

Final Draft Recommendations and Draft Report

DR. TEUTSCH: All right. Folks, we finally have a quorum and we're going to begin. Let me give you the agenda for the afternoon. We are going to go through the Patents Report recommendations and make sure we're happy with those. We are going to get any other last comments.

We have a few things we should talk about about the drafting of the final report, and then we have a few other miscellaneous items, largely from the conversation I had with Francis Collins. So maybe get a couple of ideas at the very end of the meeting. I hope to get us out of here at 2:30 or so, because some of us, I know, are going to leave, including me. So we will try to move that part along. We need to give the patents part fair hearing.

I'm going to repeat this when we have more people here, but a couple things about the report. It is obvious to everybody that there were very strongly held opinions about some of the materials that were in here in our final recommendations. That, I think, makes it incumbent upon us to do two things: make sure that the issues that are raised by those who have perspectives different than the final recommendations would suggest, we need to have those

comments in here.

I'm going to say it now, and I'll say it again. We need comments from those people in writing. We've tried to get them in the past and have not received them. We need them in writing so they can be incorporated into our final draft.

Then the other thing, because clearly some of these recommendations will not be universally welcomed, we need to make sure that we have laid out the rationale for these recommendations and why these were made rather than any other alternatives, because we need to not only be receptive to all of those differences of opinion but be clear how we reached the conclusions that we did. So I know we've got a challenging agenda.

Jim, you're on.

DR. EVANS: All right, great. I was really pleased with the deliberations yesterday, in spite of the controversy. I think that we made tremendous progress in both content and stylistic features of the recommendations.

What we're going to do here is we're going to march through them. Ones that were voted and approved, we don't need to discuss anymore, but we have a few little

wordsmithing things that do need to be discussed.

Essentially what you're seeing now represents the distillation of the comments made yesterday that changes the wordsmithing that we did on the fly and now incorporated into a final form.

There were no changes to Recommendation 1, so we don't need to go over that again.

Recommendation 2. The issue came up, this is the research exemption, do we need the last sentence. The creation of an exemption from patent infringement liability for those who use patent-protected genes in the pursuit of research, period. It could stop there.

What we had yesterday was related healthcare and research entities also should be covered by this exemption.

I actually don't think that last sentence is needed, but do people agree, disagree, have alternate suggestions?

Rochelle.

MS. DREYFUSS: The reason there's something similar to that in Ganski-Frist is because it's possible to sue the hospital for aiding and abetting essentially the infringement and so that's why those things are there.

DR. EVANS: Do you think from a legal standpoint it's safest to leave it then because you would not want that to occur. We obviously don't want to just --

MS. DREYFUSS: This reads a little different from Ganski-Frist because there, it's an insulation from the remedy rather than an exemption from liability. So it would be harder to make a contributory infringement case here. So maybe we could take it out and just put something in the --

DR. EVANS: That's a great idea. That's a great idea. All right.

So what I'm going to do here, going, going, gone, is we will now fold that into the rationale. That's a great idea.

All right. We will include this statement -- oh, I'm sorry. And this is just the rationale that we had taken out before that deals with association patents. So remember originally Recommendation 3 was this and we decided that there isn't a lot the Secretary really has to do with it. It's more we want to be on the record. So what we're going to do is we're going to fold this into the discussion and the text. People okay with that? All

right.

Now between those recommendations and the remaining recommendations, we feel some explanation is required and we have the following. Although the committee believes the changes described in Recommendation 1 offer the most effective means -- and that should be 1 and 2, shouldn't it? Yes. Oh, I see. Gotcha. Those are Sub 1. All right.

Offer the most effective means of addressing the identified problems and promoting ongoing access by patients to the fruits of emerging genetic advances, the steps outlined in the following recommendations should be undertaken in the interim to help address identified problems.

In other words, if those two were immediately enacted, okay, you wouldn't need most of these, but we all know that's not going to happen. All right.

Is that Mara? Okay.

Next one. "Promoting adherence to norms designed to ensure access." I would have to say that it's really been nice to get a lot of this folded into the text. It makes the recommendations much simpler and pithier.

All right. "Using relevant authorities and resources as necessary, the Secretary should explore, identify, and implement mechanisms that will promote more than mere voluntary adherence to current guidelines that promote non-exclusivity in licensing of diagnostic genetic/genomic technologies.

"The Secretary should convene stakeholders, for example, industry, academic institutions, researchers, patients, to develop a code of conduct that will further encourage broad access to such technologies.

We took out a variety of things, and now we'll fold it into the rationale. Oh, yes. Let me blow this up. Sorry. Okay.

"The Committee supports guidelines that encourage broad licensing and broad access to diagnostic genetic tests," and I think we should have "genetic/genomic." I don't want there to be confusion about, well, you just said "genetic" because nobody really quite knows the difference.

DR. WILLIAMS: I would just say, from a clarity perspective, you articulate in the report that you're using the same definition.

DR. EVANS: We don't need to do that.

DR. WILLIAMS: Use it, and just say this is how we're defining it.

DR. EVANS: All right. That sounds good. We'll go through and make sure that's consistent. I think that's a good point.

MS. DREYFUSS: Can you go back to the recommendation itself?

DR. EVANS: Yes.

MS. DREYFUSS: You have industry, academic institution, researchers. The problem with academic institutions is you get technology transfer offices and although it says researchers, researchers could be industry researchers or academic researchers. If we have TTOs, I would like to see some academic researchers.

So I don't know whether you could explain that in the notes or put it in there to make sure that TTOs don't come in and say they represent academic institutions.

DR. EVANS: Perhaps the easiest way to do that is make a note of that in the explanatory stuff. By academic institutions, we mean this in a broad sense, including researchers as well as technology transfer. Okay.

The Committee -- so that asterisk refers to,

obviously, the Nine Points, OECD Guidelines, et cetera, and we didn't feel like we needed to clutter up the entire thing with reiterating those.

NIH's Best Practices and OECD Guidelines encourage limited use of exclusive licensing for genetic/genomic inventions. Points 2 and 9 of the Nine Points to Consider included in their explanatory text are also relevant for genetic tests.

In particular, the explanatory text under Point 2 recognizes that "licenses should not hinder clinical research, professional education and training used by public health authorities, independent validation of test results for quality verification."

MS. DREYFUSS: I really don't like "encourage limited use." It sounds like you're encouraging exclusive licenses.

DR. EVANS: Oh, wait. Where?

MS. DREYFUSS: I would rather see it say "discourage use of exclusive licensing."

