledge. As there are gaps that knowledge, the research will have to be done, but there has to be funding. Laboratories will not be able to perform some of these studies or will not have the power to do collective, multi-site studies to really gather the information that will be needed.

So I think a focus of this group has to also be trying to identify or trying to recommend sources of funding for that research.

DR. EVANS: Alan addressed my issue.

DR. TEUTSCH: One of the things I would like to throw into this mix in this discussion is that the wide clinical utility is of particular interest to the future of healthcare issues. We have touched on it. So many issues that we are facing in personalized health care don't fit into the old paradigm of the clinical epidemiology or RCTH. If you go into personalized health care you are talking about smaller groups and more tailoring, and large clinical trials and other kinds of things are going to be very difficult to do.

We have been dealing all along with rare clinical disorders for which, clearly, that kind of work is never going to happen, all the way up to dealing with very common diseases with complicated genomic profiles. Getting to an understanding of the value in all of this is going to be a whole lot more complicated than many of the things that the traditional clinical EPI community has been doing in the area of clinical utility in terms of the nature of the studies, evidentiary standards, and so forth.

My feeling is, if we are going to get there, not only is it going to be relevant to the reimbursement issues that we talked about but it is going to be very critical to how this will ever fit into health reform in a way that we can be assured is actually going to deliver real value. It is going to be tough.

DR. EVANS: I agree with you. I think it is also important to keep in mind that some of the rules haven't changed, even though it is a new landscape. I think there is tremendous, understandable impatience with the desire to translate and get things to the bedside. That is perfectly understandable.

But I think that one of the reasons the focus is on genetics in this context is because we have had an unprecedented burgeoning of basic science knowledge in genetics, more than in any other field, arguably, for quite some time. So the gap is simply more apparent in genetics. I agree with you there are going to have to be novel ways of figuring out when has evidence been sufficiently met, but in the end it is a slow process. Impatience can cause problems with it, too.

DR. WILLIAMS: I think, though, that one of the things that could come out of this is that we could improve efficiency if the people that were in the earlier stages of research were given a view of ultimately what evidence is going to be needed to move things into the clinical arena. That could potentially influence how research questions are asked earlier in the translation pathway. Then, when the movement comes, we are not dealing with what we are frequently encountering when we look at EGAPP or other reports, which is a lot of gaps in evidence and key aspects that just are not available.

It seems like communication across the continuum of research might more efficiently more allow us to have the answers to those questions at the appropriate time. That really wouldn't add cost to the infrastructure, at least to a significant degree. It would certainly be less costly than going back and redoing the study to answer a key piece of evidence that was not addressed.

DR. FITZGERALD: Actually, I think that is one of our recommendations in the Pharmacogenomics report. You are right along that line.

DR. WISE: Other comments or suggestions specifically related to the clinical utility, Cluster No. 2?

[No response.]

DR. WISE: Great. Could we move on to Joseph's cluster? Scheduling issues require that we move to Cluster No. 6. Joseph?

DR. TELFAIR: Yes. Thank you very much. I know it is a skip-over for a lot of the other work. Just to cut to the chase, we in public health believe very strongly that the Committee in its deliberations should consider what is a balanced view. Much of the discussion so far this morning really has been on the issue of translation. But I think what was just said by Dr. Williams a second ago is actually where our stance would be. We need to really look at the very beginning at how you pull this information in.

The paradigm is really the idea of assessment. Many times the program is up and running before the assessment actually is even considered or takes place. So you have to go back and relook at things.

I would just bring to your attention to two parts of the short-term actions. The second paragraph is the idea of a systems review. The question really becomes where do the different elements fit together and then where are the commonalities and the differences. But a systems review really means looking at the different areas in which program function and the issues that we are looking at fall together. Then, where are the commonalities and what can be done.

The bottom line is really the last part of the sentence, which is both the differences but the assurance of effectiveness, accessibility, and quality of services. Then the question is, how do you move from the basic science to this area. One way is to look at what is being done and what are the common areas that are being looked at.

The other part I would really push is that you do it in a systematic way. If you do a systems review or a review of what agencies are actually doing in order to meet this goal, then you move into how can you work together to effect that to meet the other needs that are consistent with what the push for this actual Committee is, which is dealing with these other issues related to application, risk assessment, et cetera.

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I would leave it at that for conversation. I think that cuts pretty much to the chase on that.

The other element that I would add would be also the social, ecological, and environmental fit, which is looking at the interaction of genes, environment, and health applications.

DR. WISE: Marc.

DR. WILLIAMS: I would just strongly endorse what Joseph said about the systems review. As we have heard presentations at different meetings -- and the most recent example was yesterday afternoon -- we hear different groups that come to us and talk about what they are doing and then we realize, wait a second, there are at least three different groups that are looking at biospecimens that could be used for a variety of purposes in terms of standardization of proficiency testing, et cetera. That is an inefficient way to do it because we are essentially doing some degree of duplication of effort.

Inasmuch as we can assess what everybody is doing and look for areas of commonality and use that to build consistency, we can get more bang for our buck. We don't have to be spending money on duplication. I think that is a great idea.

DR. WISE: Other comments or questions?

[No response.]

DR. WISE: Thank you, Joseph. That was great.

DR. TELFAIR: Like I said, when it's clear, it's clear.

[Laughter.]

DR. WISE: We are convinced.

DR. TELFAIR: Thank you.

DR. WISE: We will then move to Cluster No. 3, Barbara's genetics education and training.

DR. McGRATH: Actually, before we discuss it, I just wanted to say that I have been listening this morning and, obviously, yesterday as well. Our first action item was a small one, to talk to FDA about devices and educational standards. After listening to Cluster No. 7, I think it really fits.

I don't want to punt, but it is just a suggestion. It's a thought. Perhaps we could work together on that one; let's put it that way. That was one thought I had after listening to your presentation. Anyway, that is one thought.

The other actions really are what we are doing on the Committee, which is heavy data gathering and, more importantly, synthesizing the data from a lot of different places about existing programs and looking to the future. I think that is a logical way to go. I would welcome any suggestions for other ways.

But what I'm thinking about is the whole notion of looking to the future more. Part of it is Julio's comment, and I think we are trying to do that, to avoid the old way of looking at it and to think

about what are the needs in the future of the new generations of people on Facebook. We are all dealing with information differently, so we need to get out of that old paradigm.

The other one is that what is frustrating to me is that there are lots of specialty agencies who are involved in biomedical education and are in the traditional silos of medicine, genetics, internal medicine, OB/GYN, that way we have been dealing with biomedical care in our healthcare system since it was organized. Yet, on the other hand, we have this dialogue going around with these terms like "systems medicine" that Leroy Hood has been using. That is on the horizon. It is not our landscape yet, but it is on the horizon.

I don't know if that is a direction to go in, but if we really head off in that direction, that really changes the way those silos are set up about education and training. It might be worth thinking a little bit about looking to the future of that as well, while not ignoring what is happening now because we have to deal with the landscape. That is something I have been listening to the last couple days.

I think those are my only new thoughts on it.

MS. DREYFUSS: I was very struck yesterday by various comments that patents were important for education. I should say shocked. Just as we said yesterday that utility is its own issue and quality is its own issue and we shouldn't be mixing patents with that, it seems to me that we shouldn't be mixing patents with education, either. As the speaker just pointed out, the kind of education that is provided by people who have a very strong interest in the sale of whatever it is they are selling is not going to be really good education.

So I would really endorse doing more on this particular topic so that the pressure isn't on either patentees -- and you do have this in what I take to be this cluster -- or industry groups alone but also includes patient advocates and healthcare providers. I think on numerous occasions we have found that relying on patentees for educating people about what their patented products are is not a recipe for a good way of utilizing public resources.

DR. WISE: Mara.

MS. ASPINALL: A few comments. First, on the cluster, I think this is one of the most important ones and absolutely essential. I would agree, though, that the first short-term action is not consistent with the rest of the in-depth report or the policy questions, partly because it doesn't fit here. I'm not sure it fits into No. 6, but I think it get into what is a very current issue around the FDA requirements and laboratory tests. There are a number of associations and groups working on that.

There are questions right now about how those tests will be or will not be touched by the FDA. So I would also endorse Barbara's comment that the short-term action in No. 1 about working with the FDA officials does not make sense.

However, as Rochelle said, to broaden No. 2 to understand the regulation today, I would broaden it to say it is not just to encourage the development of voluntary standards but to understand what the standards are today, how they work, and therefore what recommendations we might have in the future.

I would probably take issue with what Rochelle said. As the speaker said, somebody who owns the patent or has an interest in it may produce a great piece of material. I don't think we can

assume it is necessarily a bad piece of material. But in and of itself there may be a perceived or real bias that says it would be better coming from a neutral organization.

