

Gene Patents and Licensing Practices

Discussion of Final Draft Recommendations

DR. TEUTSCH: I think everybody has now got a clear sense of the diversity of perspectives on these issues. If you haven't, you had too heavy a lunch.

In addition, one of the ad hoc members provided some additional comments. These comments were also provided during the deliberations of the Task Force. They were sent this morning, so they're provided to you now.

MS. ASPINALL: That's what I wanted to ask. Is Brian here?

DR. TEUTSCH: No, he's not here.

MS. ASPINALL: Is he going to talk through these comments?

DR. TEUTSCH: No, and they were expressed before. The Task Force has considered them. So most of the folks who have been on the Task Force had an opportunity. What we have here is not a unanimous document but one that best represents the --

DR. EVANS: What was your first clue?

DR. TEUTSCH: Anyway, with that, I'm going to turn the opportunity back to Dr. Evans, who will help walk

us through this.

DR. EVANS: Thanks a lot.

DR. TEUTSCH: I don't know, Jim. Did you want to spend a few minutes on the issues?

DR. EVANS: Yes. I think that we have a goal here that by the end of the day we'll get through the recommendations. I do think, given the degree of dissent and given the kind of explosive nature of this issue, that it's only fair if we spend, say, half an hour so people can vent, and then we'll tackle the recommendations.

I do get some prerogatives as the Task Force chair. So what I'm going to do is just spend a couple of minutes. If you can turn the slides on. I do want to mention the Task Force composition and how we came about things.

Of the people who were really deciding policy and the content of the Task Force, these are the members and the ad hoc experts. The agency experts, consultants were extraordinarily valuable, but they are consultants, basically, and here to lend points of fact and information.

Although Mara was not able to participate extensively in the process, I think Mara is the dissenting

voice of the five members within the full members who are on the Task Force.

Of the ad hoc experts, I think it's fair to say that it's basically Brian Stanton who is the dissenting member of the ad hoc experts, as you can see from the document that he wishes to have circulated around.

So I tell you that not to single out any particular individual. It's great to have -- no, it's good to have dissent, and dissent shaped our conclusions in a very good way, but I do want to emphasize that this was not a split decision; this was not a close call, as we went through this.

Maybe it will turn out to be a close call in the Committee, or maybe what the majority of us favored won't carry in the Committee, but I do want you to understand that, that this was not a few people who rammed through a sketchy or minority position.

What I want to do to open up the discussion is I just want to frame briefly, again, the rationale for our recommendations. We have heard a lot about some claims. Those claims include, Number 1, that our original charge had nothing to do with looking at benefits. That is

absolutely not the case. We were charged with looking at both harms and benefits of the patent and licensing process on patient access to quality genetic tests. It's not only, I think, illogical to ignore benefits but it would have been contrary to our charge.

I think that, Number 2, we did find harm as opposed to the statement that is selectively quoting, saying that we did not find widespread and pervasive harm. The next sentence states: "However, there was harm found in segments of the population." When I see members of the population who clearly, because of patent-enabled exclusivity, are unable to get genetic tests, that's meaningful to me as a medical provider.

Number 3. The issue that perhaps struck me most forcefully, and I think several on the Task Force most forcefully, was the almost non-existent evidence for the need for patents in the development of genetic diagnostic tests.

Over and over again, in every example you can give, whether it's BRCA testing, whether it's HFE testing for hemochromatosis, whether it's hearing loss, many labs quickly began offering tests, and then the field was shut

down or narrowed dramatically when IP was invoked. The combination of harm, along with the very difficult ability to show benefit, I think, is a highly persuasive set of facts.

I want to just mention that we consider our recommendations to not be dramatic. I think they are narrowly tailored. We should not conflate therapeutics with diagnostics. The scope of our charge was to look at diagnostics. That's what we did.

Our recommendations are attempting to tease out the ability of laboratories to perform diagnostic tests without fear of infringement, and [they] do not alter, do not touch the therapeutic realm. This was for two reasons.