DR. EVANS: Okay. Let's see now, where are we?

DR. WILLIAMS: It's encouraging limited use.

MS. DREYFUSS: I understand what it says, but you

see the word "encourage" next to exclusive license.

DR. EVANS: Oh, I think it's basically --

MS. DREYFUSS: I think it's a very hard phrase to parse.

DR. EVANS: What if we say "discourage exclusive licensing"?

DR. WILLIAMS: That's what we had previously, and then we had with the exception that there may be rationale under --

DR. EVANS: That's in here.

DR. WILLIAMS: Okay.

DR. EVANS: You'll see that.

DR. WILLIAMS: That may be clearer.

DR. EVANS: That's very important, that when warranted, exclusive licensing, yes. All right, good.

To be added to the rationale:

"In identifying mechanisms that will promote adherence to the guidelines, the Department may need to initially determine the scope of its authorities. For example, because it is unclear whether the Bayh-Dole Act gives agencies authority to influence how grantees license patented inventions, the Department

should seek clarification about this legal question."

Then two possibilities. If it is determined that the Secretary has the authority, one way the Secretary could promote adherence to the above guidelines would be to direct NIH to make compliance with the above guidelines an important consideration in future grant awards.

Alternatively, the Secretary could promulgate regulations that enable the department's agencies to limit the ability of grantees to exclusively license inventions resulting from government funding when they are licensed for the genetic diagnostic field of use. Exceptions could be considered if a grantee can show that an exclusive license is more appropriate in a particular case, for example, because of the high cost of developing the test.

All right, "enhancing transparency." Yes.

DR. WILLIAMS: Related to this, in the public comment this morning and in a couple of the others, I think there was a specific position expressed that in fact Bayh-Dole is being applied appropriately in this area.

So I would ask that, as part of our revision of the report, to reflect that we specifically articulate that and then we would then -- obviously, it would be incumbent

on us to defend why we think that it doesn't quite --

MS. DREYFUSS: I disagree that that's what was said this morning. What was said this morning is that universities are in fact doing what we would like. They didn't say that Bayh-Dole was being applied to do this. They were saying that universities were voluntarily doing this, and I'm sure there were some that are and we should certainly acknowledge the fact that many do, but I don't think they were saying that this is the current interpretation of Bayh-Dole because NIH doesn't think it's the current interpretation of Bayh-Dole.

DR. WILLIAMS: Well, what I heard clearly from the speaker this morning was we should leave Bayh-Dole out of this and I agree with the statement, I think, that we do need clarification. I think we make a good case for it.

I'm just saying that I'm sensitive to the idea that this report was criticized because we did not adequately reflect other interpretations, positions, and I don't see, since this does not affect the recommendations or the rationale, how it harms us by reflecting the comments that we're receiving as part of this process.

MS. DREYFUSS: The comment was that universities

are voluntarily doing that and I think we should reflect that. I think a lot of universities are, but I don't think this is an interpretation that anybody has made of Bayh-Dole and that's why we need clarification.

DR. EVANS: And I think Rochelle's point is a very good one, that the contention the universities are doing this is demonstrably wrong, that's just incorrect, and I think that we need to point that out. I'm all for being balanced, but we also need to reflect reality.

All right. Enhancing transparency. Using relevant authorities and resources as necessary, the Secretary should explore, identify, and implement mechanisms that will make particular information about patent licenses readily available to the public.

The specific licensing terms that should be made available are those that pertain to the type of license, the field of use, and the scope of technologies, and then in the rationale, as a means to enhance public access to information about the licensing of patents related to gene-based diagnostics, the Secretary could also direct NIH to amend its Best Practices for the Licensing of Genomic Inventions to encourage licensors and licensees to include

in their license contracts a provision that allows each party to disclose information about its licenses, particularly such factors as types of license, field of use, and scope, in order to encourage next generation innovation.

Do we want to say anything in there about the possibility that the Secretary could also use more than just mere encouragement ala the discussion in the previous recommendations about authority and granting, et cetera, or do we want to leave it as is?

Rochelle.

MS. DREYFUSS: I think if the previous one said that they should have the authority to enforce best practices, if this is part of best practices, it goes along with that.

DR. EVANS: Right.

MS. DREYFUSS: A question I would ask is whether we want to put in that allows each party to disclose non-financial information.

DR. EVANS: Well, I think that might go a long way towards placating those who can be placated. In other words, I think that that could be a red flag that we don't

need to bring up.

Gwen.

MS. DARIEN: I think if we leave it at encourage, it will end up being just like the clinical trials registry that NCI has, which is so incomplete and not enforceable.

DR. EVANS: I agree. So taking both of those things into account, if we disclose non-financial information, that would avoid a lot of problems with proprietary information, and then we also will use in the discussion, we will use the same wording about authority in this as in that, the previous recommendation. Does that make sense?

DR. DALE: In Line 3, --

DR. EVANS: Line 3 of which one?

DR. DALE: To be added to rationale text.

DR. EVANS: Gotcha. Okay.

DR. DALE: Is the word "should" or "could?" If it's put encourage, it's pretty soft.

DR. EVANS: I know.

DR. DALE: I would say should encourage would be more in the spirit of what we're doing.

DR. EVANS: I would agree with that. Do other

people agree? Okay. All right. Okay.

Then, Darren, you'll get the language in parallel. Okay.

All right. 4. Advisory board to assess impact of gene patenting and licensing practices. The Secretary should establish an advisory body to provide ongoing advice about the public health impact of gene patenting and licensing practices.

The advisory body could also provide input on the implementation of any future policy changes, including the other proposed recommendations in this report.

My only problem, as I read it now, with this is public health has perhaps almost a more narrow meaning than we really want here. We aren't really talking here about just public health. We're talking about patient access, the whole bit. Health impact. Yes, yes. Not trying to dis public health, Mr. Chairman.

Okay. All right. To be added to that rationale. This advisory body would be available to receive information about problems in patient access to genetic tests from the public and medical community and could review new data collected on patient access and assess the

extent to which access problems are occurring.

One of the advisory board's missions would also be to recommend what additional information should be systematically collected through iEdison so that iEdison can be used to determine whether grantees are complying with the guidelines mentioned in Recommendation 2, and the only thing I wonder, you know, this is a presumption in a way of access problems.

We could say data collected on patient access and assess whether and the extent to or assess whether access problems are occurring to make it a little less pejorative. Whether access problems are occurring and to what extent, if that's even needed, I don't know.

MS. DREYFUSS: Monitor access problems.

