Committee Discussion and Next Steps
Facilitator: Huntington Willard, Ph.D.

DR. TUCKSON: Let's say if we were to have a discussion of about 45 minutes. Let's say we went to 2:15, and that would give us from 2:15 to 2:45 to do the reimbursement deal, which I'm sure we can get done in a half an hour. Of course we could. So how about we go to 2:10? We'll take this discussion until 2:10.

DR. WILLARD: Thank you.

I'd like to focus this back on the question that I raised 40 minutes ago, which is to try to say are there issues that we don't yet feel we have sufficient information on and/or are there specific gaps that we want to continue to study so that as the business of the committee, we can then advise the Secretary?

The only issue that was raised was the one that Ed raised. I'm trying to catch his eye, or his ear, but I'm not being successful, of having national IRB, or at least a global IRB rather than institutional IRBs. I'm not sure that specific issue is limited to these kinds of large cohort studies. The same kinds of issues are raised all the time for multicenter studies of which there has been hundreds, if not thousands. I might just raise that issue and see if anyone else reacts to it, or whether in fact this is not one.

Michael?

DR. CAROME: I thought it would be helpful to give the perspective of the Office for Human Research Protections on the use of central IRBs for multicenter trials.

First of all, it's important to note that the office's regulations, which were written for the Department more than 20 years ago, have a provision that allows for cooperative or joint review arrangements for multicenter trials. So the authors of those regulations contemplated just these types of circumstances.

I will tell you, though, that when I joined the office about eight years ago, there was a general thought process that thought that local IRB review and IRB geographically located at the institution doing the research was better.

Over the last seven to eight years, the thought processes of the office has evolved, and has come to realize that joint review arrangements of multicenter trials certainly are permissible under the regulations, as I noted, and probably are good in many circumstances, given that many IRBs are now overburdened with workload, and having 100 IRBs or more review the same study when one or a few IRBs could review the same study, relieving that burden is important.

There are lots of models out there. The National Cancer Institute has an IRB for adult oncology trials, Phase III oncology trials. They have recently set up another central IRB for pediatric oncology trials. These IRBs review on behalf of many, many sites. Upwards of 100. Again, that's certainly permissible.

A couple of factors that need to be taken into consideration is A, the need for the IRB when it reviews on behalf of multiple institutions and is going to approve research on their behalf, it needs to understand the local context of where that research is going to be occurring, or it needs

to have some joint arrangement with the local IRB that lets the local IRB address a few limited local issues, but otherwise accepts the review of the central IRB.

The other thing is making sure you find individuals with appropriate expertise to review the research who are not conflicted. That is members of the IRB who are not going to be involved in the design, conduct, and the analysis of the trial. That issue has arisen on occasion with the NCI central IRBs, and we've worked with them to address that.

DR. WILLARD: So is it your sense that nothing you heard this morning would raise different issues that would require a different solution than is already available?

DR. CAROME: There is certainly no need for regulatory or policy changes within the Department. The biggest factor has been institutions accepting a central IRB. For a variety of complex reasons that are sort of cultural, sociologic, and legal liability concerns, even within the use of the central IRB, there are institutions and major medical centers who are not willing to accept an IRB review from another institution or another entity.

Again, even when we say it is permissible, it is allowable, we encourage it for such multicenter trials, they either think our lawyers don't want us doing it because it puts us at risk of some liability, we do better reviews, so we're going to review it, and other things like that.

DR. WILLARD: Ed, are you satisfied?

DR. McCABE: Well, I was going to say, the issue is culture. You already mentioned that. I think if we're going to do the kind of studies that need to be done in the genomic era, we have got to help the local IRBs overcome this culture and assure them that in fact it is getting a better, more informed review by drawing experts nationally than they could ever do locally.

But I can tell you, at UCLA, this would be a major cultural issue for them. They seem to have gotten away from this by developing a cancer IRB. So a separate IRB for cancer seems a little more amenable to these multi-institutional clinical trials. But we might have to help the institutions deal with the cultural barriers. That would involve education. That would be something we could recommend to the Secretary, because it would be a major educational undertaking to deal with this at all the institutions nationally. Especially if you're getting out to community hospitals.

DR. WILLARD: Does anyone else want to weigh in on that discussion?

Suzanne?

DR. FEETHAM: My comment is not related as much to a gap, but just as a reminder. As I listened to the presentations earlier and identification of characteristics and using the Census data, it is just a reminder that another perspective when you're looking at gene environment is the classification of biomedically underserved areas.

