SACGHS Discussion and Prioritization of Issues

DR. McCABE: Let's go ahead and get started. I got sidetracked when somebody asked me about organic chemistry and premedical education, and I lost track of the time because it's one of my current soap boxes.

Well, I hope everybody had a good lunch, and now we're going to really knuckle down and identify specific priorities. A couple that have come up that I've heard about, one is to look at what expertise the agencies would have in genetics. For some, that may be obvious but for others may be less obvious. But what expertise do they need right now and anticipate they will need in the short run, and then what do they have on board, both at -- and then at what level, doctoral level, board-certified, and look at really where the human resources are in the various agencies, and it was suggested to me that this might help not only identify needs and where the needs were for future hires but also allow some sharing between the different agencies which would be good. So I just want to throw that one out as something that we should think about.

Another one was exploring a little bit more in terms of the large population studies but not just that there's a need for large population studies but exploring a little bit about what those needs are, and Alan, do you want to expound upon that a little bit?

DR. GUTTMACHER: I can maybe expound a bit about what the status of present thinking is, at least in several of the departmental agencies, about this because this is in fact a topic that in recent weeks particularly a number of them have been talking together about, particularly CDC, HRSA, and NIH, talking about what is the proper sort of need and scientific approach to a large population-based study that would really try to look at sort of genotype/phenotype correlations across a normal population.

As many of you will know, there have been a number of attempts to look using genotype/phenotype correlation around specific illnesses and those kinds of things which have been quite helpful in lots of ways, but this would be the idea and not a novel idea, an idea that's already been used in such efforts as BioBank in England, Estonia's launching something like this, Decode in Iceland.

So there have been a number of sort of national studies to do this, but for multiple reasons, including not just underrepresentation but the complete lack in some of those of some of the population groups in the U.S., especially if we're going to worry about issues of access and those kinds of things, so we really need to have knowledge about.

So there's some real scientific reasons why it might be worth thinking about having such a study done in the U.S. There are in fact in the U.S. a few efforts towards this. The Marshfield Clinic and others in the U.S. have started talking about doing studies like this. The rough back of the envelope kind of thinking, though, is you probably would need some place on the order of 500,000 to a million people enrolled in a such a study and following them over a decade or more to really get meaningful results.

So there have been some early thoughts about how this might be done. There's been, for instance, some sort of unofficial consideration about perhaps asking the IOM to help out with sort of an expedited review

of this kind of thing to look at some of the options, to give some opinions about what exactly would be scientifically particularly useful in terms of approaching this.

I think it would be particularly helpful as this moves forward for this Committee to be thinking about, is that, if the science of this can be figured out and it's a somewhat daunting task, and I think it needs expertise of a lot of the agencies, the IOM and those kinds of groups might be helpful in this, I think, again looking as I've heard people correctly around this table thinking about what is it in particular this group can contribute that others might not be doing, would be advice to the Secretary if we can inform you a little bit more about some of the scientific bases, about the real usefulness of this kind of thing because this is not a study that, even if the scientific utility looks great, that one could ever launch lightly.

It will cost hundreds of millions of dollars to do and in fact would require not just funding beyond the NIH but beyond the Department of HHS probably, would have to really be a kind of federal and perhaps a very good opportunity as well to have some public/private collaborations kind of thing, and would clearly need to be something that the Secretary understood well and felt was an important kind of item I think to move forward in the current budgetary climate.

So I think this Committee being informed somewhat more about somewhat of what the science might look like, what the need might look like, to consider that and to see whether, through the various expertises and eyes that this group has, to really consider that and see how important it seems would be very useful.

DR. McCABE: So the argument then would be to assess where we were, to work with Sarah and her staff to bring together a report to us, working with you and you mentioned CDC and HRSA, to look at the status, but then where it needed to go and what was required to really move it beyond where it is right now, just to put something concrete.

DR. GUTTMACHER: Yes.

DR. McCABE: And bring that back as a report to the next meeting. So we're not asking for a half a day of meeting to gather data but we could really do those among the ex officios working with staff to bring a report and then present the report, and then we would decide at that point whether it was something that we wanted to take to the Secretary.

DR. LEONARD: Could we get the report before the meeting, so that we have an opportunity to read it? Is that asking too much? It's just that it will make the discussions at the meeting more fruitful if we have an opportunity to look at that report.

DR. McCABE: Do you think that's doable, Alan?

DR. GUTTMACHER: As long as you don't want it two months before the meeting, yes, sure, I think that's doable.

DR. LEONARD: No, no, but I mean a week by email or whatever.

DR. McCABE: Yes, a week or two before.

DR. GUTTMACHER: I can do that. There's not much point in giving you a report the day you walk in. I agree.

DR. LEONARD: And I would just comment that regardless of how expensive you think this is, the Human Genome Project sequence was thought to be outrageously expensive and we did it, and if that is to be brought to the fruition of all the health care advantages which are one of the major reasons that that was done, then I think that this is one of the best ways to spend our money.

DR. McCABE: Yes, and this is something that I've been interested in because of this issue. How do you translate the fruits of the genome into improved health care, and without an evidence base, we're not going to be able to do that, and this is the way you're going to get the evidence base.

DR. LEONARD: Right, because you need such huge cohorts.

DR. McCABE: Well, we've been talking about common diseases and rare diseases, but in fact they're a continuum, and if you begin to think about the whole genome genotypes for common diseases, the groups that are going to have the identical whole genome genotype are going to be relatively small groups, and so you're going to have to treat them somewhat similar as you treat rare diseases and if you're going to get genotype/phenotype correlations.

So it's going to take large populations, and I think that the study that I like to refer to, and it's a loose analogy, but if we look at the Children's Oncology Group, 95 percent of kids are enrolled in studies, 85 percent in treatment studies, and if people had said back in the '60s or whenever the precursors to the COG got started, oh, this is an impossible task, we're never going to be able to invest enough money in this to really understand this, then we would not have begun what has become an iterative approach which really has led to the successes in children's cancer. So at some point, we're going to have to do it and the question is do we decide just to do it now or 50 years from now.

MR. BAKER: Yes, I think the important thing that I hear from Alan is, it's not a question of if, it's a question of when, and then given that feedback from this group, the question then becomes how and whether this process.

I think it's important. One of the things we've constantly commented on is this is clearly a national study. It's not a federal study. It's not an agency study. It's a national study, and there's some lessons to be learned from the BioBank experience as mentioned as well as from NHANES and some large population-based studies that we do need to bring to bear, and there's some other related activities that are going on that we need to assess pretty clearly and take input from and perhaps include in the report that we're talking about having.

DR. GUTTMACHER: That's a piece. I think part of the report that we ought to give you is some reference to these other things, the National Children's Study and the other kinds of things, pieces of which are analogous to this and none of which is exactly the same.

DR. McCABE: As well as to the extent possible what's going on in the private sector because we know that activities are going on in the private sector.