DR. EVANS: There you go. And monitor access problems. To monitor access problems and if any are occurring --

MS. DREYFUSS: To monitor access and --

DR. EVANS: Oh, to monitor access, yes, collected on patient access. Okay. Let me start over.

This advisory body would be available to receive information about problems in patient access to genetic

tests from the public and medical community and could review new data collected on patient access and monitor access. That seems awfully awkward. And identify whether problems are occurring and to what extent.

DR. McGRATH: So maybe to address the issue of pejorative language, in the first sentence take out the word "problem." The advisory board available to receive information about patient access.

DR. EVANS: About patient access. That's good. From the public and medical community and could review new data collected on patient access and identify whether problems are occurring, and maybe we could make that two sentences, public and medical community, the body.

Okay. All right. One of the advisory board's missions -- oh, we already went through that. Everybody okay with this?

To be added to the rationale, the advisory -- oh, we went through that. Okay.

All right. The advisory body should consist of federal employees and outside experts from a broad array of areas. For example, the body could be made up of clinical geneticists, patent law experts, representatives from the

diagnostic kit industry, commercial laboratory directors, technology transfer professionals, laboratorians, and federal employees from the USPTO and NIH.

The advisory body could also explore whether approaches to addressing patent thickets, including patent pools, clearinghouses, and cross licensing agreements, could facilitate the development of multiplex tests or whole genome sequencing.

One option to avoid the creation of another committee would be to create a standing subcommittee of SACGHS to serve as this body. SACGHS already has much of the necessary expertise and by its charter focuses on highly relevant issues.

MS. DARIEN: Can you add in consumer to the list?

DR. EVANS: Yes.

MS. DREYFUSS: Also researchers?

DR. EVANS: Yes. Okay. Clinical geneticist.

Let's put --

DR. TEUTSCH: Jim, I think we have some concerns about expanding the mission of this committee. We do not have standing subcommittees at the moment. We could, but we don't at the moment. It is an option. I don't know why

we want to necessarily suggest that we want to expand our mission that way.

DR. EVANS: I guess the reason it came out was not in a self-serving sense, right. It was more because we had some reticence to say you need to create a new body and we wanted to say to the Secretary, hey, we already do this kind of thing. If you want us to do it, we will. Now, again, I'm agnostic about it.

DR. TEUTSCH: Or you can leave it more general. You could establish this function within an existing committee.

DR. EVANS: We could. Okay. Yes. So you're saying get rid of that, right, and instead say such an advisory body could be established within a relevant existing committee. Great. Okay. And then we need consumers up here who should be fairly -- let's put researchers, consumers. Say what?

MS. DREYFUSS: Research geneticists.

DR. EVANS: We've got, let's see, clinical geneticists here and researchers. So I think that would cover it. Yes, and the advisory body should have a variety of federal employees. Could we just say the advisory body

should consist of a variety of experts from a broad array?

I mean, I'm okay with it as this.

DR. WILLIAMS: You're never going to get -- I mean, the solution to these never-ending lists that could be drawn from but not limited to or something like that.

The only other point I would make, though, on this and this is another structural thing is that the last sentence of this particular paragraph is a non-sequitur because it's not talking about the composition. It's talking about work of the committee which actually should go back to the previous slide.

DR. EVANS: So now you're talking about this last --

DR. WILLIAMS: The advisory board could also explore whether approaches to addressing. That's a task. That's not a composition.

DR. EVANS: Okay.

DR. WILLIAMS: And so I'm saying move that to the -- doesn't the previous slide talk about things that the committee should be addressing?

DR. EVANS: It does.

DR. WILLIAMS: That's where I think it should go.

DR. EVANS: Very nice, Marc. Very nice. All right. I like it. We'll have to clean up the formatting. Okay. All right. Nice. All right.

All right. Two more. Providing needed expertise to USPTO. The Secretary, working with the Secretary of Commerce, should designate a liaison between this committee and the USPTO. This liaison, along with technical advisors the SACGHS could recommend, would provide input to the USPTO about scientific and technological developments related to genetic testing and technologies. This input would help inform the USPTO's examination of patent applications in the realm of human genes.

Marc.

DR. WILLIAMS: So which this committee are we referring to? SACGHS or this committee that we're proposing in the previous recommendation?

DR. EVANS: Okay. So we're talking about a liaison. This is --

DR. WILLIAMS: Liaison between -- we've referring to this committee.

DR. EVANS: Provide input to the USPTO, and where are you saying?

DR. WILLIAMS: So I'm saying in the first sentence, designate a liaison between this committee.

DR. EVANS: Oh, okay. We're talking about --

DR. WILLIAMS: Is that SACGHS or is that another committee? So we need to say the other committee.

DR. EVANS: Wait a minute. This committee is SACGHS.

DR. WILLIAMS: Then we should just say that.

DR. EVANS: You're right. There we go. Now, the reason we have -- oh, I'm sorry. Rochelle.

MS. DREYFUSS: I don't know that this committee, SACGHS, is always going to have the information that the PTO is going to need. I would like for it to be able to advise the PTO on who relevant experts are for new issues that arise.

DR. EVANS: We have that here, right, along with technical advisors that SACGHS could recommend?

DR. BILLINGS: Do advisory committees to the Secretary play this role in other aspects of the world, recommending experts, blah-blah-blah? Is that something that is novel that we're asking for, something that's kind of commonplace?

DR. EVANS: Is it novel? Sarah would know.

MS. CARR: I think it is a little bit. I'm not aware of another committee that does that, and I was initially a little concerned about this in that it's having a member, an SGE, in discussions with PTO, I think, not in a public way, but we conferred with PTO this morning, John LaGaider, and I don't think he was interested in -- he was neutral on the matter of whether a PTO would want to actually establish a FACA committee.

So I think we -- I don't think they're necessarily interested in such a formal body, but I think there would be some issues to work out with us.

DR. BILLINGS: That's my guess.

DR. EVANS: The question is because of the questions that arise about this, is it feasible, et cetera? Are there modifications that might help it? If not, it would be one that we would put out there and if it can be worked out, fine. If not. All right.

And then to be added to the rationale, the committee believes experts in the field could help USPTO in its development of guidelines on determinations of non-obviousness and subject matter eligibility in this field,

once pending court decisions, such as Bilski v. Kappos, are decided.

Would we want to say in its development of guidelines on determinations of such matters as non-obviousness so not to confine it?

MS. DREYFUSS: I would also get rid of once pending decisions are decided because in six months, this will already be dated.

DR. EVANS: Yes. There you go. Pending court decisions.