Again, with our agency and the focus on the underserved, this would be another way that investigators could identify their populations. Not just urban rural, but by the classification of underserved populations.

DR. McCABE: A different point, and that is I think it was wonderful what we heard today. Like Debra, I'm excited by the possibility. I think we aren't going to be able to use the information from the Human Genome Project without these kind of studies. So it is absolutely critical.

On the other hand, I personally don't feel that I would have at this time all the information I needed at hand to say to the Secretary, you should support this study, that study, or some new kind of study. So I'm not sure how we can move from where we are now with this wonderful introduction that we had to getting to that point, but I would feel that if we were to make a recommendation, we need to move beyond where we are now. Or at least I would feel personally that I needed more information.

DR. WILLARD: Kevin?

DR. FITZGERALD: On that note, a couple of things are of concern to me, and I imagine to other people, too.

Perhaps veiled in the global question I raised earlier was a question that was trying to get at what you wanted. That is, what kind of information do we think we might need in order to go forward from here?

The idea in looking at the AGES or whatever they are going to end up calling the project, when Alan presented, I thought it was very interesting. In one of his slides, he said public consultation should be extensive. They mentioned town meetings and they mentioned focus groups. I know those are two ways that are kind of hot right now for engaging the public.

But we could even make it a more general sort of question and say, if indeed as Teri mentioned, you do the best that you can do, what is that? Who determines what is the best we can do? Do we have that data? Have they looked at those studies? Where is that information? Maybe they have. Maybe that's out there. We don't necessarily have it together yet.

Then could we, looking at that information, at least suggest a process that would have a beginning where again, as was mentioned, the public would have some input into design? So this isn't our excitement being sort of sold to the public so that they will buy in in a sort of way, but to say no, they have to be empowered in this entire process. Then have standards or mile posts along the way to say all the way along, this is going to be a potential for public interaction, review, and evaluation.

I imagine, as we all do, that this information is going to be there, and it is going to grow and expand, and it will be shared among different nations, different groups, and that sort of thing.

So that in the end, we can say that this is something that the public is definitely a part of all the way along. Again, I think we're going to run into questions later on, like what happens when you do find something? Especially in the United States. What does that mean? Is it only going to be available to some? If there is a treatment, is it only for those who can afford it or have the proper coverage?

So all those kinds of things I think need to be in from the beginning. That would be the type of information I think we could gather, at least at the beginning.

DR. WILLARD: Ed?

DR. McCABE: There's a model, not for this specific question, but for this kind of question. How do you engage the public? How much information do you need? How involved can they be? That's designed through focus groups. That's with Kathy Hudson's Center on Reproductive Genetics. The Pew Center, it's a Johns Hopkins Center.

So I know they have been coming out to the west coast to do focus groups. From my discussions with Kathy, at least, they have done a bit of a scientific approach to how much information is enough.

DR. FITZGERALD: Just to build on that, that's right. That group is one. There are a bunch of different groups that are using that. Part of that comes from work by Dan Yanklovich that he put together. So as I said, there is material out there, and studies have been done.

I know that Canadians had an extensive process whereby they had focus groups, task forces, and town meetings to look at some of their health care issues. I think we should at least start to gather that information and see how we might want to build a process out of that sort of thing.

DR. GUTTMACHER: Hunt?

DR. WILLARD: Cindy first.

MS. BERRY: I was wondering, in terms of what we can recommend, if it would be appropriate for us to suggest to the Secretary that when the administration devises public health plans or programs, and I'm thinking obesity was one that Secretary Thompson focused on, and I'm sure cardiovascular disease or women's health issues, whatever it is, when they launch public education, public awareness, and other types of programs, that the Secretary always infuse into those programs at the outset, the genetic component.

So if maybe part of that big effort, whatever it is, would involve some sort of commitment in terms of funding studies like what we were talking about, enhanced funding, more than what is currently being done, so that it recognizes the importance of genetics in all of these issues, keeps the issue out in the forefront for the public, and helps to educate the public appropriately.

So in public education campaigns, when the Secretary goes out across the country and holds the town hall meetings and all these other things, genetics is always there, whether it is just talking about a study, encouraging people to participate in a study, whether it is announcing an infusion of funds, whatever it may be, that our recommendation would be that the Secretary always include, or look to include where appropriate, a genetic component to whatever your new public health activities are. Maybe we can give a few specific examples.