But there are high-quality materials coming out of individual companies and out of universities that hold the patents, and there are poor materials coming out of universities and companies holding the patents or not holding the patents or involved in the commerce. What we are talking about here, I think, is the broader scope, which is ensuring a regular process so we don't have to depend on the individual involved in the commerce to ensure that we have the right materials for the purveyors of health care, whether they be physicians, genetic educators, nurses, or others.

In summary, eliminate No. 1, expand No. 2 under short-term action. I think the in-depth report, though, is very consistent with the policy issues you raised.

DR. WISE: Joseph.

DR. TELFAIR: I would agree with the last statement on the in-depth report and would add that it is important to consider that education is not only multidisciplinary but is also a multidirectional process that has to be comprehensive, particularly in this arena such that you are looking at the general public, specific consumers, and professionals of all types.

The second thing I would say is that because it is that kind of process it is going to be important to assure that there is clear understanding and there a means of both monitoring and evaluating the specific outcomes of the education process itself, given that it is multidirectional. Those are critical pieces. I would just add that to this action step, if possible. Thank you.

DR. WISE: Marc.

DR. WILLIAMS: I would just request that we make something explicit that is implicit. That relates to discussions both from Mara and from Steve about the way medicine and delivery of medicine are going to change. We are going to be moving toward very complex information sets that are going to have to be combined and that are going to require informatics tools like clinical decision support. Some of that, I think, is going to be offloaded into personal health records and algorithms that run on those that the individual can control.

There has to be education embedded around those types of tools so that if an individual says, wait, I'm getting this message, what is this based on, that they can rapidly find that information within the context of the clinical decision. The idea of "just in time" point of care education within electronic health records and personal health records is going to be critical.

The doubling time of medical knowledge has changed from when I graduated medical school. Then it was about 30 years, so I only had to relearn everything I had learned once in my career. It is now seven years. That means that somebody graduating from medical school now is going to have to, essentially, relearn everything four times in their practice career, and actually, depending on how their 401(k) looks, maybe six times.

[Laughter.]

DR. WILLIAMS: But clearly, traditional educational approaches, while important, are not going to be sufficient to do this. We really have to make sure that we are responding to that future.

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DR. McGRATH: In response to that, I have more of a question to the group. Even if you just limit yourself to the "just in time" primary care providers, it is a number of different silos, if you will, or specialty groups. In other reports -- I'm thinking of Oversight in particular -- we have suggested that when we felt like it was dysfunctional because there was little communication one of our strongest recommendations was coordination across groups.

I don't know if that might be something that this task force should put as one of its things to consider. Is there a recommendation that there should be better coordination across everyone using the electronic health record, which is many groups. That is a question.

DR. WILLIAMS: Just a couple of responses to that. First of all, I think that there have been efforts to try and create those types of groups. I think the National Coalition for Health Professional Education in Genetics, NCHPEG, is a good example of that. They have really tried to do some cross-disciplinary educational efforts.

I think that there is clearly a movement within the medical informatics community to say if we are going to have guidelines and the guidelines are going to be embedded within electronic health records, then there have to be some standards relating to computability and how the information is obtained. There is actually talk about establishing a national electronic clinical decision support repository, much like Guidelines.Gov.

If that actually moves forward, that would be an important partnership to link onto to say what are the educational things that you need to have that would associate with these vetted clinical decision support issues. Those are the types of partnerships that I think would be important.

I think we need to also recognize that, assuming that the incoming administration continues what has been a strong push of the current administration, which is to have a fully interoperable electronic health record in this country by 2014, we have a very good window of opportunity where there is going to be a lot of energy and investment to make that happen.

DR. WISE: Steve.

DR. TEUTSCH: I heard a question here about the information that comes from industry and how that gets done. We didn't address that all that completely in the Oversight report, as I recall. This Committee worked with FTC before, as well as with FDA, on labeling and promotional information. I wonder if that is something that we want to have at least as a short-term thing to talk about in light of the comments we heard. Clearly, there is a lot of promotion that has escaped the FDA labeling system.

MR. DAYNARD: I just have one comment. We heard a speaker and the Committee members talk about promotion that may need additional oversight and reigning in. The problem is as follows. When the FTC challenges advertising, it is for one of two reasons. One is the claim is just blatantly false and is never going to be true, like losing 30 pounds in 30 days or something. Unless you have the right gene, I don't know.

The second would be because they lack substantiation. Substantiation is what the scientific community says the evidentiary standard is, RCTs for example. So when we are looking at a promotion that says you can link a genotype to a healthy living recommendation and that that is going to help a specific genotype person, the question is, what is the evidentiary standard to show that that is true. Is it case control association studies, which is what is happening now? Is it an RCT that may take a long time and a few million bucks?

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And, is the FTC the right agency to say what these evidentiary standards should be. If we challenge a claim and say, you didn't meet the evidentiary standard, they will say, what is that evidentiary standard that you are saying we didn't meet? Gee, I don't know, because the community doesn't know.

This is going to be a continuing issue. I'm not sure, frankly, where the FTC is going to come out on it. But the question still stands to you all: What is the evidentiary standard? It is another linkage that has to be laid out.

DR. WISE: Peter.

DR. KIRCHNER: On your short-term actions, or perhaps longer-term actions, you didn't include the establishment of some type of a Web-based information area that would list what evidence is accumulated for linking associations. This, of course, could be indexed in two ways, one by genetic findings and specific genetic markers, and the opposite direction would be by specific disorders.

I think this could be maintained by a group of professional editors that would assess the reliability of published data because you only want to update it with things that are very secure in terms of their contents.

I would think something like that would be extremely valuable both to physicians who, like myself, do not have enough expertise in this area, but also of course to the public. There would be some indication then as to how reliable some information has become or what is missing still.

DR. McGRATH: We have talked in the group about that. There is a number of them out there. Part of the data gathering is to pull them together to look at them because they are like genomic Wikipedias out there. It is like the Wild West. I think that would be a good contribution.

DR. KIRCHNER: It is a major task of how to pull that data together, but I think it would be of great utility to everybody in health care and also to the public.

DR. WISE: Yes, please, Robinsue.

DR. FROHBOESE: Robinsue Frohboese from the Office for Civil Rights. I just have a quick question. I know that in this Committee's 2004 resolution that workforce diversity and cultural competence were critical issues. I think that in the summary of the clusters workforce diversity was in parentheses. It wasn't highlighted in our background materials. I wondered whether in the report that is in progress culture competence and workforce diversity are going to be key issues that are addressed.

DR. McGRATH: Yes. It is a bullet, not a parentheses. It has risen up to the top.

DR. WISE: Important point. Other comments or suggestions?

[No response.]

DR. WISE: Kevin, you are up.

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DR. FITZGERALD: I'm just going to punt to Sylvia. Actually, I think this issue is not one that anybody would disagree with. Everybody is certainly interested in protecting privacy and confidentiality, and for continued application of informed consent.

I think the issue is a little different from some of the others, in the fact that it sprung out of the pursuit of personalized health care and the application of the various advances in technology that we want to do, which brought about this scenario that maybe didn't have to happen but is certainly, I think, happening.

The whole idea of the application of these technologies and the pulling together of all this information in some kind of accessible form in large databases with interoperable healthcare records and all that, brings up this issue.

One of the things, I guess, that we really need to wrestle with is what is the role of SACGHS in addressing this. I'm not sure that this is the place where it should happen. I think there are arguments for and against. Maybe that is what we could explore a little bit.

I will just put it in some context here. It is not that, again, this is an issue that hasn't been looked at or even experienced by other places. I think the experience in Iceland over the past several years would be instructive.

I think in the United States we have represented here at the table two groups that are in the midst, probably, of addressing some of these issues. I know Ellen mentioned the VA being involved. Also, DOD. Daniel is here. The idea is that we have two large groups managing numerous people's healthcare records. How is that going to be integrated and what will the issues be coming out of that.

We have a third issue that is moving very rapidly on the horizon, and that is the newborn screening issue. What are we going to do with that information. If one wants to be logistically efficient, that should go immediately into some kind of national database that we could start now and use for longitudinal study.

Again, I think the issues are with us. How we wrestle with it and what our role is, is the question. I think we would have to take into consideration Department of Justice issues and Commerce issues. There would be other things outside of HHS, like civil rights.

Again, it is something, I think, that could lead to some rich discussion for this group as part of a larger sphere. That, I think, is the question that is really before us. What role do we play. Are we some kind of a not objective but, in a sense, less invested third party that can provide some kind of distance. I don't know. I think that is what we have to wrestle with.