MR. MARGUS: The best thing I heard was the idea of having the IOM or someone like that look at it, too.

My impression from talking to a lot of scientists on this is that it's nowhere near, decide that it's when, it's still an if, and there are definitely different sides as far as whether it's better to have one huge group that's kind of standardized on how you're going to phenotype them early on and it's quite difficult to change your mind later or, with the same billions of dollars, can you design a lot of different studies that are still very large, have all the power you need? So I think there's still a lot of scientific debate.

My impression also from Francis, to be fair, is that I think it's an idea being floated right now. I don't know that it's been explored that much yet.

DR. McCABE: Well, even if we come to the conclusion that it was a recommendation to the Secretary that the Secretary consider sponsoring an IOM study, the IOM only does studies that are funded for the IOM. Frequently it's the government going to the IOM asking for a study. So even that would be a benefit.

DR. LEONARD: I forgot what I was going to say.

DR. McCABE: Alan, any follow-up?

DR. GUTTMACHER: No, only that I would very much agree with what Brad is saying. I think that we're clearly not in a position where we would present some study for this group to endorse or something and that is the reason to go to the IOM. We think we have some expertise in the federal agencies, but I think purposefully, one of the reasons to involve a group like the IOM would be that in some ways they can be even more dispassionate than we. We like to think we're dispassionate about it, but I think in some ways they can be even more dispassionate about it in terms of really weighing various kinds of options because I think even if you said you were going to endorse this study, there are many different ways this study could be constituted. It could be one large study. It could be actually sort of harnessing the studies that are already out there and somehow trying to get them so that they're using more consistent phenotyping or those kinds of things. So there are a number of different approaches one could use scientifically even beyond the question of the actual worth of it.

DR. FELIX-AARON: My question is a sort of a clarifying question. In terms of the study, are we saying that the study is to sort of understand the interactions between sort of the genotype, the environment, and health care, and how these all interact to produce a particular phenotype, i.e., disease? Is that what the study is about?

DR. McCABE: I don't know that we're talking about a study or the study. I think we're talking about a type of study.

DR. FELIX-AARON: But the idea, is that what we're talking about?

DR. McCABE: It could have several different, but several it could -- I mean, it could encompass genotype/phenotype. It could encompass variability. So it's a variety of these things, but I think that would be one of the things to explore.

DR. LEONARD: Kay, are you asking about the IOM study?

DR. FELIX-AARON: No, no.

DR. LEONARD: The data, this cohort?

DR. FELIX-AARON: Right. I mean, the data cohort in terms of what are the issues, sort of getting a sense of what are the issues. So is health care included and sort of health services included in that mix?

DR. GUTTMACHER: It depends on how ambitious one wants to be and how much money you want to spend essentially. I think clearly, I mean, the overall kind of thing, the devil is clearly in the details here, is it's what are the interactions between genes and environment that create health and/or disease?

Now, how do you define the environment? Health care, social status. There are lots of factors that are part of that environment that interact with the genotype. The easy part of this study, if we ever did it, would be the genotype. Everyone focuses on that. That would be the easy part. Defining what we mean by the environment, figuring out how to measure it, I mean, if you just looked at what exposures are we talking about, are we talking about industrial exposures at work and how do you measure the -- diet? Diet when? All these kinds of things are incredibly difficult scientific questions to do.

MR. BAKER: Yes, to qualify, when I say not if but when, I definitely mean the interpretation, and the question you're raising, there's going to be a series. There's going to be layering of studies, particularly if you look at these complex interactions of genes, gene-environment interaction, gene-behavioral interactions, gene-phenotype outcomes in different populations, enormous studies.

So I don't think anybody's thinking in terms of one study. I think we're talking about a variety of studies staged over time, shared by groups of people, public and private, that build the knowledge based on opportunities, based on maturity of science and what are priorities.

For example, there are priority diseases that have risen to attention. So do you start with those diseases? This is the kind of debate that you need to have.

DR. TUCKSON: Well, actually, I've gotten, like others, thoroughly confused here, and I think that there are so many studies, as you say, that need to be done to elucidate this and that is so much a part of the research enterprise ultimately of NIH and others.

If we are talking about, which I hope what this is trying to get to in some of the questions that we just heard, having an organization like the IOM try to help give some guidance around focus and interrelationship between the development of new knowledge and its practical translation into the health care delivery system and being able to provide clinicians and others with the relevant information that helps them to take this new knowledge and apply it in cost-effective ways, I would hope that that is part of what we really are talking about here.

If we're really essentially talking about just more of the NIH budget for this work, that's a different kind of conversation, and so I think that what we might want try to do is get a little more explicit about what's here.

I'm trying to preempt or presage this idea of focus. I continue to think that if we're going to as a Committee do right by the American people, there is an inevitable march of science going forward. We could and should be advocacy-oriented towards having the basic science research budget being robust in

this field. I think that is in America's interests, and if we need to make statements about that, that's terrific, but that's moving on its own course.

I think the issue becomes how do we give affordability and access to these services to the American people which has to do, I think, fundamentally with clinical decisionmaking. It has to be how do people and how do their health care teams understand how to use these things in the most appropriate way in real life real time.

I believe that what that means to me and I become, as I listen to the conversation, more and more focused on patient education. How do you teach them about direct-to-consumer advertising, marketing, expectations? How do you help patients to have a conversation with their physicians and their other health care team so they can make rational, intelligent decisions about the use of this new technology?

I think it has a lot to do with counseling and the robustness of the counseling enterprise and how that will work, and I think it has a lot to do with technology assessment and which tests get included and paid for and funded and why, and I think it has a lot to do with the health services research agenda for determining how new knowledge and new testing and new capability in this area fits with the total disease treatment for disease and which things does it replace, which things do we get rid of? How does it fit in together so that at the end of the day, you don't have all this stuff bottlenecked because nobody can afford it, can't get access to it, and we continue to do the old medicine while we do the new medicine. You can't do both. No one can afford it. It is impossible.

So what we need is some way of giving the American people the chance for the rational use of this new stuff within the existing context of how we treat the entire disease spectrum for individual diseases, and I just hope that if that's what we're talking about trying to get at, that's at least my plea on this.

MS. BERRY: I think I got it, based on listening to everyone's comments, but to follow up just on Kay's original question, to clarify for myself on the study and the research issue, is it to have somebody, IOM or someone, do a literature review of what work has already been done and an agency review as to what studies have been funded and are ongoing and then an analysis of what gaps there are in the knowledge and the research so that you can move forward? Is it for a goal of recommending some funding, research funding level, in the President's budget or is it a more focused study with the particular objective? I think I get the answer but I still have a feeling there may be different ideas that are being articulated.