DR. WILLARD: A point of information. The Surgeon General belongs to whom in the government? In HHS? Does he report up through the Secretary?

PARTICIPANT: Yes.

DR. WILLARD: Okay. Alan, you had a question?

DR. GUTTMACHER: And the Surgeon General is actually quite aware of genetics and its role in medicine. He talks about it almost every single speech he gives these days. He is very much into carrying the public health message of genetics.

I just wanted to make the point. I can hear many people in the committee share, well, many of us around the table have an excitement about the importance and the value of these kinds of studies. Also I must admit some excitement with just the intellectual aspects of how one would design such a study.

But I should warn the committee that our experience has been with this working group that it took literally thousands of person hours to get this report that will be up on the Web very soon, to get it that far. I think the committee needs to think about how much does it want to suggest specific study design issues to the Secretary, or how much might it want simply to call to the Secretary's attention the potential value and importance of such studies and what are the design features that need to be considered for such studies to be effective, useful, and what are the questions about participation and community consultation, involvement, et cetera, rather than going too far in designing it.

It is going to be, I think, a challenge for the committee. If you want to move in this direction at all, it would be to figure how far to go with somewhat limited staff time, how far you want to go down the designing path versus just saying these are the features that need to be taken into consideration, these are some ways to look at them kinds of things.

DR. WILLARD: Muin?

DR. KHOURY: Actually, I have a couple of comments for the committee, and also a comment on what Cynthia just said.

It is very obvious at this juncture in time that in order to take the Human Genome Project to the next level, which is to translate it into health benefits for the public's health or the population, that we need to understand genes and health. That as an initiative, I think this committee is very well situated to suggest to the Secretary that you need to do something more than just sequencing the human genome, which as HHS has spearheaded with DOE and others, that we need an initiative that measures the effects of genes on the population or the populations.

That statement I think is a no-brainer, but I don't want to put words in your mouth. Now, to get down from there to the level of one study, two studies, or three studies, you guys can decide how much more specific you want to go from there. I mean, you want to enhance sort of the leadership of HHS and push it a little bit, and also this issue that Cynthia raised earlier about the integration of genomics into everything that smacks of or smells of public health.

You mentioned obesity. I just want to mention here that this is sort of the basic principle by which our little office at CDC has been operating, which is to try to integrate the messages of genomics into whatever it is. We have a group that's working on obesity right now. We are going to be part of it.

We have a STEPS initiative that is department-wide that involves HRSA, NIH, and CDC, which is a chronic disease prevention. Of course, our Surgeon General is very interested in literacy and promoting family history. So there is always an angle by which we can find that trigger, or the point of integration of genomics.

So I think these are the two points that I wanted to make. One is the encouragement for HHS to sort of develop agency-wide, multiple agencies coming together to figure out what the genome means for health, and whether it requires one study or three studies.

I'm not suggesting I agree with that, and I don't think this committee should design one study after all of the hours and many months of work that has been put into the ideal design of that AGES study. But you can make sort of overarching statements about the importance of these kinds of studies and what HHS can do.

DR. WILLARD: Reed?

DR. TUCKSON: I think I'm sort of headed where Muin is. I think the first and critical question is do we as a committee know enough to believe that we should make a recommendation that this is an area that should proceed?

It seems to me then that for me, I'm just trying to write the letter in my mind, the letter to the Secretary that says, Dear Secretary, we believe that we need a large population study for the following reasons to answer the following kinds of questions that would benefit the health of the people.

Part of that phraseology, Muin, is what you said in terms of that now that you have the genome stuff, now you have to apply that. But you need to apply it and understand it in ways that lead to some kinds of describable deliverables, that we think it will improve the health of the American people in the following ways for the following reasons.

We believe that to achieve that, certain things need to occur, like the coordination of resources across the Department to determine the best use of available funding and money, to determine the number of studies and how they ought to interrelate so that this is efficient and it makes sense.

I think that to me is a letter that I think we could start thinking about sending. But the challenge is how do you fill in now the details there?

DR. WILLARD: Ed?

DR. McCABE: The one thing I would change in the opening paragraph of your letter is that I wouldn't specify a study. I was convinced by what I heard this morning that it is probably studies, the question is how many studies, how should they be prioritized, and how should they go.

The other thing that I heard this morning and I'd like to mention that might be in the letter if the committee agrees is that this might be another thing that's a public/private partnership. Especially given the budget where it is today, given the amount of intellectual property that could potentially flow from this. We are certainly already seeing that come out of deCODE Genetics in Iceland.