MS. DREYFUSS: No. Just the patent matter eligibility, period.

DR. EVANS: Okay.

MS. DREYFUSS: There will always be pending court decisions.

DR. EVANS: Well, yes.

DR. WILLIAMS: Period after field.

DR. EVANS: Okay. All right. Okay.

DR. TEUTSCH: Can we go back? I still have some trouble with the previous one.

DR. EVANS: This one?

DR. TEUTSCH: About the liaison with PTO. I

think we want to -- this is really about them getting technical expertise. We don't really have to deal with the mechanism --

DR. EVANS: That's true.

DR. TEUTSCH: -- by which they do that.

DR. EVANS: That's true.

DR. TEUTSCH: And I think if we -- I mean, I haven't wordsmithed this, but I think the Secretary should work with the Secretary to assure that PTO has the necessary scientific expertise available to blah-blah-blah, and they can figure out the mechanism, whether it's across an agency --

DR. EVANS: Okay.

DR. TEUTSCH: -- or whomever.

DR. EVANS: So this would be something, like we can erase what is above. We could say something like, "The Secretary should work with the Secretary of Commerce in order to ensure that the USPTO is kept apprised."

Is kept apprised of technical and legal developments? Okay. "Technical and scientific developments related to genetic testing and technology."

How does that look now?

"In order to ensure that the USPTO is kept apprised of technical and scientific," okay.

So that gets away from the whole, can a liaison even work, et cetera. Now, does this still make sense?

The Committee believes experts in the field could help -- so in there, do you want to leave it like this, or do you want to say in the rationale that one such mechanism, if permitted -- Rochelle is shaking her head. Just leave it like this. Great. An honest woman, I love it.

DR. WILLIAMS: The secret of a true leader is getting others to do their dirty work for them.

DR. EVANS: Such leadership, right? When I shake my head, other people nod, and vice versa.

DR. WILLIAMS: It's the rattling that distracts us.

DR. EVANS: That's right. I didn't hear anything. I see. That's right.

"Ensuring equal access to clinically useful genetic tests. Given that genetic tests will be increasingly incorporated into medical care, the Secretary should ensure that those tests shown to have clinical

utility are uniformly covered by governmental and non-governmental payers."

Then to get to Paul's comment in the rationale, "Such uniformity in coverage would ensure that all insured patients, regardless of geographic location or economic status, obtain access. Our advocacy for such equal access is merely one component of this committee's longstanding concern about ensuring equity in the provision of genetically related tests and services." That should be plural.

Earlier reports and recommendations have called attention to the importance of equitable access to genetic testing.

So does that, Paul, address what you had brought up?

DR. WISE: It does, although looking over the report, we were really focusing on the recommendations yesterday. It's whether that belongs in the beginning. So I'm a little bit more substantially away, because the document does not say why you are compelled to spend five years of your life doing this study.

In other words, it jumps right into scope and

definitions, but it doesn't say, at all, why this came to our attention and why it's so important, that this rose to the surface and demanded amelioration.

DR. BILLINGS: I want to completely support that sentiment by Paul, not only because he has a great name but because it's a great thought.

DR. WISE: I'll take great name.

DR. BILLINGS: This goes to what Steve said at the beginning of this discussion, which is that the document currently does not make the argument for this particular remedy, the primary remedy that we've proposed, and why it's important at all, or at least not adequately from my point of view. What Paul is suggesting is in part changing the document to do that.

DR. EVANS: So, Paul, are you talking about this type of thing at the start of the report? You're really talking about something quite different?

DR. WISE: It's the same point that I'm trying to make, but just it's really a question of format. I think it's fine to keep this in here as a reminder. Sam mentioned this as part of the recommendation, just to make sure that this is a good place to remind.

DR. EVANS: Again.

DR. WISE: It could be smaller, and you may not want to go into all the prior things, but put something up, because when you look at the introduction, it's very hard to see what the goal of this whole exercise was.

It also doesn't make any case. It looks almost gratuitous, and I think you're basically putting up your dukes a little bit when you do that, because it puts a huge burden on the specifics of your recommendations by not having the initial frame being, look, there is a potential problem here; this field is exploding.

DR. EVANS: There is controversy, right.

DR. WISE: Right. And as a committee, we have long been concerned about the rapid evidence-based implementation of equitable provision of genetic and genomic capabilities, and then reference the prior reports and say it's time that we looked at this. It's a complicated issue. We know it's controversial, but we have been forced into doing our best to address this in a fair and open way.

DR. EVANS: That's good. We can couch it in terms, for example, as we do, but I don't think we do it

upfront in this obvious way that you're advocating, that other bodies have looked at this but have not focused on the patient access problem, and try to get that front and center at the very start.

DR. WISE: I mean, the second paragraph, page 3, in the middle, it's buried. The lead has been buried, and it may be to elevate the goal of this study, or this exercise was boom-boom-boom. And then why, the justification for why this came to this committee at this time.

One paragraph, and then do some referencing to prior things, but it's a very different framing than just saying we sort of have an axe to grind here and we're going after this issue, regardless of whether anybody thought there was a real problem. It puts the burden on the critics somewhat differently.

DR. EVANS: That makes sense, that's good advice. All right, we'll work on that. Good.

Rochelle.

MS. DREYFUSS: I've always thought that, too, actually, that the beginning just doesn't say what this is about, and I think we should also add "reduction of

healthcare costs," because it's not just about equal access, it's also about the problems of patent thickets, multiplex testing.

DR. EVANS: Which, all in the end relate back to our basic charge.

MS. DREYFUSS: So I do think that needs to be in paragraph 1 or 2.

DR. EVANS: Good, good. All right.

DR. WILLIAMS: I was just reflecting on this and it shouldn't be in the recommendation, because I don't think it's something that the Secretary can specifically take ownership of. The one piece, as I re-read that first paragraph over and over again, the idea about "ensure patients," I think it doesn't reflect the idea of the disparity issues that one of our commenters today mentioned, that there are issues beyond insurance that impact access.

It's not to say that we should go overboard, but I would like to see something in the rationale that does reflect the fact that we're not trying to solve the healthcare system.

DR. EVANS: Yes. I think that's important, and I

think that we can say, and hear, that we recognize that problems in access have many drivers.

DR. TEUTSCH: Jim, what we're missing here is what Mara said yesterday, which was that we need a process whereby those who do not have coverage have access, and the Secretary should be taking steps to identify and remove obstacles.

A simple process can be used between patients, providers, and the industry, that can facilitate, because that is part of this access issue.

DR. WILLIAMS: That's true. So that should be added to the recommendation.