DR. McCABE: Well, let me tell you what I was scribbling as notes to myself here listening to the discussion. The question that I would bring back, the purpose of doing this report which would be a combination of literature and agency review because there's a lot of this stuff that has gotten hung up and hasn't made it to the literature yet, but it would be the question and these are just thoughts but to begin to focus it, but the question to the IOM, the questions to the IOM would be: is the science and the phenotypic or clinical evaluation ready yet for large population studies to look at the effects of genes and environment on disease pathogenesis? If not, then where are the gaps in knowledge, and if it is ready, then how would you move it forward?

My guess is that the answers to both of those are yes, that there are gaps and yet there are parts that are ready to move forward. But it would really begin to try and identify because what one does with IOM studies is identify questions for them to answer.

DR. GUTTMACHER: Yes, let me just clarify one thing. I certainly don't want to mislead the Committee as to this. We've already begun to have initial conversations with the IOM, and because the Committee does not meet again till the fall and one of the -- those of you who've been participants in any way in IOM studies before, you will know they have much power behind them. As with anything with power, there are also some downsides. One potential downside is the length of time it takes sometimes to get the results. So that, if the agencies agree on what they're asking from the IOM, I think our plan would be potentially moving ahead with some kind of meeting with the IOM even before this Committee meets again, so that to some degree, that die may be somewhat cast.

However, it would only be cast in that we would have asked the IOM to do a study and the IOM then decides exactly how it's going to do the study. Nobody tells the IOM. That's part of the reason for getting IOM studies, is they figure out how to do it, you don't tell them how to do it, but I suspect they would be very interested in hearing from the Committee's views of various aspects of this as well and that also, again, I think for the Committee to sort of, for the Secretary, with the acumen of the Committee, to look at what is the general parameters of this kind of study, and then for the Committee, like the agencies involved, to digest the report from the IOM once it comes forward and figure out what does it say and what are the recommendations based upon that study might be very helpful.

DR. McCABE: So what would be your suggestions to this Committee then, Alan?

DR. GUTTMACHER: I think in terms of we've already in some ways brought the Committee somewhat up to speed but only, I think, a bit, and the idea of having this sort of white paper or background report or whatever for the Committee to take a look at before the fall meeting, and we can certainly update you at that point on what the status is of any IOM study or non-study, whatever, at that point and things could change, but if there were a study beginning at that point, even if it was laid out what the study's going to look like, have that be part of the background information for the Committee as well, for the Committee to have whatever length discussion at that point that you think is most appropriate and decide for yourselves how best to proceed, but it might be at that point to sort of proceed with interest in the area and say, well, this is something we're going to get back to once this IOM report, for instance, comes out and decide how best to shepherd it at that point. That might be one way to go anyway.

DR. McCABE: So does the Committee have an interest in this then? Debra?

DR. LEONARD: I have a distinct interest in it. I just feel a need to sort of clarify for the Committee members because there seems to be confusion. I think with this large patient cohort, basically what we're creating is a tool that would facilitate research. It's not the research funding. It's creating the information and the DNAs from lots of people correlated with medical information that cold be used for research to understand the genetics of asthma or hypertension or complex genetic diseases and that doesn't exist. Every physician or every researcher who wants to study asthma has to create their own cohort of asthma patients with the DNAs and do the genotype/phenotype correlations, collect the medical information, and sometimes one investigator has problems collecting enough patients to reach statistical significance when they go to do these genotype/phenotype correlations.
So it's basically creating a resource that would be the basis for all kinds of research. Correct me f I'm wrong.

DR. GUTTMACHER: No, Debra has it absolutely correct. I mean, an analogy is actually the human genome sequence itself.

DR. LEONARD: Right.

DR. GUTTMACHER: It's like that. It's something that a group of academic investigators get together and kind of get the data together and then make it freely available to anyone to mine in various kinds of ways.

DR. LEONARD: Right. So it's really creating a resource on which all this other research can be done and that resource is hard to achieve when you're not working on a national level. So that's what we're sort of out there. Should this be something that NHGRI creates or works toward as a next step to mining the human genome and understanding its variations for health care, and the IOM study, I don't know the purpose of the IOM study. I'm not clear as to what that IOM study is going to do, and I'm really distressed by hearing that it's going to take a long time because --

DR. GUTTMACHER: It's not going to take as long as some. We've already had discussions about that. So it might be --

DR. LEONARD: How long is --

DR. GUTTMACHER: One would hope that from beginning to end might take eight to ten months.

DR. LEONARD: That's a long time.

DR. McCABE: Yes, but if you look at some of the hang-ups in the U.K. BioBank study, they got hung up for years because of concerns about the open-ended nature of the study and ethical issues that were raised because of that. So investing eight to 10 months up front is probably worthwhile. Having multiple groups looking at this, as Alan is proposing, we'd be one of those groups.

For example, what's been brought up in this Committee meeting in the past day and a half is the need for diversity to assure that all of the populations are represented, so that this isn't a resource for majority populations. It's something that we've already talked about and certainly I'm sure that it's being discussed, but we could reemphasize.

DR. FELIX-AARON: I'm interested in this idea, and I think I find it intellectually stimulating and very exciting.

What I'm having difficulty with is sort of understanding how that process that you described, which seems to be on a particular track already, intersects with the work of this Committee and that's what I would like some help with in terms of seeing and sort of getting my head around what the intersection is and how the work of this Committee feeds into this process which clearly seems on track.

Again, I ask this question because in the background material, in the preparatory material that we were given, it really asks the Committee to really look at where it can make unique contributions, areas that are naive areas, areas that aren't already getting attention, and so in thinking about that and taking those instructions very literally, I'm thinking of trying to understand what we're proposing.

DR. GUTTMACHER: Yes. So I understand exactly what you're saying. Again, I'm not on the Committee, but if I were on the Committee, I wouldn't want to be spending 90 percent of my time looking at this study, as important as it might be. I don't think that makes sense.

However, for the Committee to weigh this thing, thinking about it ahead of time but then once there's a little bit more of a report to reflect upon, how important is this really in terms of -- I mean, this is the Committee that's supposed to give the Secretary advice about genetics, health, and society. This study would touch on at least two if not all three of those areas, I think, and so for this group to be able to say to the Secretary, yes, this really is important, it's worth spending both time, effort, and federal monies in terms of accomplishing it, that would be helpful.

If, however, this group says this is a great idea but it's just the NIH and CDC and HRSA trying to give themselves a bigger profile, this really isn't going to move the ball forward. As our advice to you, the Secretary, it's a nice thing. If you can find the money, go ahead, but we're not going to make a big push for it. I think that kind of thing would be helpful.

DR. McCABE: The other advantage that we have bringing this to this Committee is that our work is done in the sunshine. So that, as opposed to this being done in back room Committees and moving forward through the IOM and eventually emerging, at least the process has the sunshine on it during the process, not waiting till the very end.