One was that it was not part of our charge. The second is that you can make very strong arguments that patents are doing heavy lifting. They're doing work in the realm of therapeutics with dramatic upfront costs, et cetera, et cetera.

It's extraordinarily difficult to make that claim for diagnostics and thus I would emphasize that these proposed recommendations are narrow in their scope. They look at trying to tease apart diagnostic testing for

healthcare-related activities, and I would also just point out that we cannot forget the issue of harm when it comes to quality of testing.

The patent-enabled sole-source provider is a serious threat to quality, given the infrastructure of quality control for laboratory tests in this country. So I've gotten on my soapbox, and why don't we just turn it over for about a half an hour and then we'll get to the recommendations and I really am going to keep it to a half hour. I'm writing down that it's 2:23.

Muin and Sylvia.

DR. KHOURY: So here is the first question, Jim, for you.

We are opening up Pandora's box on diagnostics versus therapeutics, and I for one have never really believed in genetic exceptionalism, especially in the new era of biomarkers, et cetera.

So using the laws of analogy, as our WARF speaker talked about just before, could you envision the impact of making recommendations on other non-genetic areas of diagnostics? Maybe you can say we don't care, that's not our charge, but I just want us to work through the system.

I mean, I sympathize with a lot of the ideas presented today, but I just want to explore those implications outside the so-called genetic arena.

DR. EVANS: Maybe you can start me off, because I certainly have been focused on genetic diagnostics, so I'm not sure where to go with that.

DR. KHOURY: If those recommendations are read without the genetic lens. Just read them as a biomarker or an assay, or anything, for the purpose of diagnosing, predicting whatever, I mean think about that genetically.

DR. EVANS: Right. I think that, in a way, the reason you can't do that is because it may well be that other diagnostic endeavors are very different in the sense of upfront costs, et cetera. It may be that the development of monoclonal antibodies that are effective for immunohistochemistry is just a whole other animal.

I'm not trying to avoid your question. I guess what I'm trying to do is say that I'm leery that it's relevant, in the sense that we're focused on genetics here where the landscape is we've got a handle on it.

DR. KHOURY: So maybe I can help you out. Within your three types, you gave different subgroups of patents,

et cetera. One is the association types, the other is the assays, et cetera.

Which ones of these are the easiest to deal with, and which ones are the most difficult? I mean, I'm fast-forwarding to a time where genetic sequences will be cheap. Everyone will have access to them. I can see some of the hiccupping along the road, but if somebody, let's say, comes up with an amazing new technology that would single-handedly do three billion base pair, using an amazing new discovery, plus all the gene expression and epigenetics, in one big swoop, do we want to reward that invention or what?

DR. EVANS: I think that's a very important point, and one of the things I would, again, reiterate is that the narrowness of these recommendations are such that the last thing they would do is interfere with the patenting of a technique, and that's a very important point.

We are not looking to do anything to undermine the patenting of the next PCR, for example. That absolutely should be patentable. We're talking about a very narrow situation which the analysis of a DNA sequence. That's what this basically all boils down to, and I think

that what you say about cost is absolutely right.

The cost of DNA sequencing and its decline makes Moore's law look like a piker. It's going to be very cheap, and I think that substantially informs what we're talking about.

With regard to what kind of claims are most difficult to get around, I think it's clear it's association claims, all right because association claims are utterly agnostic to the issue of how you analyze this, et cetera. They simply say that if you have this sequence, we have the patent on thinking about and I'm not using hyperbole there. In fact, Claim 13 of the homocysteine patent with metabolite actually talks about thinking.

Association patents patent associating, thinking about the genotype/phenotype relationship. So they're the hardest to get around and one could see problems in other diagnostic realms for such associations.

Sylvia.

MS. MANN: I'm not going to vent, Jim. I just wanted to talk a little bit about -- to answer Sheila's question.