DR. EVANS: As you think about these issues, I would just encourage everybody to read the short article by Patrick Taylor that is in our briefing books about some of the nuances of consent. It touches on privacy issues. It is good to heed some of these things as we go forward.

DR. FITZGERALD: Just one other issue on that, just to give you another sense of how things are moving. If you look in our materials on page 24 under Tab 5, just go back to the SACGT committee. We wrote, "The major distinction between consent to research and consent to treatment is that, in the first, there should be no presumed benefit and, in the second, there is no reason to proceed without a presumption of benefit."

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My sense now is, with personalized health care, the idea is that it is all supposed to provide a benefit. So research, clinical, it doesn't matter. It is all the same thing now. So, how did that indeed change the landscape for us.

DR. WISE: Marc.

DR. WILLIAMS: As you were setting up the issue and were listing some of the stakeholders, it seemed to me that maybe one of the things that could happen in the short term would be to have one of our educational sessions focus on different stakeholders' approaches to privacy. Certainly, the people that you have already listed would be very good, but I'm thinking now of two private groups that have gone into this in a relatively large way.

One would be the Marshfield Personalized Healthcare Coalition and their approach to consenting individuals and re-consenting and recontacting. Then, the Vanderbilt program for residual blood specimens and use for research.

Then, echoing what Jim had said, [we could talk to] someone like that author or Zach Kohane, who has also written on differences in terms of how we can approach the consenting process.

I think that would be a fascinating session that might really help. The other group, by the way, would probably be representation from the direct-to-consumer folks, who would also have a perspective on consenting and privacy.

I think it would be a very interesting and very rich session that might well provide important information that would set the tone for the report.

DR. FITZGERALD: That is an excellent idea. It was one of the things I think we bounced around. Obviously, we are not going to recommend it without the Committee's support, but that is a great idea, if people want to do that. That could be a first step.

When is the HRSA meeting? February. Do you know the dates? As I said, there are a lot of people looking at this issue.

One of the things we would have to do is check to make sure we are not reinventing the wheel on this.

DR. CAROME: Mike Carome from OHRP. There is a higher-order issue that I think is implied in the cluster discussion here but is not explicit, and that is when does research involving genetic data and associated clinical information rise to the level of being research on human subjects. If it doesn't involve human subjects, then you don't have to get informed consent, at least under the regulations. So some of this would be moot.

A lot of this turns on part of the definition of human subjects, which has to do with obtaining individually identifiable private information. What does "individually identifiable" mean.

There is certainly a great deal of research involving stored specimens, stored DNA, and stored clinical information that is done in a way in which it is coded or all identifiers are deleted and not replaced with a code. Under guidance from our office, we have opined that that doesn't involve human subjects. So the consent discussion is cut short.

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I think one of the questions implied by Policy Question No. 6 is whether with evolving technologies in genetics and information technologies, are things that we considered not identifiable now identifiable and therefore we need to change the paradigm somewhat. So that is something it might be important to explicitly identify in the policy discussion here.

DR. FITZGERALD: Sure. Actually, one of the ways we could look at this is either this move toward personalized health care is going to put you out of work or you are going to become as big as DOD, one way or the other.

DR. WISE: Other comments?

DR. FITZGERALD: Is there a sense among the group that, although HRSA is doing an educational session, we need one for ourselves? Would that be a good short-term first step?

DR. FERREIRA-GONZALEZ: Do we have any representation at that conference? Is anybody from our Committee going?

MS. CARR: Actually, Joseph's term on SACGHS is ending, as is Kevin's. At the next meeting they will be coming back and we will be saying goodbye to them when our new members are on board. Dr. McGrath, at least we think, is going to be the new liaison to that committee.

MS. AU: I will be at the meeting because I'm PI of one of the regional collaboratives but not for the Committee.

DR. FERREIRA-GONZALEZ: That might be a way we can hear back in our Committee as to what are the findings and then make a decision if we need to continue or gather more information.

DR. FITZGERALD: We could put that under "monitor." Monitor the meeting and then decide based on what we find from that. That is great.

DR. WISE: Other comments?

[No response.]

DR. WISE: Moving on to Cluster No. 5, Sylvia. Thank you, Kevin.

MS. AU: I think the challenge with this cluster is that there is such a broad range of policy questions. Some may be easier to answer, like whether the Oversight report covers direct-to-consumer genomic testing. It also overlaps with every other cluster. Basically, I can punt to everybody else and we can collapse this cluster into nothing.

I think that, looking at our possible action steps, it basically comes down to where does this Committee want to weigh in on the curve. If you monitor and then you comment, then you weigh in lower on the curve. If we actually are proactively going to do a detailed report, like we often do, then we would probably be closer to the beginning of the curve.

There is a lot of interest on the Committee in this subject. I just don't know where the Committee thinks that it can do the most benefit in this area.

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DR. EVANS: I think there is a lot of interest and a lot of expertise on this Committee in this type of thing. My own personal feeling would be that monitoring would probably be too passive of an activity.

MS. AU: Darn, Jim.

DR. EVANS: And I think you should head it up.

DR. WISE: Joseph.

DR. TELFAIR: I agree that monitoring may be light but evaluation of outcomes is not. I would make that argument. There is a difference between the monitoring process and the evaluation process. So the short-term action step may be a long-term action step because this is something that should be ongoing. I would argue for that.

But it should be informed. It should be informed. I would move back to a recommendation that I made related to public health, which is starting with a review of what actually is going on and then developing the assessment based on that, with some clear, agreed-upon outcomes that need to be looked at.

That is important, and that is doable. The recommendations from that would be doable.

MS. AU: So, maybe doing an assessment and seeing if there are key policy issues that we should address and then which things we need to punt to others to include in their clusters.

DR. TELFAIR: Yes, I would agree with that.

DR. TEUTSCH: Can you comment on that issue? We did spend a lot of time at our last meeting with an assessment of the landscape and whether we need to go back and actually do that or can we just build on that.

DR. TELFAIR: Is that question to me?

DR. TEUTSCH: Either of you.

DR. TELFAIR: A systems review actually takes into account work that has been done and then uses information that is actually missing as well. You would actually begin to look at what is the existing evidence across the groups. If that is adequate based on whatever group is using that, then you would go from there.

But the key here is to develop accessible outcomes that would work, particularly with this challenge, which is moving in that direction. We would have to be able to make sure that the decisions that were made and the evidence that is there is actually very focused and targeted and will allow you to look at the outcomes you have agreed upon. That is what I'm talking about. It is a combination of those things.

MS. AU: Because this is such a moving target, there have definitely been huge updates in the last six months.

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DR. EVANS: I would just make a plea to make sure we do this in a timely fashion. We could be reassessing forever. This is a rapidly moving field. I would urge us to move on it. If we are not going to do that, then we should just monitor.

DR. WISE: I have Peter and then Kevin.

DR. KIRCHNER: I see a strong interaction between what you are trying to address here and the educational component, which is so terribly important. I would think that in some ways effective action to counter misinformation that might come from promotion of such tests directly to the public can be addressed with the strong educational approach that has been described by Barbara. I would think that you would want to see some kind of strong interaction.

DR. FITZGERALD: I'm just wondering if this could be pursued as a consequence of the Oversight report in the sense of saying we touched on it in the Oversight report. We certainly mentioned how important an area it was. Then we could just say, building on that, now we are going to take this little piece of the Oversight report and expand it within that context, over that same framework, so we don't get into all the morass that we might. But using that as a boundary, we would try and expand upon that from there.

DR. McGRATH: That would be one approach. The other one would be to make this a stand-alone topic that SACGHS works on. When the charter was written or when the original missions were written, it wasn't such an urgent or current issue. It has, over the years, really grown. Whenever we talk about it, there is a lot of new information and a lot of emotion. So maybe that is one of those that should get its own separate category.

I don't know what other agency in the government is going to be looking at this, so maybe this is something we should take on as in the spirit of our original mission, even though it wasn't spelled out like that. It does seem to fit with our overall mission.

MS. AU: I think one of the important things will be, if we want to move quickly on this, what are the options. Our detailed reports take a long time, other than the Oversight report. But we don't want to repeat that, unless Andrea wants to chair it again.

I think that that is one of the decisions we have to make.

DR. WISE: Can I just ask why we think this is so important? For somebody coming from outside the field, this seems like a gimmick. It doesn't seem crucial. If we were to move it forward as a high priority, I think we would need to frame it in a way that engages a broader challenge to the healthcare system and to public awareness about the importance, the relevance, and the implications of genetic insights in a way that doesn't make it look petty for a committee to take on in some meaningful way.

I would just take a step back and ask why do we think this is such a crucial thing.