Are people interested? And really, it would be the various agencies involved. It's not just NHGRI but also HRSA and CDC working with Sarah and her staff to put together a white paper on this with the status of this and some of the issues that are relevant to this Committee for presentation at the next meeting. Again, I don't see this as a half-day presentation. I think we're talking about a 30-minute presentation with time for questions, maybe a 20-minute presentation with time for questions, and we would try and get the paper to you at least a week or two ahead of time so that people could review it before the meeting. Is that acceptable?

I heard a motion. Do I hear a second?

PARTICIPANT: Second.

DR. McCABE: All in favor, say aye.

(Chorus of ayes.)

DR. McCABE: Any opposed?

(No response.)

DR. McCABE: Abstain?

(No response.)

DR. McCABE: Another thing for you to do, Sarah.

And what other things, other priorities that people are identifying, recognizing that we already have a significant agenda? So we probably have room for one more item to go forward.

DR. FEETHAM: A theme that I keep hearing is the access, education and workforce, and as you pursue these, and to me, they're all quite interdependent to the work of the Committee and the discussions, just

reminding you as I briefly presented to you yesterday and in the handout you received today, that these are all areas again that HRSA can inform the work of this Committee, and one of the things that we do have is a genetic counseling report that was done in 2000 that, if it would be useful to you, it's a Genetic Counselors Workforce Study that we could make available to you. It is available on the web, but we could, if you wanted those copies, we could get those to you to help facilitate some of the issues that you brought up earlier today in the discussion, and as I mentioned yesterday, we are in the midst of the genetic workforce study which is looking at both specialists and primary care and that's going into its second year but again an update on that at some point in time may be useful.

One of the things that we've also talked about among our agencies since we are complementary and interdependent in the work we do is that CDC, NIH, and HRSA and AHRQ has co-funded some of our projects in the education of health professionals, and again if it would be of interest to this group at some point, we could do a brief panel, pulling together what that work was but also at this point in time what we see as what has come out of that and how it may have influenced the community, whether it be the academic community or the professional communities, in moving forward rather than grappling with starting all over again.

DR. McCABE: This sounds much more focused than education more broadly. I think when SACGT, when we talked about the need for education, which many people have commented on here, certainly there's a need for education, but when you try and get your arms around what that really means, it's very difficult to be focused. So this sounds more like a workforce analysis.

DR. FEETHAM: Well, it's a combination. Again, we are doing a workforce analysis as part of the Center for Health Workforce Analysis at HRSA, but also again, my premise was that we have funded in combination across our agencies for several years now various grants for the education of health professionals, and since that seems to be something that keeps coming up, if that information, of the sense of where we are with that, if that would be useful at some point, that we did a presentation on that, that's what I'm saying we could do.

DR. McCABE: Discussion?

DR. LEONARD: Of the four issues that we've identified so far, the nondiscrimination, the oversight of genetic tests, this large patient cohort, and then the education workforce process, we have sort of action items for everything. We have no action items for this health care education workforce issue, and this seems to be one of the major issues if we're going to integrate into health care genetic information and yet we don't have anything we're going to do about it or on it. So maybe we need to brainstorm and figure out what we need. I mean, with the oversight of genetic testing, it's just presentations at the next meeting. I mean, maybe what we need is information on what's currently being done and wholes of ways that we could make recommendations that would facilitate additional education funding or programs or whatever.

DR. McCABE: An analysis of where it's going and whether we would agree that it's headed in the right direction.

MS. WILLIS: Just I think as a part of that, I don't know if you can give me the benefit of more information, but on the grants that were focused towards physician education, I guess I just feel like education is one step but action is a whole other one and even if you get at physicians all this information, if they don't go on to use it and really seem to change their practices, then it's all kind of for naught and I was just wondering, are any of those grants, do they try to go back and see --

DR. FEETHAM: Well, evaluation is a component of any funding that I know our agency does and NIH and the expectation with CDC, also, and that's why I did say about this was, again what is the effect? When I said community, I meant the academic and the professional practice community. How tangible those data are, I can't say at this point in time, but that is an expectation, and again our funding has been interdisciplinary. It's not just physician-based.

MS. MASNY: I would be very much in favor of that as well. In fact, I was going to make a suggestion that with the summary report that we would have from the ex officios, to actually list some of the initiatives that have been taken by the different agencies, especially in regards to some of the priority areas, and I was going to mention the handout that you gave because it does list all of the grants and the education efforts. So I think that this would be an excellent way for us to see what initiatives have been taken and then where some of the gaps are that we could then make recommendations about.

DR. McCABE: Other questions? Other comments?

DR. HOOK: Just a question to follow up on that. I know a number of state legislatures for recertification of physicians do require ongoing education. Has there been data to show the utility of that type of mandated annual or biannual sorts of requirements for HIV and domestic violence and things, and should that be something that we would consider as a possibility for genetic education as well?

DR. FEETHAM: That's a good challenge, and the discussions that we're doing right now is that NIH sees their role in the research about education and at this point in time, that we are not a research agency and so that kind of question wouldn't be necessarily ours to answer, other than indirectly.

DR. REEDE: Just to follow up on the same sorts of things in terms of understanding better, in addition to the training, just what's the state of the art in terms of where are the accrediting bodies or the certifying bodies or others? What are they doing in this area, and if that could be incorporated in the report and not just for physicians, but I think in terms of physicians, nurses, if you could cut across the health professions and health professions training.

DR. FEETHAM: As I recall, that was an activity that NCHPEG was doing and Joann was part of that Committee at NCHPEG which I don't know how current that review was, but that was an effort to try to get a handle on that certification that you're talking about.

DR. REEDE: If that could be included in the report, that would be useful.

DR. FEETHAM: Again, coming from that.

DR. LEONARD: It seems that the education is happening on a lot of fronts, and we've already asked Joann for documentation from the -- I don't know if it's private but professional sector, and maybe we need information from agencies and then I don't know if certifying boards like Joan is saying, but is there a way to have someone take responsibility, staff or whoever, for consolidating these things into something that could come to the Committee before the next meeting for review?

DR. McCABE: Well, we've asked Joan to do this for the various professional organizations. If we want to do it, would HRSA be willing to take the lead among the agencies to put together what is being done

by the agencies? You clearly have a handle on that for yours, but discuss with the other agencies on our behalf what is being done but also where the gaps are?

DR. FEETHAM: We do have that to the extent that you as the former Committee asked for it and that was broader than education, but it may be a matter of updating that profile that was done a few years ago.

DR. McCABE: Right. This is much more focused. This is much more focused than that was.

DR. FEETHAM: Only focused on education but those preliminary data were part of that initial profile.

DR. GUTTMACHER: And as a number of people referred to, NCHPEG, the National Coalition for Health Professional Education in Genetics, really has much of this information already gathered, so it should be pretty easy to provide.