I really think that this is one where, and I understand the Bayh-Dole rule and all of that, but this is one where I sort of feel that maybe there ought to be an investment up front from the private sector.

DR. TUCKSON: I would just say, Ed, I agree with you. I'll take it as a friendly amendment to my proposal. Instead of saying "a study," I wonder whether we could say "a coordinated activity." Because one of the things obviously in the stage where I'm at with my question was the sense, and I appreciate that Muin, Alan, and everybody, that they all play together nice in the sandbox.

At the end of the day, you don't really get the feeling, quite frankly, even though you all are talking, you don't get the feeling, especially when you have somebody that is authorizing language already, and somebody else doesn't. You've got three multiple activities hitting against the same budget activity.

So I'd just like to sort of see it being explicitly more coordinated, whether it's one, two, or three.

DR. WILLARD: Emily?

DR. WINN-DEEN: So I guess I would go even a couple of steps further and say review all the existing studies, analyze what the gaps are between what is already going on and what we feel should go on, and then direct additional funding towards funding studies or study whatever is appropriate to fill those gaps.

I think you have to have sort of a three-phase approach. The first of which is there is already good work going on, right? We don't need to replicate the good work that's going on. The second is where are the holes? The third is then either specifically endorse a study, or just more generally, which is where I would favor, at this point in time since I don't think we're ready to endorse a study by name at this point, to say that studies to address the gaps should be funded by the U.S. government, and where appropriate with public/private partnership, and just sort of stop at this point.

DR. WILLARD: But let me push you on that point a little bit. When you say "review the studies," what more information would you want? In what depth? I mean, what does the committee need to do to review them in order to have identified those gaps beyond what we heard today?

DR. WINN-DEEN: I'm not sure we need more than what we heard today. But it needs to be pulled together in sort of a coherent single document at least. Here is the state-of-the-art today, rather than a bunch of PowerPoint slides, some of which we got, some of which we didn't get to keep.

So I would like to see something that goes up. Here is the state-of-the-art, here is the gap analysis, and here is the recommendation going forward. The first phase might be just a letter that says this is what we're going to do, one, two, three.

DR. WILLARD: You're answering the question of what the staff was going to do when they finish the reimbursement report, right?

DR. WINN-DEEN: Well, maybe. It's a suggestion. I'm not sure that our group is necessarily the right one to do that evaluation. There might be another more appropriate group within HHS to do that summary and gap analysis. On the other hand, this might be the right group. I'm not sure, because I don't know everything about everything that goes on in HHS.

DR. WILLARD: Muin?

DR. KHOURY: May I be bold enough to push the committee to use the word "initiative" from the Department, instead of a "study?" Because an HHS-wide initiative can sort of achieve the purpose of what you're trying to do here, which is take the Human Genome Project and put it into population hands. That is sort of the spirit of this.

Now, in deference to the NIH, I guess it will all behoove you to wait to see that document that the group has worked on tirelessly for the last few months and see for yourself the amount of work that has gone into it. I suspect it has a background section and everything. It is not only focused on just the age of study, but it has much more than that. I mean, I haven't seen it, but I suspect it has all of that in it.

So I think as a committee, you can review that, and then you can recommend to the Department an initiative that takes that plus other activities that goes on within the other agencies, within NIH, CDC, and develop an HHS-wide initiative that could morph into one study, two studies, or 15 studies. I'm not sure how it is going to evolve. That study would be on the table as one of the considerations for discussion.

DR. WILLARD: Any other points on that question?

DR. TUCKSON: I just wanted to ask if Kevin could come back, then. Kevin, if right now we have as an outline here sort of that we would be thinking of sending a letter to the Secretary about explaining why this was important, that we would applaud the good work going on, the gaps identification, the calling for some analysis that leads to an HHS-wide initiative to address whatever the gaps were, and then the idea of putting public money and perhaps something about private money.

We haven't gotten to your point earlier around what the American people want. Where does that fit into this?

DR. FITZGERALD: Well, I guess it depends on how you want to look at the wording that you're using. So if you're talking about what are the gaps, as was mentioned, we haven't seen yet what the genome website is going to have on there, what the report says. I haven't looked at that data yet.