DR. EVANS: That's good.

DR. WILLIAMS: Previous slide, because I had forgotten that. So that should be in the recommendation.

DR. EVANS: "To ensure that those tests shall have clinical utility and that processes be explored which would facilitate" --

DR. TEUTSCH: "Remove barriers to securing access to those who do not have insurance coverage or access, or are unable to afford it."

DR. EVANS: "The mechanisms."

DR. TEUTSCH: "Unable to afford them."

DR. EVANS: "Explored to enable those who cannot afford" -- wait a minute. "Those who do not have adequate coverage." In a way, what we're really saying here is we need to reform the healthcare system. I mean, isn't this a little out of sight of our --

DR. BILLINGS: Isn't the point here, then, that we need to say what we think we can affect and what we can't?

DR. EVANS: Yes. I'm not --

DR. BILLINGS: Can I just finish? Then shouldn't we also, then, suggest that we have some way of measuring the impact of our remedy, including potential adverse outcomes from our remedy?

DR. EVANS: Yes. Again, so take it as one at a time, I really worry about having something like this in here. It's like, okay, thanks, we're supposed to reform the healthcare system. I mean, yes, that's true, but this is a little outside of the scope of patents.

DR. TEUTSCH: No. She was talking about specific barriers to access.

DR. EVANS: What Mara has talked about a lot are

enabling the programs that companies have, be they diagnostic or therapeutic to cover, provide free testing. We've had a lot of conversations about this. I'm far more skeptical than she is that this is even a viable way of really having an impact on much in the way of testing.

So I don't want to really, at the 11th hour, add a recommendation that the whole Committee hasn't really thought out and discussed.

DR. WILLIAMS: Well, that is what we are doing, isn't it? The point I would make here is that I think the criticism, inasmuch as we criticized the commenter yesterday, relating to the Warfarin story, about the fact that they were attributing lack of pharmacogenetic testing for Warfarin is attributable to the fact that there was not exclusive licensing.

By the same token, I think the point that was being reflected was that there may be solutions, other than alterations to patent law, that could affect this. So I think it is germane to put this in here at this point.

DR. TEUTSCH: Jim, here is my suggestion, that you reframe this so that it's about getting access to tests, period, and then you can talk about uniform

insurance policy, removing barriers as part of the text.

DR. EVANS: Isn't that what this says?

DR. TEUTSCH: No.

MS. DARIEN: No, it says for people that are covered; it's not for people who are under-covered.

DR. WILLIAMS: "Uniformly covered by governmental and non-governmental payers."

DR. EVANS: All right.

DR. WILLIAMS: So in some ways, it is. I mean, I think what this is really saying is that, because remember, the purpose of these recommendations is to effect changes that are within the Secretary's purview that could ameliorate some of the problems, independent of the statutory changes that have been recommended.

DR. EVANS: Right, right.

DR. WILLIAMS: So this germane.

DR. EVANS: So give me some wording here that is narrow enough so it's not "reform the healthcare system." I'm all for reforming the healthcare system, believe me, but that would be jarringly inconsistent to throw that in in a recommendation. Give me some defined language again.

DR. WILLIAMS: I think we have that.

DR. EVANS: Say that again.

DR. TEUTSCH: At the end, you say, given that genetic tests will be increasingly incorporated in medical care, the Secretary should ensure that those tests shown to have clinical utility are available and accessible to patients, period.

DR. WILLIAMS: The rationale.

DR. TEUTSCH: Then the rationale, you can talk about the issue of uniformity of coverage and that sort of thing. You can talk about how that can be done.

MS. DARIEN: I would put "equally accessible to patients."

DR. EVANS: "Are equally available and accessible." "Equitably available"? Then in the discussion, we would talk about --

MS. DARIEN: "Uniformity in access would ensure" instead of "uniformity in coverage."

DR. EVANS: Okay. Discuss uniformity, uniformity of coverage, alternative mechanisms.

DR. WILLIAMS: The specific point that Mara mentioned was reduction of administrative burden.

DR. EVANS: Right. We could say "alternative

mechanisms, reduction," and we can ask Mara for some wording. I don't want to put words in her mouth.

"Administrative burden when implementing plans." I don't want to say "coverage plans." "Payment plans for those uncovered," something like that. "Those without coverage." We can wordsmith this. All right, yes.

MS. DARIEN: I mean, I don't know how you're going to end up wordsmithing it. I think some of the pushback the man from Athena got was that he was talking about having co-payment coverage. We were speaking about this later, but a test that is \$5,000, somebody can't afford. I mean, if they're going to pay 80 percent, somebody can't afford a thousand dollars.

DR. EVANS: Actually, it's \$11,000 or something like that.

MS. DARIEN: Or, whatever it is, but so that it it ends not being that solution, that solution is not put forward as the solution.

DR. EVANS: Right. "Reduction," and "preventing undue burdens" or something like that, "financial burdens on patients."

DR. TEUTSCH: All right. So it sounds to me like

we've worked our way through the recommendations. There will be a few tweaks, but I think we're there.

Before we vote on this, I want to reiterate, because not everybody was here in the beginning, at least the process that I would like to see going forward is we know this is going to be a report that gets a lot of attention, and some of it is not going to be wholeheartedly endorsing it.

It is incumbent upon us to make it really clear why we think the solutions we are recommending are the best ones. So there will be some wordsmithing in here, more than wordsmithing, making sure that our arguments are as cogent as they can be, and also we acknowledge all of the other perspectives that need to be in here, and the positions, many of which we heard about in the last day or so.

What we absolutely have to have are words from the people who felt that their ideas were not fully captured in here. We need some words from you, paragraphs, so that they can get incorporated into the next draft.

DR. EVANS: Suggestions of where they go.

DR. TEUTSCH: Where they go. We need them and,

unfortunately, I know Jim's been trying to get this throughout the process but has not received them. This is our last chance. We need to get those so that they can be incorporated, and I would like to see them here by the end of next week, so that we can complete the draft and get it back out to this committee for one more look-see by e-mail.

DR. BILLINGS: Steve, are you including the long response we got yesterday?

DR. TEUTSCH: The long response?

DR. BILLINGS: From the ex-officio who wrote us a very long response, Brian.

DR. TEUTSCH: We'll look and see if -- I mean, he's been there.

DR. BILLINGS: I'm saying that that was a response by a member.

DR. TEUTSCH: We'll go back through that and pull some of the things in, although it wasn't necessarily very specific exactly where that all goes.

MS. WALCOFF: We're voting before we see all these changes?