DR. McCABE: And Joe was here yesterday. I don't see him today. But could you maybe work with Joe McInerney and NCHPEG and bring that data back to us? So that would be the action item, that we would have a report on the status of education in genetics. We would have, as Debra points to, these four actions items. We need to see if there are other ones that people feel we have slighted that are more important than these priorities and don't be shy. Feel free to speak up.

MR. BAKER: I'll point out, if you're not aware of it, the recent Institute of Medicine report on who will keep the public healthy, which calls for the training of public health professionals across various crosscutting areas, genomics being one of those, and through the development and the focus with professional education and the majority of NCHPEG's focus has been around health care professionals, and we slip in and out of that language here. Health professionals or health care professionals. Most of the discussion we're having is about health care professionals, and the public health professionals are also health professional disciplines and health education and epidemiology, environmental health and so forth, all need a dose of training and need for certain competencies that we've tried to develop.

One of the questions for the Committee is where do you draw that line as far as defining this educational challenge for developing competency among health professionals, and to what extent do you want to get over into the areas of other health professionals, other than health care professionals? It's an important area of consideration, but as you hear, as I'm reflecting the views from public health, particularly public health practice, people that work in health policy and work in disease prevention programs throughout states don't seem themselves as geneticists, don't identify with genetics information or expect to have competency, but they have a clear, very, very important role in current disease prevention, understanding environmental factors in obesity and diabetes and analyzing those diseases, preventing those diseases, and need to own this to the extent it affects their job. That's one of the challenges that I think CDC and HRSA and the agencies here particularly are sharing, and it's really a continuum from all of the training needed from very, very professional credentialed training of health professionals all the way down to an awareness level among other health professionals that are in much more of an applied field in the states.

DR. WINN-DEEN: I mean, I think one of the things that we're trying to identify really is where are the gaps, and so, I mean, I think you're right. I think we have to think first very small, who are the people who have immediate contact with the patients and really need to be educated because if they're not educated, nothing's going to happen, but then we need to keep moving this out in whatever concentric circles till we really have basically every member of the general public educated to the point where they can at least be an informed consumer, if not a well-informed person who has the right tools with which to do their particular job, whatever role it is they play in sort of the world health care effort.

But I think what we need as a Committee is we need your help to try and identify what's already happening and where the gaps are and then we can make our best judgment about what recommendations to make about either endorsing the things that are already happening or making very specific recommendations about which gaps are the most urgently in need of being addressed.

DR. LEONARD: So as part of the reports, not only what's being done but if you have a sense of the holes, the gaps, that's also useful for us to know.

DR. McCABE: So for all of these, we need to identify gaps as well as what's being done.

Over lunch, Sarah, Suzanne, and Cindy put together some items, and I think it's probably good to run through these, to just make sure that there are not any areas -- we've identified four areas. We now have actions on each of these areas, and they would come back to the Committee at or before the next meeting.

But we should check. I was suggesting that we look at what they had prepared and be sure that there's not something really big that we've missed in this discussion.

MS. WILLIS: Dr. McCabe? I've just now looked at this sheet that I probably should have looked at before, and there's also efforts under public education. I think we also talked a lot about patient education, that kind of thing. I know I would be interested. I just wasn't sure if the rest of the Committee would be interested in also getting a summary of those efforts as well as efforts for health care professional education.

DR. REEDE: I just want to say, while we're waiting to set up, in terms of the comments that came forward from CDC and Tim, that for me, even though I'm from a medical school, I don't make big distinctions in terms of that health workforce that we're talking about, and I'm thinking both in terms of if you're talking about the practitioner, the one-on-one with the patient, all the way through the public health practitioner, and I think that when I'm speaking about workforce and where the efforts that are being made in terms of education, it's across the board. I don't make a distinction.

DR. McCABE: Sarah, you want to read those to us?

MS. CARR: We definitely agreed that the Committee would be writing a letter to the Secretary thanking him for his support of the bill that emerged from the HELP Committee and recommending that concerted efforts be made to continue legislative efforts on the House side, and staff's going to prepare that letter and circulate it among the Committee and hopefully get it out as soon as we can.

There was a request for an update at the next meeting in October from FDA, CMS, and CDC on the CLIA regulation, and I guess involving also perhaps Dr. Sundwall representing the CLIAC because they're going to be discussing the potential augmentation of the CLIA regulation to address genetic testing specifically, and also to involve FTC because we want to hear what FDA and FTC is doing in terms of monitoring or having oversight over direct-to-consumer marketing of genetic tests and websites and so forth. So that will be an agency update at the next meeting.

And then, the workforce issues are to get briefed on what activities are ongoing, what the status of efforts are in that area, and I think we heard that HRSA would take the lead in coordinating a status report on agency efforts in this arena and that Joann Boughman from ASHG would graciously take the lead in pulling together what the professional societies, including NCHPEG specifically, are doing, and will you be able, Joann, to gather information on what's going on in certification as well or is that -- you can do that, too. Okay.

And then, we were talking about the NIH/CDC/HRSA plan, I guess, to carry out or develop a plan to carry out a very large population study to understand genotype/phenotype correlations, to bring to fruition the work of the Human Genome Project, to make it more relevant to clinical care and so forth, and that NIH would take the lead in developing a report to the Committee that might update us on where the IOM report stands and also describe this study in more detail, describe other kinds of population cohort studies that have been going on, and the possibility, I guess, of the Committee perhaps taking up the question of whether to recommend to the Secretary that funding for this which would be significant be considered.

I mean, that would be the goal as I understand it. This would be a report, a written report, to the Committee in time for them to be prepared to discuss it at the October meeting, and it might lead to a recommendation from this Committee to support the funding of this large study. That was what I gathered.

DR. GUTTMACHER: Yes, but I think that such support would be months away, at some future meeting. This would be sort of the baseline and then assuming that the model that goes forward is the IOM study, that one would not expect the Committee to endorse spending lots of money on something that hadn't even really been --

MS. CARR: Well, I wasn't sure I understood what question the IOM would be addressing. Are they going to tell you how to do it or are they going to tell you whether it should be done?

DR. GUTTMACHER: Some of both.

MS. CARR: Okay.

DR. GUTTMACHER: Some of both.

MS. CARR: So it won't be ready then in October for the Committee?

DR. GUTTMACHER: So we have sort of preliminary report as to the status of what's been done so far, thoughts about the future, but I think it'd be premature to ask the Committee to do anything substantive in terms of action.

MS. CARR: All right. That's great then. So maybe at the following meeting or the following meeting, you'd actually be taking it up.

DR. FEETHAM: Can you say more about the training and education, what the status of the agency expertise is?

MS. CARR: Oh, no. Actually, that probably ought to be a separate item, I think, in a way. Ed, do you see it as part of this? This was actually what you initially -- sorry.

DR. McCABE: Yes. Sorry. I had decided that the other things had risen to the top. This had to do with identifying what the needs are for genetics in the various agencies and what the expertise is in the various agencies and then opportunities for collaboration between agencies. If there's expertise residing in an agency that's needed in another, can they utilize that which exists?