But again, it would be another example of the way in which the public can be engaged and empowered in this process. That could be seen as one of the gaps that needs to be addressed further. How well can that be done? Is this something that is of such importance and magnitude that it is going to be a significant problem? Or have we pretty much found ways to address this in constructive terms so we can go ahead and figure that we're going to be handling these issues as they go along, because it will be part of the process.

I would just see that as one of the gaps for sure that would need to be filled in.

DR. WILLARD: I might raise, and I'm not sure I believe in this, but I'll say it anyway just to get it out here for discussion. That is I have been very impressed in the U.K. by a process or a group, I think it is the Human Genetics Commission or something of that sort, which was representative of the public at large, which in fact examined a whole host of issues that led up to the formation of the Biobank.

They traveled around the island, met with various groups of people, and collected that information. It was a separate group. It wasn't led by the MRC or the equivalent of any of the bodies that we have represented here, because it was really the public doing its work and registering its own opinions.

So my question of the United States is not the United Kingdom, but the question is is there a need for that kind of an arrangement before we would anticipate an HHS-led study of half a million to

a million Americans who are going to have their bodily fluids sampled and stored for all time, and eventually perhaps leading up to having their genomes sequenced when we can do it for reasonable dollars.

I mean, we are in a country right now where the Bank of America can't even protect records from members of the United States Senate. I'm not sure the public at large is prepared to assume absent an opportunity to weigh in on the issue, just assume that folks will get this right, and that people's medical information and genome information, potentially very sensitive information about medical conditions that they may or may not be susceptible to, that that somehow will be okay and will sit in a computer somewhere.

So I think there may be a lot to be gained by allowing the public in a very broad and far reaching manner to weigh in on this issue. This is the right time to do it. We did a reference sequence which wasn't specific to anyone. But before we kick off a much more extensive study that might involve a million Americans of many different ethnic groups which will have to be represented in one way, shape, or form, to allow all the representatives of those groups in fact to weigh in in a clear and deliberative manner. I'll throw that out to the group.

DR. TUCKSON: Did you convince yourself, by the way, while you were talking?

(Laughter.)

DR. WILLARD: I was just getting up to steam.

DR. LEONARD: I agree. In listening to the talks, I remember hearing the word "trust." You have to have trust of the participants. My immediate thing that popped into my head is can we create trust in the U.S., either of scientists, the government, or with the current environment the way it is. I don't know that that's feasible.

Maybe by doing this type of project, it would at least be a step toward building trust, which at this point, I think we're going to fall flat on our face.

DR. GUTTMACHER: Where are the data to support that? I'm just curious. Because, I mean, there are certainly other large studies out there that are collecting genetic information in a thoughtful way that we have not had in the U.S. Not to say that it's not a challenge, but I'm not sure that we're entering quite so dire of a situation.

DR. FITZGERALD: Well, I mean, just to address that a little bit. I think there is some data out there, and it may not be as extensive or as deep as we would like it to be. There are some issues where this has been addressed in a kind of different vein.

One has been say genetically engineered crops. Part of the idea that was wrestled with there was everybody is thinking, this is all great, it's wonderful, it's going to benefit the public. Well, does the public think it's going to benefit the public? Then you say, well, they don't. Well, then that's a matter of education. Once they know what we know, of course they'll agree with us.

Well, that may or may not be the case. That gets back to these other sort of town hall meetings, focus groups, and that kind of thing. The whole point of that process is to begin this dialogue. What I would argue, too, is that this is not just for this particular issue.

I understand, and I think pretty much if we took a poll of the people around the table, we'd all be convinced of the usefulness and the benefit of this extending what has gone on in the Human Genome Project. But I think Debra is right. We have to, as part of this thing, also recommend that the government build trust. This is just another stepping stone, and there will be something after this, and there will be something after that.

We have to look to the future to say what kind of precedent do we want to set now so we don't have to come back and revisit each and every one of these issues again and reinvent the wheel.

DR. TUCKSON: We've got five minutes to resolve this.

DR. WILLARD: I've got Robinsue first, and then Muin.

DR. FROHBOESE: Thanks. As the representative from the Office for Civil Rights and the office within the Department responsible for the HIPAA privacy rule, I just wanted to remind people of the rule, and the fact that we are working with the public in general to really raise the consciousness level of consumers and their rights to privacy of their health information.

But we also have been actively working both with CDC and NIH, and have issued guidance with both NIH and CDC on research, both from the public health perspective, and more general research issues. Research specifically as it relates to the privacy rule and protecting privacy interests.