Most of the Medicaid coverage and reimbursement

for genetic testing is done at the state level. Very few national coverage decisions are made on things like that and so having helped state Medicaid make decisions in our region on the West Coast, one of the things that makes it easier is if there is a reference lab that actually does multiple genetic tests for us because we don't want to negotiate 50 contracts. We're not going to negotiate 50 contracts.

So anything that restricts access to testing to sole-source providers or labs that are far away or labs that are inaccessible, there is going to be less and less chance that we're going to actually contract with that lab, unless it's a really bad public health problem in our state. Then we would, because we would have to because so many people have the disease or we had to test for the disease, but otherwise we're going to go with the lab with the biggest bang that we can get the contract for.

MS. WALCOFF: Right. So putting just the general market issues of that aside, if I think this committee thinks that this is such an important issue in terms of the patient access for genetic tests that are coming from sole-source labs, and not knowing the universe of sole-source

labs with exclusive licensing agreements, wouldn't it be a more straightforward fix to carve out an exception or make a requirement for state Medicaid to contract with the sole-source labs in this case of genetic testing, so that there is access for those populations, rather than leaving it up to each individual state, really trying to drive the competitive market between reference labs and the sole-source lab?

I mean, I just think we should not get into that. I am thinking, how can we do this from an HHS perspective. As you know, I'm know the fly in the ointment with this, but I want to challenge the group to really rethink how we structure these recommendations into something that the Secretary can receive and actually take action on, and that's one idea.

I was trying to see if that might be something possible, not knowing how a state Medicaid really works, but I feel that we are not going to be able to get to the solution and answer that we want to through the way these are structured because of the simple limitations of the Secretary's authority.

MS. MANN: I think that it's going to be talked

both ways because if it's going to take legislation reform, either way. I mean whichever one gets through first.

MS. WALCOFF: If it's going to take legislation, couldn't we do it administratively, too?

MS. MANN: I don't know.

MS. WALCOFF: As CMS, can you administratively make requirements like that in terms of state Medicaid policy?

DR. EVANS: No.

MS. WALCOFF: Can Jeff answer?

MR. ROCHE: I'm sorry. The question again was can CMS impose what on state Medicaid?

MS. WALCOFF: What sort of authority does CMS have to make administrative non-statutory -- under your current statutory authority, make administrative requirements on state Medicaid agencies?

MR. ROCHE: Again, I can go back and see if we can find more information that will help explore that question, but I'm not able to answer that now.

DR. EVANS: So I would love it if there was an easy way to ask the Secretary just sign off on this, do such and such and solve the problems.

MS. WALCOFF: I don't know that we can get to that ever, but I think it would be --

DR. EVANS: I don't think that's the case, and I think that even if the answer --

MS. WALCOFF: -- good to give her something that she can take the next step on.

DR. EVANS: -- had been yep, no problem with that, the problem is that it only addresses a small part of the problem. All right. It doesn't address, for example, the quality issues which are real and problematic when you have sole-source labs.

It also doesn't address the future issues which, granted, are future and therefore we don't know for sure, but I guess what I'm getting at is that I don't think there is a simple, easy fix for the problems that we've identified and if we can do it, granted, in a roundabout way, right, because --

MS. WALCOFF: I'm not suggesting simply a simple, easy fix, or even a roundabout way. I mean, if you want to look at quality, I would look to FDA and CMS in terms of it's their responsibility in managing quality, because they have the authority to do that.

DR. EVANS: That was my initial thought.

Actually, they don't in this sense, not in a practical sense. When I started this process, my view was quality. That's an oversight issue. That's an issue, let's leave it to the FDA, et cetera. The problem is that in practical terms, one cannot ensure quality with laboratory tests unless there are multiple providers in any kind of optimal way.

So the FDA could say, from now until the cows come home, that there should be stringent requirements, but without the ability to do proficiency testing, without the ability of having several labs, you compromise quality, and I think Andrea would confirm that.

DR. BILLINGS: Jim, what is the quality of the evidence for that last statement?

DR. EVANS: I think it is that the entire infrastructure of quality control rests on proficiency testing.