DR. TEUTSCH: Well, you've seen the recommendations. That would not really change.

MS. WALCOFF: To the whole report.

DR. TEUTSCH: Pardon?

MS. WALCOFF: To the whole report. I mean, we're not going to have a look at it as all of these things have gone in, because I think that was such a contentious report. I hate to say that, because I know it means a little bit of delay.

DR. TEUTSCH: If we don't do that, it means that it would be delayed until February.

DR. WILLIAMS: From my perspective, and I've been thinking about this, I've heard the comments, I've read the comments, I know where they go, I know what they're reflecting. It doesn't change the substantive recommendations that we will potentially be voting on and approving.

I personally don't need to sign off on the full report, which I think most of us around here have agreed probably is not going to be read anyway.

DR. EVANS: Thanks.

DR. WILLIAMS: If we set that snarky comment aside, to me, I am comfortable with the rationale that has been presented, the fact that we're going to be reflecting

the perspectives, but the recommendations that we have here are the ones that I think are reflected. I think we can vote on it.

DR. EVANS: Yes.

MS. WALCOFF: I was going to say that, since it is so contentious, I think we might get more favorable votes if we give the people who -- I mean, you know who is going to vote for it because of everyone who has been voting for all of them all the way along. I think the whole point is, I think you're trying to address some of the dissent, and perhaps if you do, it may become more of a full committee report.

DR. EVANS: I think we have a pretty good full committee report. The dissent was by three individuals.

MS. WALCOFF: I'm one of those three.

DR. EVANS: I know.

DR. TEUTSCH: Sheila, what is it you would like to see in here that isn't in here now that would change your vote?

MS. WALCOFF: I think that I would want to see how everything has fit in, because I do feel like we've made some substantial changes to it, and I think --

DR. EVANS: Since yesterday?

MS. WALCOFF: -- the tone in the report -- well, it's hard to really keep track of every single one that everyone has been making.

DR. EVANS: They really have not been substantial.

MS. WALCOFF: But I can support the report today.

DR. EVANS: I mean, there have not been substantial changes from yesterday. As I said at the start, these were the changes that we decided upon and voted upon. It's just that they have been now incorporated into the right place and formatted.

The changes we made today, I would argue strongly, are not substantial changes to the report.

MS. WALCOFF: But I think they do go to tone, and I think that is something that people pay attention to.

DR. EVANS: But is tone worth four months of preparation?

MS. WALCOFF: Better than five years.

DR. EVANS: Gwen, and then Paul.

MS. DARIEN: So can I just ask a process question, so I understand what you're saying? So you are -

- since the vast majority of this committee accepted the report, has read the report, has studied the report, Paul, and Marc says he knows where things are, and so you are asking that -- the suggestion is that we accept the report as it is and the people that dissent look at the report carefully and give you words that describe their dissent and indicate the places where that dissent goes so that dissent is reflected in the final report.

So is that the process you're --

DR. TEUTSCH: Right. That's what we're discussing.

MS. DARIEN: It seems like an eminently fair process.

DR. EVANS: I would add that this goes on in almost every report we do, that on the last day, there are always some changes that occur.

MS. WALCOFF: Not every report is as contentious as this one, though.

DR. EVANS: Not every report.

MS. WALCOFF: I think everyone agrees with that.

DR. EVANS: But again, to delay what has already been a long process, four months, for very minor changes,

would be nuts.

DR. BILLINGS: Jim, first of all, I'm going to speak for my vote. I could very easily vote for this report and vote in favor of its adoption, depending on how the argument is made and the options for the particular remedy, which is the primary recommendation of this. We're recommending a change in the patent enforcement around health-related testing, right? That's the primary recommendation we've adopted.

How that argument is made, what the balance of risk and benefits of adopting that, how that's portrayed in the report, that's all essential in my view to making a good report, and, frankly, I feel that it's deficient currently.

DR. EVANS: As you expressed yesterday.

DR. BILLINGS: As I did. So the changes that Steve has suggested as the chairman of this committee might actually change my vote.

DR. EVANS: The question is, is it worth changing?

DR. TEUTSCH: Jim, let me make this suggestion. One of the things that we could do offline, we could go

through the process, approve generally the recommendations today, do the revisions that we were just talking about and have, once sort of the final draft is available to all of you, we could actually have a teleconference and vote. It would not take us until February. It would have to be public, but we could do some such thing and you could get - - with the purpose of just taking a final vote.

DR. EVANS: Sylvia, you had a comment.

MS. AU: I think I agree with Steve. I think it's going to be kind of like what's happening with my report, where we have a chance to -- you're going to get the comments from the people who don't think their voices were incorporated adequately in the report, give people one more chance to look at it with a very defined timeline, but I think we can go ahead and approve the recommendations because I don't think that's going to substantially change. It's the argument about the --

DR. EVANS: So I think we voted on the recommendations and now what we're talking about is the body of the report, whether there need to be --

DR. TEUTSCH: What we would do is vote on the recommendations.

MS. WALCOFF: Even if you did do that same process, it is delaying it, I guess.

MS. AU: It won't delay it to the next meeting. I mean, it's going to be the same process as ours.

DR. EVANS: We can do it in some kind of time-reasonable way. I'm all for getting more buy-in from people.

DR. TEUTSCH: All right. So let's restate what's going to happen. We need comments on specific issues by the end of next week. You'll get recrafted a complete report with recommendations, time frame to be exactly decided. You'll have a chance to see that. We will vote on that report at that time and today we're basically going to say that we're generally correct. The recommendations are okay, so that we have that buy-in.

DR. FERREIRA-GONZALEZ: So let's say this language is incorporated into this report and the majority doesn't agree with some of the changes in the report. So what do you do? I mean, the recommendations have already been approved.

DR. TEUTSCH: That's why you get to review it and if you feel like we've gone overboard the other way, then

we'll have to deal with that, too.

DR. LICINIO: That's exactly my point. If you agree with the report as it is, absolutely fine, and you don't have anything, and then it's changed in a way to reflect the minority view, can you do a dissent from the dissent?

DR. TEUTSCH: Gwen.

DR. EVANS: Again, I will just put in one more plug for this idea. We went over this for eight hours yesterday. We voted on every recommendation. We have made a few changes. I would move that we approve or not approve this report. As we have done with many other reports, there can be wordsmithing to the report to try to change some of the text, but it would not be in substantial ways. It wouldn't affect the recommendations.

I don't know, Steve, if you're listening.

MS. DARIEN: I guess, just as a point of clarification, isn't the dissent going to be clearly marked as dissent?