DR. WILLIAMS: My response to that would be to look at analogous movements of consumer-driven care. The two that I would highlight would be complementary and alternative medicine and nutraceuticals.

I think the complementary and alternative medicine story is a very interesting one because there was obviously a huge interest in this. It ultimately led to the formation of an institute within the NIH specifically devoted to looking at the science and evidence behind complementary and

alternative medicine, essentially saying we have empiric observations that there may be something here. Should we not then take a look at this from the perspective of science.

It really addresses the issue that Matthew brought up, which is what is the evidentiary standard to say that this is good or this is not good.

That really hits home for me. In some ways, we are the emperor with no clothes. We are saying, you need to have some evidence, but if we really honestly look at the evidence that we are all developing around the things that we do on a day-to-day basis, it is pretty thin. We don't have a lot to hold up, either. We may not be naked, but we are in a skimpy negligee, I think, at best.

[Laughter.]

DR. WILLIAMS: But we know who would head it, and I will leave it at that.

At any rate, I think that there really is value there. I think also that the nutraceutical argument is if you look at the amount of consumer spending relating to things that are not necessarily well understood and where there clearly have been examples of very significant harm that have resulted to the public, these are the types of examples that really, to me, say this is something that we do need to try and get a handle on.

I think we do need to come at it from a fair perspective, which is to say there is something there. We know that this is important. We know that this means something to people. We know that maybe this is the lever that we need to get people to change behaviors, which ultimately will make them healthier. How can we pull this together.

I think it is important from that perspective, and I would strongly endorse being proactive and being relatively formal about engaging on this.

DR. EVANS: I'm just really intrigued by you bringing that up, Paul. I think that many of us who are immersed in genetics think, oh, this must be important. Given the media attention these types of things have gotten, we think, wow, it is the next big thing.

I was recently told by somebody who should know these things that, frankly, there has been very little uptake of this, aside from the splashy articles in the press, et cetera. I was very heartened by that because I think it tells us the public is more savvy than we sometimes give them credit for.

My feeling is, however, that we might be right after all, that this might be something that catches on, and there are real concerns with it. That is why I like the idea of a short-term action that, in a relatively expeditious manner, comes up with a checklist or something useful to people, something that can be promulgated in an efficient manner, that is easy to use, that brings some light to this field.

But in the best of possible worlds, perhaps that wouldn't be needed because people don't really buy into the hype.

DR. FITZGERALD: I also think that this is an area that provides a more extensive perspective beyond its own current scope. That is in the ongoing debate whether or not health care is just another consumer good to be, of course, driven by market forces and consumer desire. Or, is it a societal obligation that is to be delivered by a certified professional community. Those are radically different concepts.

DR. LICINIO: Automobiles now have become a societal obligation.

DR. FITZGERALD: I think this is one of those things that, the way it exists currently, is of such a magnitude it does raise that conceptual issue. On that level, too, I think it is worth delving into.

DR. WISE: Barbara.

DR. McGRATH: One of the reasons I think it is important is that it might be standing in for other things. I think the uptake is low, not that many people find genetics all that interesting.

But I do think it may be a way that consumers and all of us start learning about health care, and behavior change happens there. So it is a window through which to look at other things.

I think the CAM example is exactly right. That moved the science forward. But I go back even further to the HIV and AIDS activism of the '80s that moved that science forward. One thing that that did was it highlighted who the science wasn't working for: populations and subgroups whose needs were not being met. I think if we were to highlight some of this it might shine a light on the groups that genetic services and the genetic technologies are not particularly helping. It would be another way to look into the whole issue of disparities, which I think are really critical.

DR. TEUTSCH: On the same issue, I think that if you look at these emergent technologies, the best time to deal with them and help shape them is early. Once they are out there and in widespread use, it is really hard to influence them because they have a life of their own.

So in some sense, just on a timing basis it is clearly topical. It is an opportunity for us to at least have some influence over the development, which is probably timely.

DR. FROHBOESE: I actually had a question for Sylvia. Of course we see the health disparities theme throughout all of the clusters. I just wanted to get a little bit more information about this thought of doing a report on how direct-to-consumer marketing may be impacting health disparities. How would you get at that issue and what is the tie that you see there?

MS. AU: I think that that was just one of the policy questions that we came up with. Of course, the amazing task force that would be formed would come up with the amazing way to collect this data.

I think it is really difficult because the uptake is low already. People have to pay out of pocket for these tests. So it would be difficult to measure any significant health disparity at this time.

But I think it definitely is a point that we can extrapolate from other instances where society has access to pay-out-of-pocket kinds of medical care. This would be a similar down-the-road kind of thing.

DR. WISE: I think as we have talked about this in the past, particularly in relation to minority health and reducing disparities, one is differential access and differential provision of these services. To the extent that they are beneficial, they would then enter the conversation about disparity creation.

But the other is how widespread consumer engagement with genetic services will alter public discourse about questions of equity in society and public programs, and larger questions of social inequalities as well as health inequalities.

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So beyond access, I do think that there is the potential for altering public discourse around a whole variety of social issues because of direct consumer community engagement with genetic services.

Other comments or questions about this? Mara.

MS. ASPINALL: I had a comment on the timing. We are going to have to come back at the end of this process to prioritize everything. I'm assuming that we will not have the resources to pursue at the same time all seven of the clusters.

In the context of this, given the conversation around the short-term nature, I very much agree with what Steve and Jim said. If we were to attach a value to this, we should do it sooner rather than later. As we heard in the public comments, there are other people focusing on this. The timing is critical.

So I might suggest that we maybe lower-prioritize the in-depth report but higher-prioritize the brief report to be able to make a statement on this issue.

I'm worried about this. We have heard a lot of great things, at least on the first few, and maybe some more, but ultimately the toughest decision we are going to have today is to say which ones do we want to do ahead of the others. Putting this one in a slightly different category to be a brief report of a short-term nature I think may help with the ultimate decision-making.

DR. WISE: That is very helpful. Other comments?

[No response.]

DR. WISE: Thank you, Sylvia.

DR. BILLINGS: I just have one comment that I would like to make. Mara has made an overarching comment, so I thought I might interject at this point.

It might be also useful, either today or as we think about prioritizing, to look at whether there are gaps or areas very prominently which are not covered by our clusters which we do still think are part of the purview of the Committee.

One area might be the treatment of people with genetic disorders. That is, progress either in monogenic or polygenic treatments of the conditions under which people with genetic disorders receive health care in the United States.

That is not specifically addressed. It may come under a couple of the clusters, but that might be an area of obvious interest to this particular Committee.

The other area, in my view, is the relationship between the work of this Committee and its topics and the research portfolio at the NIH, as well as the interface between the National Center for Human Genome Research and this Committee and what the interplay between topic areas is.

Those would be just two areas that might be gaps. We may decide that we are covering them adequately or don't need to cover them, but those are a couple of areas that strike me as things that it might be people would be interested in.

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DR. WISE: Thank you, Paul. Any comments or responses?

DR. FITZGERALD: Paul, this is Kevin. Just for clarification, when you say people with genetic disorders I presume you mean clear mendelian kinds of disorders?

DR. BILLINGS: It is a changing paradigm. We just engaged in a discussion about consumers and their searching for what may not even be validated risk factors. I think we have an obligation as we invest more in genetic technology to ensure that the treatment of people with the older-style genetic disorders continues to improve. I think that is an ethical obligation as well as a practical one. We ought to state it and make sure that we are collecting evidence of trends in that area; let's put it that way.

DR. FITZGERALD: Thank you.

DR. WISE: Other comments or suggestions?

[No response.]

DR. WISE: I think those two will be important, certainly, in the consideration of our next cluster. We can see how it might or might not relate to the future of healthcare systems.

Mara, do you want to take us through Cluster No. 7? Then we will have time for general discussion and begin a conversation about how we would prioritize these in just a flexible, general way.

MS. ASPINALL: We go back to the words that we talked about before, "preparedness" and "future." The first piece is getting together the folks on the health plans to be able to look at how they see the future. One of the things that we had done previous to this as part of the initiative was talk to futurists more broadly. This is where this original initiative came about.

That, coupled with the idea that healthcare reform may very well be a hallmark of the next administration, gave us the opportunity to say we really need to be not just looking six to 12 months out but really five years out as to what the infrastructure needs are.

I think a piece of it is the chief medical officers of public and private institutions but also having the ability to scan the various agencies in HHS to understand what planning they have done so we are not recreating the wheel with others within the HHS environment and there look at the potential infrastructure needs in the future.

The objective would be to put together a report to be able to outline that future and the key steps that need to be taken in the short term that will help achieve the future that we see.