DR. FERREIRA-GONZALEZ: There are many different factors to this issue.

DR. BILLINGS: Just one follow-on and then I'll yield to Andrea. Okay. So I will accept the fact that

proficiency testing is important and maybe the most important factor in quality, but then you're also making the claim that sole-source labs don't do proficiency testing as well as multisource labs.

What's the evidence for that?

DR. EVANS: Well, because you simply can't do proficiency testing for sole-source labs.

DR. FERREIRA-GONZALEZ: Well, there are different kinds of proficiency testing that you can do. You can do simple exchange with other laboratories in the testing.

Having done this testing for over 18 years now, what I have learned doing this testing is that when you have more laboratories addressing the same testing, you can learn a lot more faster and you can identify the issues when you're testing, not only by exchanging specimens between laboratories but then you try to address what the different results are you obtain, but also because you're comparing results from different types of assays that might pick up the answers that you would not be aware of you're testing because you are the only sole provider of that testing.

But if you are the only sole provider of that

testing and you're re-running your own specimens, then you wouldn't be picking up some of these issues. So there's more to learning on the process by comparing results with other laboratories and we have actually data from the College of American Pathologists and the Molecular Oncology Proficiency Testing Program that, as we've gone over the years, by comparing results from different methodologies from different laboratories, that we have learned about the disorders and the testing and significantly continued to improve this and that's by collaborating with other institutions, other places that are actually doing the tests.

DR. BILLINGS: I'm sure that that's true, but I would also suggest that it's probably true that for a lab that does, let's say, DNA sequencing tests of a breast cancer gene, that they are constantly looking both at the quality of their results for any number of issues and looking at methods to improve the throughput, the costs, the kinds of data that they're generating again for their own reasons.

My question was, where are you getting the evidence that there's a big quality difference? I think

Andrea's comments are part of that evidence, and is that Type 1 evidence? Is it Type 4 evidence? You're an evidence-based medicine guy. Give me some quality of the basis on which you make this conclusion.

DR. EVANS: Well, for example, you can't do that test when you have a sole-source provider because nobody else can do the test. All right. You can't compare the results which is a necessary factor in trying to figure out the accuracy, the precision, et cetera. So it's simply undoable.

It is basically axiomatic that quality is more easily obtainable when you have several labs that are doing the test. Now, there may be times when there happens to be only one lab and you have to just live with that and you have to rely on those other processes.

I guess my question would be, as an obvious advocate for one position, why should we hog-tie ourselves into that position when what we can do is have a thriving competition between labs to provide quality testing, innovations, et cetera, with lack of sole source?

MS. WALCOFF: I want to just respond to that, and I'm hoping that we're not suggesting that sole-source labs

at this point in time because they can't do that particular type of proficiency testing are somehow providing a test that is of lesser or inadequate quality.

DR. EVANS: The quality is, unfortunately, not as good as you would have in a situation where there was --

DR. WILLIAMS: I'm not sure we can say it's not as good. We certainly don't know, we don't have any independent ability to verify and that is a very different issue. I think it's very dangerous for us to make pronouncements about the fact that the quality is good or not good.

I mean, personally, I think that Paul is mostly right in the sense that it is in their best interests to try and do the highest-quality testing that can be done. However, as someone that has to look -- is on the outside looking in, I would much rather be able to look at data to say -- and that is something that's addressed within the document. It comes back to the transparency issue.

I'll also just note parenthetically, and then if you'll allow me, I'll go into my other comments, --

MS. WALCOFF: You guys interrupted me. Actually, that wasn't my point. Can I just say one quick thing and

then let you go on and on? Not that you go on and on. I'm sorry.

DR. WILLIAMS: I'll accept one on.

MS. WALCOFF: Okay. Just go on. But I was going to get back to my challenge again of sort of relooking at this because as I would receive these, just hearing sort of all of these arguments and assuming that I just accept them, if I am the Secretary and this advisory committee is suggesting to me that I should go to the President because, of course, if we're going to be changing laws at the recommendations of the federal government, it doesn't come through one agency or department or another, it comes through the Administration as a whole which is the White House.