DR. TEUTSCH: No. We're just going to identify those issues as part of the considerations in coming to conclusions.

MS. DARIEN: That there wasn't agreement around these issues, are we going to say there wasn't agreement around these issues?

DR. EVANS: No. As we say in the report now, there is dissent, that there is dissent about some of these points. That, I'm sorry, guys, is not going to change. We could change this report so that people from Bio would absolutely love it. Then there would still be dissent. They would just be from other people. I'm not sure what we're going to accomplish by dragging this out.

Paul.

DR. WISE: I'm sorry, Steve. As somebody who was not identified as one of the dissenters, I'm actually quite worried of pushing this through without adequate time.

One [reason] is, I'm not sure what the rush is. Is there any particular reason, after five years or so, that a few weeks or a month, one way or the other, is going to make a difference?

DR. EVANS: Right, if it can really be done. What I'm talking about is, we could go from meeting to meeting every four months and have this same discussion.

DR. WISE: I understand.

DR. EVANS: If we really have a mechanism where we can deal with some of this stuff, remote control, then I'm fine with that. I would ask, though, pursuant to, for example -- it was either Julio or Gwen -- do we really have that mechanism to do this?

DR. WISE: Let me just finish my point, [which] is that this is not only controversial; we've dealt with other controversial issues, but this is potentially lethal to the Committee at a time when things are very unstable, I would say, in terms of how the Committee fits into very active policy considerations and new mechanisms, coming up all the time, for advisory roles.

So my sense would be to be attentive to the requirement to get this done, get it done efficiently, respect the hard work that has already been done to make this work. At the same time, if there isn't some critically pressing reason to do it immediately, like today, that we respect these requests, which I think are actually quite worthwhile and legitimate, do the best.

Or, you'll do the best you can to integrate the wording that will definitely come, within the next week, to you about this, put out the report so we can all look at it

again, and then get the true feeling of the Committee, given the conversation we've just had.

Unless there is a really compelling, time-focused reason why we can't do that, my suggestion is that we do this right.

DR. EVANS: I am all for doing it right, as long as we have a mechanism by which we can do that.

DR. TEUTSCH: Marc, and then David.

DR. WILLIAMS: So what I would propose is that [since] we're obviously going to be getting comments in to do the revision of the report, that that report can be sent out for review and then final comments, and that then when we meet, it is essentially a non-discussion, thumbs-up/thumbs-down.

DR. EVANS: Whoa. You're saying meet?

DR. WILLIAMS: Steve is actually running this part of the meeting, if I'm not mistaken.

The problem that I see is that, again, this could be a beach ball. This could hit back and forth, ad infinitum. We do need to have some closure. We do have recommendations that the Committee has agreed on.

I am in favor, if we can present this information

in a better way -- I advocated for that yesterday -- but we have to have a defined process with an endpoint.

DR. TEUTSCH: I think I agree with what Paul is saying, that the deadlines are ours and we need to bring it to closure.

What I would like to see, having gone through the review process, which we just described, we will have a public teleconference to vote up or down on that final report, because I agree we owe it to ourselves and to everyone else to make sure that this report reflects, as broadly as we can, as completely as we can, our rationale so it is clear, and the different perspectives that we had to consider in getting to that decision.

I'm sorry. David.

DR. DALE: I agree with that position, Steve. And we would do this before Christmas, and we would have a mechanism, if anyone could not participate, that they could vote, cast their vote without being on the phone, a proxy?

DR. TEUTSCH: That's a challenge. That's a challenge. I don't know, we would need to look into that. I don't know whether you could give a proxy. I hope it's going to be an up-or-down vote.

DR. DALE: We need to be prepared for that. It's awfully hard to get everybody on a call, unless you have multiple calls, because you don't want to have the option of eight votes.

DR. TEUTSCH: Let us go back, because this gets to be a technical issue with the FACA Committee.

DR. DALE: We have these two pieces on parallel track. They both need to be reviewed.

DR. TEUTSCH: Two pieces? That's approved.

DR. DALE: That's approved, okay.

DR. TEUTSCH: We are talking just about the Patents Report.

DR. DALE: Well, I would advocate for us trying to do it before Christmas.

DR. TEUTSCH: Yes, we will do that. We'll find out what can be done. I understand people have other commitments. We will try and find out what mechanism you have to cast your vote if you can't be on the phone, but hopefully, we will be able to have that conversation.

What I need now is some agreement that the recommendations are agreed to and that, directionally, we're on track so that we can proceed with that.

All in favor?

DR. WILLIAMS: So, just to be clear, this is not a vote to approve?

DR. TEUTSCH: This is not a vote. This is a vote

--

DR. WILLIAMS: This is an endorsement of what we currently have, and the procedure that has been outlined?

DR. TEUTSCH: The recommendations and the process.

DR. WILLIAMS: Yes.

DR. EVANS: So this is a vote on the recommendations?

DR. TEUTSCH: All right, you want me to split them up? Let's first vote on the recommendations. We're going to vote on the final report. What you want is some assurance that the recommendations are the ones we just did this afternoon.

DR. EVANS: We went through all of them.

DR. TEUTSCH: All in favor of approving the recommendations.

[Show of hands.]

DR. TEUTSCH: Twelve. Opposed?

[Show of hands.]

DR. TEUTSCH: One. Abstentions?

[Show of hands.]

DR. TEUTSCH: One. If there is not approval, you will still get to vote on the final report.

Mara, are you on the phone?

[No response.]

DR. TEUTSCH: I'm sorry, and then the process.

All in favor of the process we outlined, whereby the revisions will occur. We'll have a teleconference to approve the final report, presumably in December sometime. All in favor.

[Show of hands.]

DR. TEUTSCH: Fourteen. All opposed?

[No response.]

DR. TEUTSCH: Abstentions?

[No response.]

DR. TEUTSCH: Who said we couldn't get to an agreement on this report? Okay, thank you, all. I know it's been a long slog.

Jim, thank you. What do we have to do? Jim,

thank you for all your leadership on this. I know it's been challenging.

DR. EVANS: My pleasure.

DR. TEUTSCH: Before we break up, there are several issues that Francis raised to us, and I would just be interested in getting some of your suggestions.

There were three issues. One is incorporating the value, economic value, of technological innovations in the Cost-Utility/Cost-Effectiveness Task Force activities. The second one was about considering addressing the implications of an affordable genome as a discrete topic. The third was about publishing a paper highlighting prior SACGHS recommendations.