DR. WISE: Marc.

DR. WILLIAMS: Just a couple of things. I think from what you said, I'm seeing something different in what is written. When I see health plans, I assume that that is an insurance. I think that it would be important to be inclusive and to have chief medical officers not only from payers but also from integrated health systems, hospitals, academic medical centers, et cetera. I think they are all going to have an input.

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As much as I think we like to think that we docs are in charge of the future of health and how that is going, the reality is that it is really a partnership with administrative leaders. So we really need to have some innovative administrative leaders that are not CMOs but CEOs from those same organizations. They will have the business perspective in terms of where they think things are going.

I think it is a great idea. I just would vote to be more broadly inclusive.

MS. ASPINALL: I think that makes a lot of sense and that we should do it. What we meant by "plans" is the broadest definition but that it is not just the M.D.s and their key strategic thinkers and those pieces. The emphasis, which may not be clear, is this is public and private as well, and to look to the chief strategy officers, whether they are called that or not, from the agencies, again to ensure that we are not recreating the wheel.

MS. AU: I think that we can build off some of the work that Deb Doyle in the State of Washington got funding for. She did bring together leaders of healthcare plans and third-party payers to discuss what they were doing currently about genetic reimbursement and then what they thought the future was. I believe the work was completed about two or three years ago, so the report should be out there somewhere.

MS. ASPINALL: That's great. I'm not familiar with it. That would be helpful.

I'm glad you brought up the University of Washington. During the break somebody also mentioned to me talking to the key healthcare providers in terms of the medical associations and the groups of hospital systems in and of themselves. This implies just the reimbursement piece, but we really need to be broader on that. So, does the hospital of the future, in anticipation of genomic medicine, look very different in terms of its in-patient/out-patient mix, in terms of its information systems. So we would also include that.

DR. WISE: Other comments or suggestions?

DR. WILLIAMS: Are we going to go through other parts of this or is this the discussion piece?

MS. ASPINALL: We can keep going through any parts you would like to. What we haven't changed on the slides on the screen but I have changed on my slides is the initial earlier comments about clinical lab careers and broadening that, as we discussed earlier.

DR. WILLIAMS: I would like to second what Paul had put forward. If there was one thing that was really exciting about the American Society of Human Genetics meeting last month, it was just how close it looks that we will actually have some treatments for traditional untreatable diseases based on small molecules and taking advantage of axon skipping and other things of that nature, not to mention some of the interesting work that is going on with RNAs.

I think we may in fact, in the future window of five to 10 years, have some extremely effective therapies for some of the traditionally untreatable genetic disorders. I agree with Paul; I think it would be a shame if we let that drop off the radar. I think it probably does fit within your cluster.

Whether we need to do anything at a high priority level right now other than just to monitor where things are I don't know, but I think it should be represented. I know there are at least a couple of them that are in phase two, and maybe even one in Duchenne in phase three, clinical trials?

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MS. ASPINALL: Yes. But basically, what you are talking about is that with the advent of genomic medicine in a broader scope there are diseases that are today not fully addressed that may become long-term chronic diseases.

The example that I would use here, and I think it absolutely fits, is AIDS. As the AIDS community changed from a disease with a very finite life span to a long-term disease, we needed to change the infrastructure, whether that meant hospitals, reimbursement, life insurance plans. Quite frankly, that shift happened quickly enough that many of the institutions were not ready to do that.

If you look at probably two or three scenarios about these kinds of inventions occurring and being successful, how do we indeed put together the infrastructure to be ready for that without undue cost.

DR. WISE: Joseph.

DR. TELFAIR: Just a point of clarification on that. When you are looking at the planning, do you anticipate as part of the discussion looking at both workforce development as well as education of the workforce? Once you make decisions about where it is going, then who is going to actually be there to do the work. That is where I'm going. Do you anticipate that as part of the thing?

MS. ASPINALL: We do talk about that, and we talk about it as one of the policy questions. I'm wary of recreating the work of the other clusters. We would take this at a much higher level as opposed to getting to any specifics of this type of material or this type of education. Rather, we would more broadly talk about the type of healthcare providers.

For instance, one of the futurists really talked about the dramatic change -- if you believe in personalized health care and much more precision -- that there will be fewer physicians providing care and more non-physician care. That would be an example of the high level that we would look towards. If that is the case, how do we set out an education program for non-physicians.

We would not, I would anticipate in this cluster, get into the level of detail that says how would you educate them. That would be handled with other clusters. But we would look at that big piece to say what is the mix and how does it change.

DR. TELFAIR: I guess I brought it up because of the admonishment with which you started off your beginning statements with, which is the question of integration and priority setting.

I recognize and respect the fact that you were trying to stay away from that, but I also recognize that we have to set some priorities. We have to look at how there is some integration across these clusters. That is what my question is. It seems that actually would be less efficient than looking at where integration might be. It shouldn't mean, to me, working with some of the other clusters. We are going to have to do that anyway.

MS. ASPINALL: Yes, yes. I think that is a good point.

DR. WISE: But it does seem like for this Committee to engage this issue, which of course touches every committee that exists related to HHS and beyond, we are making a special claim of relevance. In other words, healthcare reform cannot realistically move forward without engaging in a very purposeful way the explosion in genetic insight and capability.

The second is that this is an intensely anticipatory project for us to take on. In other words, this is really tilted forward and looking at very big-picture issues to ensure that the healthcare reform conversation is not only about changing CPT codes over the next six months, although that may be very important. Particularly given the trajectory of genetics and genetic capabilities, healthcare reform must engage these issues in a very meaningful but also in a highly anticipatory way.

Am I hearing that correctly?

MS. ASPINALL: I think that is well said.

DR. WISE: I think, Joseph, you raised the fact that genetics in the service of reforming the healthcare delivery system could in fact embrace clinical utility. It certainly, as I mentioned, relates to reimbursement policy shifts and workforce.

So it clearly will have strong linkages to other clusters. I wouldn't call it a task force yet. It may be that in our priority setting we could suggest that if healthcare reform becomes a framing activity for us that it include other issues that would then not be seen as the highest initial priority but would be included in the anticipatory special claim arguments that the Committee would make in this area.

MS. ASPINALL: I think that that is right. I think the challenge in front of us in doing that is keeping up with the potential progress in the real world outside of this room and ensuring that we remain relevant in a way that if healthcare reform moves quickly -- and I don't think we all have the answer to that now -- that we will have a seat at that table short-term. One of the priorities may be stating that to ensure that our interest in doing that is clear to the next administration.

DR. WISE: Other comments specifically on Cluster No. 7?

[No response.]

Determination of Priority Issue Areas and Action Plan

DR. WISE: Steve, did you want to make a comment?

DR. TEUTSCH: Yes. As we move into now trying to triage all of this in an orderly fashion, I just want to remind everybody that at the end of the grid that you have in Tab 5 is a list of the things we have already done and the reports we have already issued.

Not all that we have recommended, strangely enough, has actually come to be. We actually are continuing to monitor the recommendations that we have already made for the reports on genetic discrimination, where indeed there has been substantive progress, but we are in the midst of seeing what comes out of the Oversight of Genetic Testing Report and the pharmacogenomics one as well. Then there will probably remain policy issues related to the large population studies that were made several years ago.

So we will continue to monitor all of that work. We should have that in our minds as we begin to think about what the new projects are that we want to take forward and what the nature of that work is. I just wanted to remind everyone that that is there as well.

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DR. WISE: Thank you, Steve. Just to remind everybody, we are not going to be voting on priorities here. This is not a formal listing but rather to get a sense of the group of how we would prioritize these cluster issues, how we may want to relate one to the other, and to provide some guidance on next steps, recognizing that we need to be flexible in how we approach this. We need to be responsive to the new administration's priorities and their needs from us.

I will just open the conversation for general comments. Please, Marc.

DR. WILLIAMS: This is a daunting task, to say the least. But thinking about it from a process perspective, and reflecting on the conversations that we have had already and the investment that all of us that have taken leadership in one of these areas have made, it seems to me that maybe the way to think about this going forward would be not to necessarily take the seven clusters and try and arrange them in some type of a rank order but to reflect that each of the clusters has certain things to bring to topics that the Committee as a whole may feel heavily invested in.

The concept that I would put forward as a straw man would be to perhaps leave the seven clusters as they are with leadership to keep appraising what is happening in that area but then to focus in on what are the areas where we really think we have some opportunities to leverage.

For example, we are in the middle of the Education report. We have heard about how several of these clusters are going to be relating. If that is going to be something that we prioritize, can we then have the cluster leads in the other areas say, this reflects directly onto that, therefore this is going to move up as a priority to support that particular effort of the Committee as a whole.