So if I go to my boss which is the President and say, Mr. President, we have an issue here, we have an access issue, sometimes the states don't want to contract with these sole-source labs, they find it cumbersome, expensive, whatever the case may be, some people have suggested there are proficiency testing issues related to quality with some of these labs, I would like you to propose that we change the intellectual property laws.

I would have to say, having been in some meetings that are not exactly like that but somewhat like that, there would be a lot of challenges made to that. So you're looking at a huge, huge hurdle changing laws at all, but changing these laws, and I think that some of the challenges you would get back are, so you're telling me our agencies, these amazing agencies, FDA, CMS, can't figure out different ways other than comparison testing to improve quality? You're saying that we can't figure out another way to get these people that cannot afford to pay for these tests?

DR. EVANS: And what I would say to that is that, Number 1, absolutely. We're not asking for things that are easy to do. I wish there were some things that were easy to do that would fix the problems and take care of these issues.

It was the general feeling of the Task Force, it's my feeling, that targeted changes that are statutory are the best way of dealing with those problems as well as the evidence that is there that we've gone over that we don't really need the patent protection for the development of these genetic tests.

I think the other thing that I would just touch on is that there is considerable feeling in the community and in the country that perhaps we've gone too far with some of the patent protection for genes in general. You heard that today from two of the public commenters.

So I don't think that suggesting statutory change is necessarily a crazy idea just because it's hard.

MS. WALCOFF: No, and I wouldn't say those other suggestions are easy, but I guess my point is to be more realistic because I think that whether we like it or not, it's a nation of lawyers.

DR. EVANS: Right.

MS. WALCOFF: What lawyers will do is exactly what the gentleman proposed earlier. What are all these unintended consequences? What can we analogize to this? I would suggest that this is not just a hard ask, it is a very, very, very high hurdle, and wouldn't it be more effective, wouldn't we -- rather than causing years of debate which has already been happening over patent and trademark and intellectual property issues, wouldn't we be better served as this committee to find our target again and direct things that are within the immediate authority

of the Department of Health and Human Services?

DR. EVANS: That's exactly why what we have done is divide our recommendations into, basically, two levels, two tiers. The first is -- okay, these are hard -- we think that these are best, at least the Task Force as a whole thinks that these are best, but we understand, as we'll get to with the slide when we get to recommendations, that these may not happen. They're very hard.

There are issues that you may not even decide to pursue because of things like unintended consequences, and therefore, here are a set of other recommendations where we think we could at least address, to some extent, these issues. So we are taking that approach to an extent.

MS. WALCOFF: I obviously have serious problems with that and challenges, but at the very least, if those are the first things I read, I may not get to 2, 3, 4, 5, 6, 7, and 8. I would probably say, oh, well, this is going to be quite a challenge and what's wrong? I would be calling my agency and saying what's going on here?

DR. EVANS: I'm sorry, I think you should read the entire page or two.

MS. WALCOFF: I did, I did. I'm saying the

person receiving this report may not.

DR. EVANS: I think we can rely on the Secretary of HHS to do due diligence and look at the recommendations. I think I have a little more faith than you do.

MS. WALCOFF: I'm not suggesting that she would not.

MS. WALCOFF: Number 1, I would start with talking to my agencies and doing that exact due diligence, and finding out exactly what the problem is. It sounds like there are still some open questions from the agencies. We want their support. We want, when the Secretary goes to do that due diligence on these first primary recommendations that the others support, to get that.

DR. EVANS: I think she will get through the one or two pages.

MS. WALCOFF: But my point is, I hope that in terms of doing her due diligence with the agencies, that those questions we have answers to, and that we know what they're going to say and we know that this is helpful to them.

DR. EVANS: Maybe there are modifications and

wording suggestions that you can make that will help ensure that the Secretary gets to those issues if we do decide to keep the general structure intact.