I'm going to take them in a different order. How do people feel about us trying to get some more visibility for our recommendations by writing a paper highlighting recommendations, something like a commentary in JAMA, or something of that ilk?

I'm seeing several nods. I'm seeing nods here. Are there any people who feel that is not a good idea? The people who are going to write it may feel it is not a good idea.

Okay, so given that we want to move in that direction, do I have volunteers who will help write such a paper? Dr. Dale, Dr. Evans.

I'll work on it, Julio, and I know we'll count on staff. Okay, Andrea?

DR. McGRATH: I am not volunteering exactly, but I would just like to put in a plea to think carefully about who we aim it at and where we do it, and not necessarily a clinical medical journal, because then we get too narrow with just one discipline.

DR. TEUTSCH: I think we could think about a variety of journals, but I think what was being suggested was we need to get to a very broad audience, a policy audience. So it could be in "Health Affairs," it could be "New England Journal [of Medicine]", JAMA, but that type of a journal as opposed to specialty journals.

Gwen.

MS. DARIEN: So after we finish doing the more scientific version, I will help you do a lay version.

DR. TEUTSCH: It would be great. I mean, if we could get the kind of manuscript that could be adapted for different audiences that would be great.

MS. DARIEN: I will help do that.

DR. TEUTSCH: The second issue is, and this is talking towards Marc -- and he has not been forewarned -- about incorporating the economic value of technological innovations in your Cost-Utility Task Force. Or, is it already there?

DR. WILLIAMS: Well, I think that we are certainly not ruling out that the cost-effectiveness legislation, at least for some of the monies, as I read it, indicated that there are certain places where research would have to exclude consideration of costs from the effectiveness.

I think that any rational view of comparative effectiveness has to include issues around costs, including cost-effectiveness in the traditional sense, opportunity costs, doing this versus doing something else, comparative costs, cost minimization, et cetera, et cetera, et cetera.

So we have reviewed what has currently come out from the different agencies that have issued that, and there are a number of other things that people have written on this that I haven't had a chance to review yet with the group, including from RAND and the new NIH studies.

So the intent is that we will definitely try and capture that as a piece of what it is we are doing.

DR. TEUTSCH: We are going to talk about this in February, as we oversee the charge of the group.

DR. WILLIAMS: Correct.

DR. TEUTSCH: So we will have a chance to get people's perspectives.

DR. WILLIAMS: Right. The thing that we have been waiting on is the one thing that the Secretary has direct control over, the money that was designated to the Office of the Secretary around comparative effectiveness research. From what Sarah was saying earlier, that is still within the Office of Management and Budget, and is still being vetted. I don't know what else they are doing. That was a joke.

I think that will give us a much better direction about how we want to target where we think we need to go, since we're responsive to the Secretary as opposed to AHRQ, or, as Alan reminded me this morning, designating what NIH does with its money. So we want to be responsive to the Secretary's role in the whole realm of comparative effectiveness.

DR. TEUTSCH: The last item was considering the implications of an affordable genome as a separate topic that we would take up. I think where Francis was coming from, he said we need to be forward-looking. We are really talking about an affordable genome in the foreseeable future; what are the implications for health and healthcare, healthcare systems.

It is not that we have not discussed this. It has come up in other reports, and it will [come up] in some of the ones we are currently doing, but it is a reframing with a focus on that as the, what shall we say, critical technology, the change -- what's the right word? -- disruptive technology that could really change the landscape.

I don't want to get into a decision today, but I would be interested in your thoughts about whether that is something we should be taking up in that frame.

DR. FERREIRA-GONZALEZ: I think this is a very important topic. As we have seen the technology exploding and the bioinformatic tools starting to be developed, when you talk about the foreseeable future, I think it's very real, that in the very near future, we will be able to have

these tools for the clinical. We still don't know what it means to have the whole genome sequence, but we definitely need to have a very indepth look not only at the analytical-clinical validity and utility, but also the ethical issues behind that.

DR. TEUTSCH: Sheila.

MS. WALCOFF: I was just going to add that I do think it's an interesting topic, in particular, related to the work we've just done on DTC, because some of the criticisms, and there was a recent article this week about this, between the testing of two of the most popular DTC companies.

We have the whole genome available quite inexpensively. How does that affect it; is there still a discussion about health versus not; how does that interrelate to the new way we are talking about research, if there is a new legitimate way, and traditional research.

So I would be in favor of it.

DR. TEUTSCH: Sylvia, and then Marc.

MS. AU: I think that this really does need to be addressed, because it's going to throw our whole concept of genetic healthcare upside down, because if someone is going

to have full genome sequencing, then you're going to have to take the family history to help you figure out maybe some of the variants, what is going on with the family.

So instead of it being the way it is now, where you take the family history to see who might be at risk, to do genetic testing, you're going to have the genetic sequence and you might have to take the family history to figure out how that sequence is interpreted.

Also, it's going to have massive impact in the public health arena if we start doing this, if it gets cheap enough, and we're doing this for newborn screening.

DR. FERREIRA-GONZALEZ: Are you talking about the germline whole genome?

MS. AU: Yes.

DR. FERREIRA-GONZALEZ: Remember that you're going to have cancer.

MS. AU: Oh, absolutely. If they know about things that happen later in life.

DR. FERREIRA-GONZALEZ: You can imagine where a chimera of genomes --

MS. AU: Absolutely. And, is it going to make healthcare disparity even worse? Because we're going to

know things about people. People aren't going to have coverage, and they're not going to have treatment.

DR. FERREIRA-GONZALEZ: Different ethical issues before the germline versus the change in the market.

DR. TEUTSCH: Marc.

DR. WILLIAMS: As I'm thinking about the work of the Committee going forward, it seems to me, barring some recommendation or some request from on high, that we will probably have a fair amount of available time at our second meeting in 2010, and I would suggest that we do an educational, probably a full-day educational program, around this particular issue. I think that would be highly useful.

DR. TEUTSCH: Barbara, and then we'll wrap up.

DR. McGRATH: I was thinking of adding a cautionary tone, but I like the idea of an educational session. I think certain technologies come along, like whole-body scans, and they're interesting and intriguing to think about but they may go nowhere. This is a pretty important committee. I think, that we should really think hard about where we put our priorities.

So, are we looking at tools, perhaps, to the

privileged? Are we looking at how genetics can help society and health more generally? I think a great step is to do an educational session but not go full down that road and bump aside other issues.

DR. TEUTSCH: All right. Well, I am hearing enough interest that we will try and put something together, whether it's an educational session or whatever. I think we'll have at least a little more discussion of this in February.