It seems to me that using that sort of a modular approach, particularly in terms of trying to be nimble in an environment that is going to change rapidly and in ways that are likely to be unexpected, might allow us to maintain expertise around these very important areas and yet readjust the focus within each area to support a communal effort.

DR. WISE: Please. Kevin.

DR. FITZGERALD: Joe and I would like to suggest an alternative approach, that you do everything, and do it all with really large reports.

[Laughter.]

DR. FITZGERALD: And start in March.

DR. WILLIAMS: They are representing those going off the Committee.

DR. WISE: Thank you for that helpful suggestion.

[Laughter.]

DR. WISE: Other general comments, particularly about process and how to think about going forward?

DR. EVANS: I was just going to say, one of the good things that could help is to identify specific niches. Here is something quick we can do within one of these. Then the rest of that particular agenda can be put a little bit on the back burner.

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DR. KIRCHNER: Actually, to be somewhat concrete and hopefully helpful, I think there are a couple things that came up that we could put in an order. For instance, on the informed consent thing, the HRSA meeting will be happening in March. We could have something set aside where we would decide what sort of educational segment you would want, say, in July. That is one thing we could just put down right away.

Similarly, with Mara's suggestion of pulling people together, once you look at the report from the University of Washington you could at least frame questions for the next meeting, which then would allow you to go out and look to see who are the people you would need to bring in to answer those questions.

It would be another thing that we could do concretely. Line all these things up for the March meeting and then we can jump off from there. You might have a better sense of where the next administration is pushing, at least, at that time.

MS. ASPINALL: I like that idea, but I wonder if we have time for that and whether we need to move faster to start things before the March meeting, or at least prioritize them.

One option -- and obviously things are still in flux, but we have some data -- is to be able to attempt to meet with the new administration relatively quickly. Maybe seven is not such a large number to propose and say these are our seven priorities. This is a committee reporting to the Secretary, so the Secretary's preferences are pretty important in the context, but this is the process that we went through and these are the seven that we have.

In the January time frame, if that is not too unrealistic, we could present all seven of them, unless there are some that the group today would like to say they would like to take off the list. But assuming that is not the case, present those in the January time frame and say these are our seven, we would like your input, what is most important to you as the new incoming Secretary. We would then have the ability to hit the ground running so that by the time we are at our March meeting we already have their input and can begin to move forward.

DR. WISE: South Dakota is beautiful in January.

I think that is helpful, particularly as it relates to the next thing on our agenda, which is putting together a brief report of our activities and plans with a cover letter that would precisely introduce not only the Committee to the new administration but what we feel are our strategic contributions to the issues of the day.

In going through the different clusters and listening to the conversation and the very helpful public comments, I was struck that there were not quite principles but what I think of as strategic contributions that could help us frame the seven clusters.

One is, and clearly it is going to be crucial, genetics in the service of reforming the healthcare delivery system. That includes Cluster Nos. 1, 2, and 3, and certainly No. 7 is the overarching one. But the clinical utility, coverage and reimbursement, and ensuring that there is a workforce capable of actually implementing what everybody is hoping for in healthcare reform, are going to be crucial.

Second is the idea that genetics will be crucial to improving public health and population-based prevention. That is clearly Cluster No. 6, but there is also a larger framing construction that

would allow us to engage in those issues and which came up very high in the ranking that we had prior.

Third, individual engagement with genetics and protections and the public's growing awareness and engagement with genetics. Direct-to-consumer marketing is merely one important component of that, but this issue is going to be crucial, and protections for individual engagement are going to be as well.

The last is to ensure that the new genetic technologies will enhance equity in health outcomes. We ensure that we will reduce disparities in health as the health of all is improved. There is no single cluster for that strategic contribution but rather we have decided that that would in fact be a component of all.

In thinking about how we would frame our seven clusters, we could just list these as our priorities. But there are different levels and they have different histories. I'm looking for ways to frame our seven in ways that would definitely be clear as to why we picked these seven.

So I'm just coming up with, say in our cover letter to the new Secretary, to say we need to make sure that genetics is a central part of healthcare reform. Then we have specific priorities that we think are the best ways to do that.

Second, public health and prevention clearly is going to be engaged by this administration. Genetics actually has a meaningful role.

Third, we need to talk about public engagement, public awareness, and protections.

Lastly, health equity is a crucial component of everything we do. We need to ensure that the genetic insights and capabilities address these issues in a meaningful way.

I will just throw that out again just to concretize the situation but really building on what your suggestions would be.

In the document that follows the cover letter, we have all seven. We would include all seven clusters in greater detail. They all have components of the issue briefs. But this overall framing I think is important as to what we are about and what we feel the new administration needs to address.

Do you have a comment?

MS. ASPINALL: I think it is great. I agree with doing it that way and organizing it. I think you described three major fundamental areas for which the seven would then fall, but having the information on the seven is a great step forward and just organizes it in a little bit more context.

I would obviously like the ability to edit things given the comments that we had today going forward, but I think getting it out and emphasizing to the new Secretary having his and the staff's view of that before our March meeting, will allow us to hit the ground running quickly.

DR. EVANS: In that editing, the one thing that I think is really important is, as it stands now, there is quite a prominent slant on how healthcare reform can bring genetics into the fore. I think it is really important to go the other way. I think it is really important to emphasize to the Secretary and to the public that the advent of genetics in medicine is going to drive medical care.

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It is going to affect medical care in that other direction. I think that is very important to articulate.

DR. WISE: Other comments about prioritization?

[No response.]

DR. WISE: Steve, did you want to make a comment? Are we fulfilling what you hoped to accomplish?

DR. TEUTSCH: I think we are fulfilling it. I think we still have the actual heavy lifting. I actually like your framework about the clinical care system, where it is going, where the population system needs to go, and then how individuals engage with things, as well as disparities.

I think that is a rubric that people can relate to and understand. Then we can get to the pieces below it.

I do think, for our own purposes, we need to think about, given all the things that are on the table and the areas where we might actually make a substantive impact over both the short term and then over the longer term, how would we think about which of these issues we want to tackle in a way that we can manage within the resources we have available to us. I do think we should have that discussion.

I do think this is actually helpful. Your reduction from seven to four is actually pretty helpful in communicating effectively, what are the components. Maybe one thing we could do is get that up so people can see it. Then we should have a little bit of a discussion about what we think would be the most important short, immediate kinds of things that we can do, as well as a couple of larger reports that we really could undertake over the next few years.

How many do we usually manage at one time; two or three, right? She is thinking one. We manage, usually, a couple to three at a time.

DR. WISE: The Workforce is going to move forward. Is that correct?

DR. TEUTSCH: That is ongoing. The Patent report is still in the midst. That is two. But then, hopefully, we will get to the end of the Patents over the next year and we should be prepared to take on what we think would be --

DR. WILLIAMS: Jim just fell off his chair.

[Laughter.]

DR. TEUTSCH: That means Jim can take on the next one because he will be in such fine shape.

But we should think about what are the next important topics that we actually want to take on and then which of these we really want to get on with in some more shorter-term agendas.

I would be very interested in hearing Committee members' thoughts as to, given all of the important issues that have been put on the table, which are the ones that are likely to be the ones where we can make the most difference.

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DR. WISE: Andrea.

DR. FERREIRA-GONZALEZ: There is an issue that touches all laboratorians, and it has been touching us for about the last five years, or even more and we haven't realized, which is the critical shortage of laboratory personnel. We have this as a brief report in Cluster No. 7.

We are at a very critical time point where our current workforce, working not only in genetic laboratories but the entire laboratory community, is reaching a mean age of about 40 to 45 years old. We don't have a lot of people going into this type of work.

One of the issues that we have is that we don't have enough schools. Schools are being closed due to lack of funding. But also, there doesn't seem to be enough incentive for young individuals to go into the field. Another problem that we have is that we cannot retain them. They usually go to work in IT, information technology.

This is a critical issue that I think we are currently facing in many different areas in the country. Maybe we could start developing a brief report or a white paper where we can start investigating the issues of where we are and what can be done. That could have a huge impact on the crisis that we currently have.

DR. WISE: Is that part of the Workforce purview at this point? Is that a central element?

DR. McGRATH: We talked about including laboratorians and decided to put them next. But certainly this is not cast in stone. We could move it up and include it as part of the three groups. But there was a decision made not to.

DR. WISE: Other comments?

MS. ASPINALL: Even if it is part of the education group, that is, I think, a little bit different from what Andrea is talking about, which is the availability of the personnel. We take it up in No. 7 but again on more of a long-term basis, less of a short-term basis in terms of reacting to what many have described as a crisis in the field.