So Marc, and then Mara.

DR. WILLIAMS: I'm going on. So I'm going to move off this area and just highlight a couple things that I reflected on as we heard the public comments in relation to the document.

The first is, I wanted to remind the group that in the charter of our committee, one of the specific, explicit tasks that we're asked to address relates to disparity. So, in some ways that elevates the potential for harm in the Medicaid population a little bit higher, because I think we are specifically asked to look for where there are potential health disparities within our charter.

The second comment relates to the example that was raised by one of the commenters about Herteneu, which I think is a really interesting example for a couple of different reasons. It illustrates several of the points.

I think it's very clear that this has been hugely important. It is directly related to the appropriate use of a therapeutic. I think it is also fair to say that

where we're really going to see expansion in the next couple of years, relating to, if you will, personalized medicine, relates to the use of tumor markers to characterize and direct chemotherapy.

This raises a potential issue relating to some of the points that are made in the document, because if some of these tumor markers end up being sole sourced, there are some pragmatic issues that will have to be addressed.

One is, is that it's hard to get enough tumor to run the markers that we currently have, and if we have to somehow divvy it up and send it to five different laboratories, that would be, I think, extraordinarily problematic.

I think we also found that within Her-2, it was only through the collaboration of a lot of different laboratories that we identified some of the very significant quality concerns relating to how to do Her-2 testing.

So that obviously falls into the realm of a potential harm, but I think it is an issue, and I know that we're struggling right now in terms of do we have adequate amounts of tissue to do what really is medically

appropriate to do using a provider that can provide all the tests.

The third thing is relating to the patent thickets. I do think that this is a real potential problem. I think we do have evidence that laboratorians are now in a position of not being able to report medically-significant results because of the concerns about infringing on other patents and in the long run that is harmful to patient care, but I think we also have to think about, if we're going to go in this direction and I certainly would favor trying to explore solutions in this area, then we have to understand how we can incent companies that don't have right now any incentive to really participate, I think for good reason, how can we incent that participation so we can really move through this area, and I think I heard that reflected in a couple of the industry representatives, that there has to be that type of incentive put forward.

Lastly, and this just relates to the support for the report, I am not as sanguine about this from the perspective that I think in many ways this is analogous to what we see coming out of committees in the Congress, that

you can say what we had overwhelming support, but it was divided on party lines, and if you kind of look at the composition, I think in some ways, and I'm not saying that we should have tried to have equal representation, that's not what we do, but I am concerned that overwhelming support should not be overly-emphasized, given that there may well have been less representation from people that had more direct interest in patenting.

And the last thing about the composition which I think relates to your question, there were a number of Department of Health and Human Services ex-officios that participated in this which I would hope would have raised some of the issues that you were raising about is this something that we could do, and I would be very interested, at least in some course of the debate, to know where the level of support for the recommendations that would involve some of the very difficult problems.

DR. EVANS: So what I think we ought to do is we can extend it a little beyond half an hour, at 3:00, we are scheduled to have a break anyway. Let's come back from the break after we're done and then tackle the recommendation issues.

Mara.

MS. ASPINALL: Okay. Well, as the not singled-out/singled-out dissenter here in person, I'll take a little bit of prerogative.

DR. EVANS: I figured you'd singled yourself out.

MS. ASPINALL: And I've said a lot to this committee not just here but to the broader committee but on previous times we've talked about it. So I have several comments, but I will try to get them done before 3:00.

First, I want to say how much I respected the committee and the process we went through and particularly, Jim, your leadership, your commitment and your persistence. We didn't often or always agree on things, but your attempts to ensure that I stayed with it, stayed with the committee, and heard my comments, Brian's, and occasionally others that had dissenting views is very much, I need to say that to the whole committee, acknowledged.

So while you say it wasn't rammed down anyone's throat, and I would have been the throat there, there was not agreement but the process was well done and we took the extra time from two or three meetings ago where I felt very strongly that we needed some more time, as did others, to

get public comment, and I would like to publicly acknowledge that and your leadership --

DR. EVANS: Thanks.