It felt to me like these other things were probably more important to that, so I had let that slide down on my own list.

DR. FEETHAM: I mean, from a different perspective, I mean, it may be useful to this Committee if again we did a brief panel for you at the next meeting to just clarify how we see our roles. As I said, we're complementary and interdependent, and, I mean, that might be a more informational kind of thing that may be more useful than anything beyond that.

DR. McCABE: If you were willing to do that, I think it would be helpful to us, because we've heard, as we did the round robin, that what's going on in genetics but that was very brief and it would be helpful to us to know why everyone is sitting at this table and why each of these agencies were identified, and then I think it would be also helpful to identify if there are agencies that you all think should be here that aren't here, like we've already talked about FTC and yet they're not sitting here. Is that something that should be here?

DR. FELIX-AARON: My comment relates to the patient and population cohorts and, I mean, I would just want to offer Alan, Suzanne, and Tim, the expertise in health services research at the Agency for Healthcare Research and Quality, seeing that the endeavor is anchored by practice and what goes on in clinical care. I think the process could be informed by sort of an understanding of health services and what goes on in clinical care. That's one point.

The second point is that I don't see on this list some of the issues that have come up in terms of again the application of the technology, sort of trying to help and sort of bring clarity and support to some of the issues around the application around technology in current practice.

I mean, did this fall to the bottom or I just wanted to get a sense from the Committee because I think that is a theme that has come up in a number of different ways and said differently in the sense of direct consumer advertising, but also understanding this technology and how it relates to current practice and the realities of changing practice.

DR. McCABE: Anybody wish to comment?

MS. CARR: Is that the health care issues here?

DR. FELIX-AARON: Okay. I guess you didn't get those.

DR. McCABE: There were other issues that we had not identified. This was why I wanted to put up the list to be sure that there weren't topics that we had forgotten about, but they're lower on the list, probably not to be taken up at the next time, unless we move something that's in that top four down and move one of these up. So that's the purpose of the current exercise.

DR. FELIX-AARON: I see. So this is to identify the next four topics for the next meeting?

DR. McCABE: Well, yes. The topics that we can engage at the next meeting. We have action items for the next meeting, but the real goal is to then identify from that are there actions that we can take in terms of recommendations, consultation to the Secretary, or to the other agencies? So the papers themselves, while they're a product, they're really the foundation upon which we would make decisions and move things forward.

DR. LEONARD: Could we relabel that population patient cohort studies? Because it's really development of a population patient cohort tool and studies -- I mean, that is a tool that will be used to do large cohort genotype/phenotype complex disease studies, and then the IOM study is evaluating process and utility of developing that tool.

MS. CARR: So this would not include genotype/phenotype studies. This would be how do you go about putting --

DR. LEONARD: Developing a database.

DR. McCABE: Conducting.

DR. LEONARD: This is a database tool.

MS. CARR: So how to enroll, get a million people in this study? How to go about literally recruiting a million people?

DR. LEONARD: And how do you store that DNA so that for all the whatever, however many studies are going to be done, there's enough DNA to do it once you have it and all that stuff.

DR. McCABE: Alan, is that acceptable?

DR. GUTTMACHER: I don't think we can design the study right now.

(Laughter.)

DR. GUTTMACHER: So I don't know. I mean, again the IOM will not have us tell them look at 1, 2 and 3. They're going to want to study the whole area to some degree. So again, this is an information item. For now, I think maybe we'll bring to you sort of the status of what's been done out there in BioBank, Children's Health Study, et cetera, et cetera, what other kinds of things are out there and presently launched, and perhaps by October, we'd have a pretty good idea of exactly what the agenda would be for the IOM.

DR. McCABE: But from my perspective, this will not be a passive, just present it to us, and we'll sit there and nod. The purpose of presenting it to us --

DR. GUTTMACHER: Right. But I'm not sure whether there would be much -- eventually for the Committee to take some real action on it, but I don't know whether there'll be much action to be taken in October as opposed to a future meeting.

DR. McCABE: Well, but if we feel that --

DR. LEONARD: Information about what they're thinking.

DR. McCABE: I mean, if we are looking at this critically, not just passively, but are looking at it critically, there might be opportunity for input to the IOM.

DR. GUTTMACHER: Oh, absolutely.

DR. McCABE: Because I don't think we're really interested in a passive receipt of the information.

DR. GUTTMACHER: And eventually, you're going to have an even more active role, but sure.

DR. REEDE: Just so that for what I thought would be coming forward is beginning information sharing so that we can start to articulate the need for such a study and that's what we would be moving forward. So that, we really would not be looking at how you would design a study or what would be the data elements of a study but really being able to articulate the need and maybe within that being able to raise some of the types of concerns we might have in designing a study.

MR. BAKER: The term we were using in earlier discussion was feasibility of and considerations for this type of activity.

DR. McCABE: Sarah, could you move so we could move the page so we can look at the ones that have fallen off?

MS. CARR: Sure.

MR. MARGUS: Ed, and one of these points includes the information we're going to receive from the woman from the genetic counselor organization about --

DR. McCABE: Yes. Yes, that was part of the workforce and I think was with the stuff that Joann was doing.

Yes?

DR. BOUGHMAN: Maybe I can try and tell you what I have conceptualized that I'm going to be able to bring to you before the October meeting and see if I really am on target here.

Certainly, from my position and working with NCHPEG and with the College and with a variety of other organizations, I will be able to tap them for some of the activities that are going on now.

I'm not sure whether you got the handout or not, but yesterday in the National Association of Social Worker News, the lead article was "Genetics Guidelines Issued." The Board of the NASW approved the set of guidelines that are now a part of the genetics issues that are included in social work curriculum.

So in fact, those are kinds of things that we have in our scan of the environment we know about and think it would be useful for you all to have, and it will be the professional aspects, the accreditation aspects and so on that we are in contact with through our interactions with NHGRI, HRSA, CDC as well, and NCHPEG, but also the American Board of Medical Specialties and the genetic counselors themselves, and I think that list will at least give you some feel for where people are, and that's the kind of scan I was hopefully going to bring to you.

DR. McCABE: And Robin, do you want to see how what we asked of you would fit into all of this? Do you feel that it fits in?

MS. BENNETT: Yes.

DR. McCABE: Why don't you come to the microphone? This is Robin Bennett from NSGC.

MS. CARR: And I just typed this, so if you want to make any edits in that, go ahead.

MS. BENNETT: Since I spoke this morning, I've had a chance to make a few phone calls, and I don't think within a month's time we can come up with a dollar amount for you, but I think that we can come up with a design for a study that may have outside funding that within a year's time we would have. We could even do it on the back of an envelope in a month or really do a quality job for you, and I think that we could come up with a recommendation in a month's time.