DR. FITZGERALD: But, on that note, Mara, in your long-term view, one could differentiate between the things that are in crisis now, or will soon be, which could derail the long term. So, would we be able to break out of your report those issues? First of all, identify the workforce issues and other issues that have to be addressed in the short term if we are ever going to get to the long term. That may be something that this Committee could do which would be unique.

MS. ASPINALL: We could do that. We actually highlighted that in one of the policy questions for exactly that reason. We got some comments to broaden that. But I think the perceived current crisis is in the laboratorians of all types.

DR. FERREIRA-GONZALEZ: That is why I'm bringing it up a little bit separate but within this group. If we are going to develop a brief report in the long term, this could take, with all the other reports that we have, two or three years to really come out. I think we have to start investigating this very proactively. Maybe there is something that we can recommend.

DR. TEUTSCH: Barbara, I hope your memory is sharper than mine. When we made the decision for your committee I thought we made the decision to exclude laboratorians explicitly?

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We can always revisit that. I wonder, given that decision, what has changed. Maybe I should address this to Andrea.

If it is clearly established that there is already a problem, is there something that we could do that is something less than a full report that could begin to help with the solution to that rather than to evaluate it?

DR. FERREIRA-GONZALEZ: One of the questions is do we include it in the Education report with a very specific scope, which is to start looking at specific areas of the crisis: why are there no schools, why are we not attracting or even retaining people, and what changes can be made. That could be part of the Education report, but I'm not sure how far along that has already gone and how wide the scope of that report is. Is it going to get diluted in everything else that we do.

I think we can do a brief report or maybe a white paper where we can get something up and going to deal with these specific issues.

DR. WISE: Mara is next.

MS. ASPINALL: I still believe that laboratorians may be included in the Education, but I think that is a different issue than what Andrea is talking about. The kinds of things that people have talked about in this field and we could take a stance on short term are seed funding -- I'm familiar with this in the education arena -- for community colleges to take on programs in laboratory medicine. That has been incredibly effective in the education field, where, as a result, in about 10 years the number of programs that were available both at the two-year and then four-year colleges was tremendously enhanced.

The private industry councils and the workforce development monies, which are increasing in the context of a recession where retraining happens and there are federal dollars not necessarily from HHS but ones more broadly, can be directed to careers. This happened in the nurse community, where there was a tremendous amount of money funneled off specifically to train nurses for the next generation of nursing. This was about 15 years ago. Even after that, we are still dealing with a nurse shortage.

So there are some very short-term pieces that, in my mind, don't require legislative support or new laws fundamentally to do it but to prioritize laboratory medicine in a way that brings what very well may be a larger number of unemployed individuals into the field in a short period of time.

It is not quite that easy because there is a fair amount of education. So you don't pull a lever today and have it work tomorrow. But it is comparable to what happened in the nursing shortage, where both universities and companies got together, priorities were made in these private industry councils and in workforce development money. Those, to me, are the kinds of initiatives that we might be able to put together in a relatively short time in a white paper.

DR. WISE: Marc.

DR. WILLIAMS: A comment and a question. The comment relates to the reimbursement aspect of that particular issue, which is particularly for Ph.D. laboratorians. There are some reimbursement issues -- you are shaking your head no. There aren't any reimbursement issues?

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DR. FERREIRA-GONZALEZ: The laboratories get reimbursed for the CPT codes and the different procedures, but I professionally cannot bill for it.

DR. WILLIAMS: Correct. But when you are talking about retention, and I know this from speaking with other institutions, some of the issues have been, why should we pay for these folks to be there if they can't bill for their services or we have to do work-arounds, or whatever.

I think there are some reimbursement aspects of it that may impact retention to some degree.

DR. FERREIRA-GONZALEZ: I think you are right on the money on that. I'm not talking about the Ph.D.-level individuals like myself but the medical technologists of the bench. We are talking about a crisis at the bench. So the issue is also that, due to the short reimbursement, we don't have a free market to be able to increase salary support for these individuals. It is not because we don't have people, it is because we don't have money to pay them more. Normally, we lose them to information technology, to be honest with you, at least in our case.

So reimbursement could be tied into decisions, but I like some of these ideas about the white paper and trying to see how we can reeducate some of the individuals that are in the workforce to do this.

DR. WILLIAMS: The question I have relates specifically to the creation of the white paper. I don't recall this specifically, but what, if anything, was addressed within the several Banbury conferences on education and genetics? Was there much time spent around that?

In other words, we shouldn't create a white paper if Banbury has addressed this. If they haven't adequately addressed it, then I think that would be a worthwhile investment of time.

DR. FERREIRA-GONZALEZ: I think this goes beyond the inherited disorders genetics field into other areas. It is not just the cytogenetic technologies and the molecular biology technologies. It goes to all parts of the laboratory. We have to assume that genetics is percolating to every area of the laboratory. So it is just not that narrow. It has to be a broader scope.

DR. WISE: I was just going to ask about the role of the Committee. I know other groups have tried to address this issue and have put out reports. HRSA has. The Bureau of Health Professions relatively recently put out a large report specifically on this issue. Some professional groups have been working and advocating on this issue.

What would you see would be the role of this Committee given that the clinical lab workforce issue is much beyond genetics? What would you see the role of this Committee as being given the other reports and other work being done more broadly around clinical workforce?

DR. FERREIRA-GONZALEZ: I think we can look at what other groups have been doing or what has been reported and see if there are areas that we continue to discuss and then contribute to because there are gaps or nothing has been moved forward. I think we can start surveying what has already been done and then move forward from there.

DR. WISE: Barbara.

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DR. McGRATH: I was just going to ask that same question. I think there is a difference between genetics education, like basic education and continuing education and training, versus workforce issues, which is getting people into the pipeline. Maybe that is a little bit where the line is.

I don't know agencies as well as the rest of you, but I think HRSA has often picked up that workforce part of the territory. I'm not sure about that.

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

DR. FITZGERALD: This falls under Mara's purview in the future piece, so we are talking near future. In the near future, if we have the \$1,000 genome, what does that do to the demand for clinical laboratorians? We can put it in that context, too. If this is really going to ramp things up, that is something else we need to look at.

DR. FERREIRA-GONZALEZ: Exactly. If you have the \$1,000 genome or everybody gets screened for genetic disorders, like carrier screening, we still have to have people to run the tests. It creates an issue, but it goes beyond just the molecular biologist in the genetics laboratory. You have to have individuals in other areas of the laboratories where testing is going to be done.

As we continue the implementation and move these personalized medicines and genomic medicines, it will require more testing in the laboratory. We need to have a workforce and retain that workforce.

DR. EVANS: Just so we don't forget, the ripple effects will be huge. We will need a lot more genetic counselors, for example.

DR. FITZGERALD: And maybe even some clinical geneticists, but I don't know.

DR. WISE: Other comments more broadly? Steve.

DR. TEUTSCH: I want to push folks a little bit here. We have heard a lot of things. I don't have a magic number, but three to five short-term terms, three to five monitoring things that we can afford to pick up, and then a couple or three longer-term projects. I would be really interested in what people think those things should be. I can push back on each of these cluster leaders to talk about what those might be, but I would be very interested in which people think are likely to be the most impactful that we should take up.

DR. FITZGERALD: Just on the monitoring, I think we have some for those. First of all, the informed consent one, because there is a HRSA meeting coming up. OHRP may be looking into this too at some point in time, I'm presuming. So that may be adequately addressed by other people and we don't need to wade into that. That could be a monitoring.

The DTC issue, again, is something that we need to monitor to decide how we want to frame it for this Committee. Although I know there is some desire here to move quickly on that, I'm not sure we have decided how we want to weigh in on that yet. So that is already there.

Then the short-term needs. We could certainly pick two or three of those, as we have already discussed. I think you are right; genetic counselors have to be in there, too, because that is obviously part of that ripple effect. The long term I guess I will leave to others.

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DR. EVANS: In response to Steve's plea for specifics, I would just throw out there that, of the things we have discussed this morning, I think that two short-term items that could be addressed, one very short term, would be something along the lines of what Mara suggested, a letter to Daschle emphasizing the importance of genetics and the changes it will bring about and that it has to be factored into plans for healthcare reform.

I think that a second, relatively short-term item could be something along the lines of a checklist in the DTC arena, as has been suggested.

Then I would personally advocate that, given the incredible importance of reimbursement for the practical functioning of the field, including genetic counselors, that would be a high priority for an in-depth report that should be pursued and initiated quickly.

DR. WILLIAMS: So you think we need a new in-depth report.

DR. EVANS: I saw the puzzlement. What I'm saying is we need to act on those and proceed vigorously with what has already been done.