DR. WILLARD: Muin?

DR. KHOURY: As a follow-up on your comment earlier, Hunt, about the British way of how they went about it with the Generics Commission. I wish John Newton was here to explain more. But if there is such a group in the U.S., I maintain to you that this committee comes as close to that, I mean, the name Genetics Health and Society implies that. You are advising HHS.

If you want to undertake sort of the martialing of the post-genomics or the genomics era and how to translate the genome into health benefits to help society. I mean, your group, if you decide you want to undertake such a process to help the Department undertake such an initiative, would be the right thing. That's up to you.

DR. TUCKSON: We need specific recommendations as to how to proceed. You've got four minutes.

DR. WILLARD: I can't read your name, so I'll call on you.

DR. FOX: I'm Ellen Fox.

DR. WILLARD: You're not Willie May, even though you're past the sign.

DR. FOX: Reed, in your suggestion regarding the wording of the letter, you mentioned looking at gaps, and then looking at where there were gaps, assuming the government would fill them. Perhaps in association with public/private partnerships.

I think there needs to be a little more attention, and there hasn't been much discussion today, but somehow I think we need to address the issue of the appropriate role of the government relative to the private sector.

I wouldn't want there to be an assumption that the government should just fill all the gaps that exist in this endeavor, particularly when there is an opportunity for private industry.

Also when we were talking about public/private partnerships, I think we need to be very careful about that. I think that in the U.K., my understanding is there were some concerns among the public about the commercialization aspects. That was a particularly sensitive issue.

In our own experience in VA, this was I think the single most controversial aspect which caused us to actually completely reverse our course and pull back from our original thinking on the issue, because of significant concerns raised about the relationship between public and private sectors.

So I for one would like to see some language in this letter that acknowledges that tension.

DR. WILLARD: I have Joe first, then Alan, then Kevin until we get cut off by the Chairman.

DR. TELFAIR: I'll pass on my comment. I'll wait. That's okay. I'll pass on my comment.

DR. GUTTMACHER: And I'll try to speak very quickly. I think, again, I agree with Muin's point that this group is as close as we have to the U.K. Commission.

It seems to me that it gets back to this question of how far you want to go down the road of designing the study. What would make most sense to me would be simply strong wording the letter to the Secretary that it is just completely vital to the success of any such study that community participation be often, early, frequent, ongoing, and giving ideas of the kinds of ways that might be achieved, rather than going out and doing that first.

We know that it is necessary, so just make it very clear that that really needs to be done, it needs to be meaningful, and it needs to use the latest state-of-the-art kinds of things to do it, and maybe invent some new ones.

DR. TUCKSON: I think we've got a good sense of a charge to our committee. We have a good committee that put together one heck of a discussion today. Clearly they are focused and know what they're doing.

I think the overall committee has given pretty good specificity as to first of all, there is a consensus that I hear that's very strong that we do want to communicate with the Secretary about this. I see a very strong consensus that we think that this is an important area that needs to go forward.

I think that we have agreed at least to charge our subcommittee with the task of fleshing out the first draft of a letter that would say why we think this is important in terms of the health of the people. Why it is important, as Muin's language was, that says that having done the human genome, putting it into play is for the benefit of the health of the people. This is an important thing to do. So I think that's important.

Secondly, we do want in this letter to praise the good work that is already going on. Third, we're calling for some type of a gaps identification. We are then calling for a coordinated effort which we are using the suggested word "initiative" as opposed to a study that would address the gaps.

We are clearly saying that one of those gaps is looking at what is important to the American people, and seeing what we need to say there. We are saying that we would be calling for public

money, but also perhaps, and this is something for you to look at in a little more detail, private dollars.

We just heard a comment around maybe even putting in something that has to do with the appropriate relationship between the public and private sector on initiatives such as this.

Then finally, what we didn't resolve, but I think we have given a mandate for you to look at is this notion then of the question of establishing trust, which I think is related to the gaps around what American people want, and how that might be phrased.

I don't think we were as prescriptive as the rest of the letter, but we leave it to you to take the sense of it.

Kevin, I'm not sure whether you're on that committee. You are on it?

DR. FITZGERALD: I'm not on it.

DR. TUCKSON: But I would urge you to connect to the committee and get your points in.

With that, I think we have the expectation, Hunt, that as the Chairman of that subcommittee, that we will get a report back from you with a draft before the next meeting. Our commendations for an excellent set of presentations today.