DR. McCABE: So what Sarah has typed here, would that work? Receive information from NSGC on initiatives needed to increase training.

MS. BENNETT: Absolutely.

DR. McCABE: Increase the numbers of genetic counselors in training. I think that's really the --

MS. BENNETT: And quality of training.

DR. McCABE: Okay.

MS. BENNETT: We can certainly provide the educational pieces.

DR. McCABE: Okay. Good. Thank you.

MS. CARR: Is quality of training -- did somebody say quality?

DR. McCABE: Yes, quality was in there as well as numbers. Quantity and quality.

MS. BENNETT: In terms of improving existing training programs, are they at risk of not being funded in the future?

DR. McCABE: Thank you.

MS. CARR: Can I just ask? Did you say that you were going to come forward with a proposal for a study that would take a year, and you would be doing the study?

MS. BENNETT: I think that we could come forward with the initiative. From my understanding, this group doesn't have money to fund the study.

MS. CARR: No, we don't.

MS. BENNETT: So that's not where we're at. What I think we could come up with is the plan for when we would have that data available and what type of data.

MS. CARR: But you would be gathering the data?

MS. BENNETT: In collaboration with other groups.

MS. CARR: Are we comfortable with Number 4, the wording of that now? Alan, genetic basis of common and rare, is that what --

DR. REEDE: We need advice about the stages. I don't think that's what we're --

MS. CARR: I'm sorry. Tell me what it's supposed to be.

DR. REEDE: I don't think, from my take on it, that the plan was not for NIH to come to us to provide information for our advice on how to design the study because it's more advice from us or thoughts from us in terms of you mentioned feasibility. I think in terms of is there a need for this type of study and documenting, right, right, and what would be some of the concerns that we might have for this type of study.

MS. CARR: And some of the concerns?

DR. REEDE: That might be some of the legal or ethical or other types of concerns that we might have, if a study were to be conducted.

DR. LEONARD: I think it's also just including us in this process of deciding to do that, so that if funding is needed or letters are needed, if we can be convinced that this is something that is useful to do, we may be able to facilitate or effect the process somehow.

DR. GUTTMACHER: I think that's right, and also, as Ed brought up, the ability to do this in an open kind of way where you can all invite comments in some ways that the IOM may not, for instance. So there are other interested individuals, organizations, or whatever, might be able to talk about some of these same kinds of issues in a way that might not happen in any other setting, I suspect.

DR. REEDE: I think the other part, I see this as a start. This is a start of a conversation that will be ongoing.

DR. LEONARD: Can I bring up another issue?

DR. McCABE: What I'd like to do is look at the ones that are at the bottom that keep being off the bottom of the page, just because I want to be sure that everybody's comfortable that we have gotten the four that are really important that we're going to focus on and that we haven't missed something.

MS. CARR: This came up in the presentation from all the agencies on their mission and roles related to genetic technologies.

DR. McCABE: Yes. I think I would postpone this. I would not put this as something for the next time.

DR. LEONARD: But there could be individual agency input if there are other agencies that have a voice that we need to hear that aren't at the table, that the agencies may be aware of, to have input to Ed and Sarah, that maybe they should be invited to be at the table.

DR. McCABE: And at some point, I think it would be good to do this, but I think this is more of a catalog, and I'd rather take more actions where there's need than go into a catalog at this point in time.

I think this is the big one. We've talked a lot about access and the question is how does this one fit in? The integration, insurance coverage and reimbursement, affordability, disparities in access. A number of people have mentioned this.

MS. BERRY: Well, many people here have mentioned the health disparities issue, and I know it's a priority for the Secretary and I know there are health disparities grants and there may be a specific program. In the back of my mind, I feel like I've read a bit about it and maybe the folks from HHS or some of the agencies would be able to tell us, and I'm thinking maybe our action item is to make sure that genetics is incorporated into the larger initiative that the Secretary or some office or division is already undertaking, so that we don't necessarily have to do a separate thing, but that we integrate our thoughts and recommendations and study into the larger piece because genetics is only a piece of the health disparities issue.

DR. McCABE: Yes, that can be done in one of two ways. We could ask someone from the Secretary's office to describe what efforts were underway or we could write a letter to the Secretary, saying that we understand that these efforts are underway, we want to make sure that genetics is included. How would you like to proceed?

MS. BERRY: Is anyone familiar with what –

DR. WINN-DEEN: Well, it's hard to know how to proceed unless you know what's already ongoing. So I mean, I think at least we need some baseline of information.

DR. McCABE: So Sarah, could we ask you to make inquiries and maybe have a presentation?

MS. CARR: And would this be in October?

DR. McCABE: Well, the question is, where does it fit in? Does anyone feel that this is any more important than things above it? Just knowing how much we can fit into an agenda, it might have to wait till the meeting after, so Sarah could begin to work with the Secretary's office and warn them that this question was coming so that they could be prepared.

Would that be okay, Sarah?

MS. CARR: Sure.

MS. WILLIS: I just have a comment. I'm not against pushing it to a second meeting, but I just feel like before we can worry about even workforce issues, we need to have someone to serve. If there's nobody there to serve because their insurance isn't paying for it, then it just seems like that needs to be a little bit higher up on your list, but that's my own personal bias. I don't have a problem with it being pushed.

DR. McCABE: No, I think it's a big issue. I guess I'm worried that it's too big of an issue to really accomplish, but certainly access is a major problem in health care in general and in genetics in particular.

I think the first is a letter that is staff time, and you all will see that letter. It's not something that will occupy time other than to report that it was sent at the next meeting.

The laboratory and test regulation, I would guess that that's going to take two or two and a half hours. That's not trivial to get through that and then we'd want some discussion.

The workforce issues, probably somewhat similar in time allotment, and we'd want discussion. So we're pretty much almost to two half days right there.

We'd already talked that Number 4 is really probably more like a 45-minute to an hour presentation and discussion.

So we would have time to begin to address what the issues were in access, though I don't know that we'd have time to do a report before then.

MS. WILLIS: I was just thinking maybe if we just pick one aspect within that to address, like if we decide to just do insurance coverage and reimbursement or if we just decided to focus on health disparities or other -- we appreciate they're all interlinked, but maybe a report on one aspect of it.

DR. McCABE: Why don't I suggest that we focus on health disparities, and since we know that that's an interest of both the Secretary and the Surgeon General, why don't we try and identify what's ongoing in the DHHS regarding health disparities and any of the other agencies who may have some insight into that and use that as a springboard for an action item in terms of how could we look at that in more depth and assist the Administration.

Sarah, do you think that'll work?

MS. CARR: Yes.

DR. McCABE: Anything else that's down at the bottom there?