DR. WILLIAMS: Right. I think that that would be good.

DR. EVANS: I think you should do it again.

DR. WILLIAMS: I know. Right. I was going to throw my BlackBerry at you.

[Laughter.]

DR. WILLIAMS: I'm sure it was almost implied in your sense that that will be something that we will be doing. I don't see that as an item that is even on the table for debate.

DR. TEUTSCH: Let me see if I can try this out on you. Having listened to this discussion, I'm going to try and run through each of these. You can tell me where I'm miles off base.

Under coverage and reimbursement services, what I heard is that in fact the most important things we have to do are monitor and look to the implementation of the things that have already been out there.

DR. EVANS: Yes. Not just monitor, push.

DR. TEUTSCH: Yes. But we are clearly having an interaction, particularly with CMS, on those issues that we will continue to, yes, more than monitor. But it is in the sense that they are there and our job is to work with the organizations to help move them forward.

We heard that the clinical utility is important but, under the rubric that we talked about, emerged under the future of the healthcare system. I'm not convinced that we need anything there because we have already made some of the salient recommendations as part of the Oversight and Pharmacogenomics reports.

We just heard about genetic education. With that, we probably need to add the laboratorian component in a stronger way. But that is already underway.

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DR. FERREIRA-GONZALEZ: No. It is the definition. That is what we were talking about with Barbara.

DR. TEUTSCH: You talked about a white paper and some shorter-term things. I'm sorry. I didn't mean in the context of a larger report.

We talked about informed consent. This is going to be really important in the privacy issues as we get to the \$1,000 genome, the EHRs, and all of that, as to how we are going to do that research. It is going to be central to the clinical utility if we are going to be able to use those kinds of resources.

I heard that we are going to at least listen to what comes out of the HRSA conference and then identify whether there is something that needs to be done there. That ties into what Michael was talking about with protection of human subjects.

I also heard strong interest in at least doing some short-term assessment of the DTC, direct-to-consumer testing. That would be a short-term thing that we would probably want to take up in a way that we could stay on top of that, more than just watching it. Details to be worked out.

Public health applications. There is a lot in there. I haven't quite got my head around exactly what that is going to be. We talked about performing a systems review. That gets you on to things, but even within that there is a lot that can be done. I would be interested in others' thoughts about what can be done there.

Then I'm going to push a little bit on Mara because it seems to me that the big one is about health reform and the key things that can be done. Clearly, we could do an in-depth report and spend several years, but I know you don't want to do that. I don't want to do that, either. I want to pick out a few things within that area that we can get on with. But I suspect that that is going to be an ongoing major effort.

MS. ASPINALL: Are asking for comment now?

DR. TEUTSCH: I'm trying to put out a straw man of what I have taken away from the conversation. That is my interpretation of most of it. So yes, I am looking for some thoughts. Paul.

DR. BILLINGS: Sorry. It is hard for me to raise my hand and get noticed.

I didn't hear whether the regs and recommendations associated with GINA, which is in my view an immediate issue rather than a long-term issue, are part of the discrimination cluster or whether we have spent our wad on that one already.

DR. TEUTSCH: It is currently listed as one of the things that we are going to be monitoring. We have those four items that we have already issued reports on.

DR. BILLINGS: Sure, sure.

DR. TEUTSCH: That was one of the items within that.

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DR. BILLINGS: But more than monitoring, given that we are at a crucial period and that the incoming administration will have some impact on the regulations and enforcement of the legislation, do we want to be a little more aggressive on that issue?

MS. LEIBIG: Hi. I'm Kerry Leibig. I am from the EEOC. I can tell you at least in terms of Title 2 of GINA we are moving along as quickly as we can. Actually, the person who was most involved in drafting the notice of proposed rulemaking for those regs has recently left and accepted a job with Department of Justice. I'm his replacement. You are familiar with Peter Gray. He has been working on this issue a long time.

I'm doing my best to fill in for him. We have high hopes that the NPRM will be coming out soon, at least in terms of Title 2 employment discrimination.

DR. TEUTSCH: Right. So that will be sent out for public comment; is that correct?

MS. LEIBIG: Right, right. Under the Federal Rules of Civil Procedure, they would be published for a 60-day comment period. Then we would take in all the comments and then come out with a final rule after our commission signs off on them. So we are still in the steps of drafting the notice of public rulemaking, which is our proposal for what the regs will be, which we will then get comments on.

DR. TEUTSCH: So that is one part of the implementation. Yes.

DR. WILLIAMS: Just a clarification. Will all of the titles come out for public rulemaking at the same time or will they be issued independently?

MS. LEIBIG: They will be issued independently. EEOC only has the authority and knowledge to do it on Title 2, which is the employment section.

DR. TEUTSCH: We have the insurance one, too. I think that is due for release we said in November of next year?

MS. CARR: The law becomes effective in November. My understanding is that the HHS, agencies within HHS, Treasury, and Labor are working together on the health insurance provisions. I'm not sure whether that will come out as an interim final rule or as a rulemaking for a proposed comment. I'm not really sure. Alan, I don't know if you know more about any of that. I wish Robinsue were here. I'm sure she would be able to fill in some details for us.

DR. GUTTMACHER: Yes, that is consistent with what I know. I'm not sure whether they have made any decision. But there may be a decision; I don't know.

MS. CARR: Perhaps at our March meeting we might want to have a fuller report. I bet things will be clearer by then.

DR. TEUTSCH: That would still be timely, wouldn't it?

MS. LEIBIG: I would hope that the NPRM would be published prior to that and we would be working on the comments that we received. Our hope is to publish a final rule by May, but it depends on how things go at the Commission. The new administration is going to have to weigh in.

DR. TEUTSCH: Paul, what did you have in mind beyond trying to coordinate with these agencies?

DR. BILLINGS: If there are key components from the Committee's point of view of the law and either stricter interpretations of potential rules or less strict interpretations of rules. As we have just heard, the new administration is going to have its say on the construct of these enforcements. We should educate the leaders on that.

DR. WISE: Thank you, Paul. We are heading towards lunch.

DR. TEUTSCH: Yes. Good.

MS. ASPINALL: I have a narrow comment and a broad comment. On the narrow comment, which is in answer to your question about Cluster No. 7, I think I could, given the comments that we heard today from the Committee and the public, have probably three priorities within Cluster No. 7 that I would focus on: workforce, health information technology, and monitoring and evaluating effectiveness.

If you wanted me to at least put a straw man out to prioritize within No. 7, I could do that. But I think the bigger issue to maybe think about over lunch is, to me there look like two very different ways to go. One says we leave all seven priorities, organize them the way Paul described, send them to the new Secretary, and leave it at that. Continue to focus on the two that we have going in the interim and wait until we get feedback. That is one approach, which I think would be a reasonable approach.

The other approach is that we prioritize amongst the seven and either start working on them or send them to the new Secretary with a prioritized list amongst the seven. My concern is that is hard to do. I would like to know what the new administration would like to do. I don't think seven is so large a number that it is overwhelming or looking scattered.

DR. TEUTSCH: I was not proposing that we don't give them the seven. I was just proposing that we begin to clarify our own thinking about how we would take on all the pieces within that. There are other things. For instance, you had laid out the idea that over the short term we could actually convene a group of chief medical officers and other kinds of people that we could actually bring together in the near term. It is hard to believe that this isn't going to become an important topic. We could then get on with the agenda so that when we meet in March we are not back here again.

MS. ASPINALL: That is exactly what I'm trying to do so that we don't have to go through this again in March and we have clear marching orders amongst ourselves and with the new administration. I'm with you.

DR. TEUTSCH: That is basically what I was looking for. So, yes, we have these broad issues. Yes, they will probably say they are interested in all of them. But if we have a little bit of clarity where we can begin to take it on, then I think we will have a richer discussion with them at a different level of granularity. Then we can move forward.

Why don't you think about that over lunch. I'm not sure whether the hypoglycemia is worse before lunch or after lunch. It probably depends on your insulin status.

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DR. WISE: Before we break, I want to thank everybody for being humane with the leader of this task force and all your really informed, very helpful contributions over the last nine months or so. We really appreciate it, particularly to Sarah and the staff and to the members of the task force. Thank you.

DR. TEUTSCH: Great. Thank you, Paul. This has been great. We will probably revisit this, if there are any other comments after lunch. The rest of the day we are going to be reviewing the draft report, which you had in Tab 6. I think it was also handed out in your folders. This is the note that we are going to have to send to the incoming Secretary. So we would like to get your feedback on that.

My guess, for those of you making travel plans, is that we will wrap up a bit early. I think we have made good progress. But, why don't we take our break for lunch and be back at 1:15.