DR. FELIX-AARON: Ed, I agree with you that this access issue is a huge issue, but I think getting a handle on it in terms of, again for our purposes, in terms of looking at the diffusion of innovation and genetic testing and all this therapy being a diffusion of innovation and how that relates to access, I think it's an area which is pretty specific. I mean, there's work being done in that area, technology over time, and how it relates to this field and what we can learn and what we may be able to do or to guide the further development of that, I think, would be worthwhile.

DR. McCABE: Maybe you could help Sarah in looking at future directions.

DR. FELIX-AARON: Sure.

DR. COOKSEY: If I could just make a comment on the access issue, and Suzanne is representing HRSA, but I'm the principal investigator on the workforce study, and as we've looked at that, we've had strong messages from one of the funders to be sure and look at the public health aspects of genetics services which cover a lot of, I think, basic access issues, and we've been looking at it in a little bit more depth. We should have information that can be incorporated into the report on the types of patients seen, the sponsors, insurance coverage of patients who are seen by geneticists. We have bits and pieces of information.

Plus, as we've looked in more depth in a few of the metropolitan areas, sort of what the public hospitals are able to do and what other sources are available, I think we can touch on that in the context of genetics services. It's only touching on a big, big issue, but we can contribute that.

DR. McCABE: Thank you.

DR. REEDE: Just one thought in terms of the health disparities issues is, I think sometimes issues around health disparities, diversity, et cetera, can get marginalized when they are pulled out as separate entities, sort of like if we're going to spend the next two hours looking at diversity or looking at health disparities, and I think that is an important thing to do. At the same time, I think that there are components of this that can be seen in any of the other areas, so that when we are addressing workforce or when we are addressing education or when we are addressing putting together this large database, et cetera, they get revisited. So it's just a concern that we not marginalize them into one component but rather understand that they're an integral component of much of the topics that we have.

DR. McCABE: So themes or threads that should run throughout are gaps, disparities, and diversity.

MR. BAKER: I'd suggest adding to the discussion, following Cynthia's suggestion, your comments, Ed. In fact, the Secretary has identified a commitment to particular diseases that are in the current disease prevention this year in cardiovascular, diabetes, and asthma, and that certainly includes the consideration of differential impact on populations. Health disparities is amplified to that lens. So you may want to walk that through your consideration here following the theme of what's already important to the Secretary. How does this help clarify and target those efforts that he's already got underway?

DR. McCABE: Can we see the bottom of the list again, Sarah, please?

DR. HOOK: To what degree do Items 6 and 7 need to be done in the form of presentations or simply could be collated in, as you say, a catalog that could then be distributed to us?

DR. McCABE: First of all, 7, I don't think we were going to take up at this time. Maybe ask at some time in the future, but I'd rather focus on the other things at this time. So 7 is for future consideration.

DR. FEETHAM: But the first part of 7, the way it's written, belongs, I think, with Number 6, and then the education and training, et cetera.

DR. McCABE: But again, I don't know that that's a presentation. That could be a written presentation.

We will have to communicate that in writing. So Sarah and I will work on that, but again, from my perspective, it will have a lower priority than some of the other issues above it and we may not get to it until the next interval. So we have 5.

MS. BERRY: Do you think we need 6 at all?

PARTICIPANT: No.

MS. BERRY: I think we should just take it out.

PARTICIPANT: I thought we were going to just try and get some written background.

MS. BERRY: That would qualify as a priority issue. If we're talking about priority issues and action items for us, I don't --

DR. McCABE: So those are additional items but not priorities. The first five are priorities, but the goal of those is then to determine what actions we can take beyond the products that will be presented next time and advice we can give. The products themselves will not be the ultimate product but it's really our advice that will stem from those. So we will have adequate time to discuss each -- well, really four items because Item Number 1 will be at that time informational only.

Everybody comfortable with this? We've created the agenda for the next time. We de facto made a decision.

Just to let everybody know, the decision that's been made, because it hasn't been discussed, I suggested that we work as a Committee of the whole rather than splitting up into work groups. By creating this agenda for the Committee as a whole, not identifying work groups, you have gone along with my recommendation and I just want to acknowledge that so that if anyone disagrees with that, that you can speak now, but I really felt that that was a lesson we should -- I don't know if I'd call it a mistake, but certainly it didn't work as well in SACGT as when we worked as a Committee of the whole.

DR. REEDE: Just one last comment about that, the issue, in terms of on health disparities initiative. If there's a way to incorporate in that not just racial/ethnic health disparities but it may be geographic. It may be rural, urban, other kinds of things, sort of thinking broadly in terms of health disparities.

DR. McCABE: Debra, did you have something?

DR. LEONARD: Can I understand the process by accepting these five issues? Will there be time at the end of each meeting to figure out which ones may move up to the top and are no longer action items that need our attention and time and adding ones at the bottom?

Because I think the gene patent issue, even though Francis Collins says it's the horse out of the barn and there's nothing that can be done, the impact that this is having on health care and the ability to translate patented genetic information into tests, diagnostic tests, which are the first fruits of the Human Genome Project, has a real impact on access and this translation and integration -- I mean, we can't fit this in now, but I don't want that to fall off the bottom of our list because it impacts access and integration tremendously.

DR. McCABE: Right, and PTO is under Commerce, and Arden, he couldn't be here this afternoon, but he offered that if we wanted to have an update from the PTO. He suggested that we get it from one of the examiners, that by getting it at too high a level, we might miss it. I think there is a value in the high level thing, and I would remind everyone that my recollection is that the patents that were let before the requirement for function, based on sequence and homologies, were to have been revisited in the fall of 2001. Obviously we as a country have been distracted with many other things.

DR. LEONARD: Right.

DR. McCABE: Important issues, but certainly not concerned with gene patents at the same level as many other things. But I agree with you, that this is something that we probably should revisit. We might want to revisit it, though, at several levels and not just at one level or another level.

DR. LEONARD: Well, I think also, having the PTO perspective is one perspective, but they're in the business of approving things and if they raise the utility bar, it doesn't matter because those things that have usefulness are exactly those things that need to be translated into health care most urgently, and I think it's more important to hear it from the health care perspective of genetic counselors having to send tests only to one source or laboratories who can no longer do tests for their patients because of patent issues, and I think more the impact on health care and the translation into health care.

DR. McCABE: Yes, and so the answer to your question is yes, our goal will be to have time to discuss the agenda for the next meeting and as well as what actions we will take on the items presented at that meeting.

Any other items of business to bring before the Committee?

(No response.)

DR. McCABE: I want to commend everybody for really focusing on task and helping us to develop this agenda, and I look forward to the next meeting. We've set out a lot of work for a lot of you here, but thank you for taking this on and we'll look forward to the fruits of your labors at the next meeting.

MS. MASNY: I just wanted to, on behalf of all of my fellow Committee members, just to thank you, Dr. McCabe, for being such a wonderful chair and getting us through this process initially.

DR. McCABE: Thank you. Thank you.

(Applause.)

DR. McCABE: Travel safely. We'll see you at the next meeting.