MS. ASPINALL: -- in doing that. But now.

DR. EVANS: But.

MS. ASPINALL: That's right. But that was an important process step and it's great actually on a day like this to even twice now agree with Marc.

First, I'm going to start with the charter issue and I wasn't planning on actually going here, but I think the comment that I have to make is on the comments today about quality.

First of all, if we're going to debate the charter, the charter was on access and disparities. It had nothing to do with quality, and you could argue that's a piece of it and I won't go through what the single source labs do which they do on both proficiency and additional time with CAP inspectors because of that exact sensitivity that the labs themselves had, but I have to say that I'm extremely uncomfortable with saying by definition they're less good quality because there are plenty of great labs out there and I'm sure there are plenty of lousy labs out

there. But by definition, I can't let that stand. I just have to comment on it.

Secondly, in the charter and you spoke today and in the past because I've spoken about the commentary between diagnostics and therapeutics, if indeed, as it is in the charter, that it's only about diagnostics, I think one of the issues that you summarized today should not compare the development costs and you called it sufficiently low for diagnostics versus therapeutics.

If what we're talking about is diagnostics, the comparison of what it takes is not relevant and even more relevant, although I would say, as a diagnostic developer, it's not particularly low and it continues to increase, regardless of the patents, just because the burden of proof is and continues to increase, is that we cannot look at it by the amount of dollars that goes in because the reimbursement rates, as we've talked much in this committee, patents or not, unless you have exception pricing, you don't get any premium for patents, as we talked about, is about economic viability. It's not about that it costs \$10 to create a test, a thousand dollars or \$10,000.

So I think in the summary that is not an accurate depiction of what the issues are, regardless of either because of a comparison or it's not about upfront costs, it's about the full cost of educating, running, and selling the test. Those are the two comments on charter.

Next, as we look at the summary comments and probably the thing that I'm most disturbed about today and read all the public comments and in detail, I have my 10, as the rest of the committee did, I don't think that we have adequately represented the comments from some of the largest academic institutions in the country who supported the idea of access, supported the idea that we need to deal with disparities, but did comment that the committee's recommendations go too far and solve a problem that, even at the academic centers and some of these were representing technology transfer offices and some of them were representing the university management in the broadest sense, are saying that the committee's recommendations, while there are pieces of it that make sense, go too far.

And I think, again in a summary comment, that needs to be represented and that the comments that you had in here are obviously accurate, but I think more commentary

on what the other piece was, not just from industry, is important.

Next, composition of the committee, and as Marc said, the composition of the committee, as I look at it now, I'm wondering why I didn't see that earlier, but, indeed, it's not fair for any one person to represent fully an industry because this is a diverse industry that is not monothematic. So I don't believe that all of industry feels one way and all of academia doesn't, but I think it is important to -- and I actually don't even know where Brian's institution is, but that to be fair, we probably did need more representatives from non-academic laboratories and that's why I acknowledge again that it wasn't just that academic universities and others felt one way. They're not monolithic entities any more than industry is a monolithic entity.

Next, and then just right before my last point, I will go back to the reimbursement point, and Sheila brought up a couple of issues today about it, I think the report needs to also acknowledge the process that needs to be eased, patented or not, but as we're talking about patents and as one of the key findings of the group is that patents

create sole access.

Sole access creates access problems which is the way I saw the three steps here, that one of the things that HHS and other agencies can do more readily than some of these other recommendations is make a process for access when companies and laboratories want to be able to give the test to people who need it and can't afford it, whether they have insurance or not, make it a transparent easy process, so we can, regardless of the bigger issues and changing the world there and that may or may not happen, we can begin to get access to patients which to me is the broader issue that this committee is about.

So, in summary, having those five points, I believe that the purpose of the patent system was done to create innovation in a time-delimited way and having that time-delimitation is the piece that provides the checks and balances that both allows innovation and then allows others to come in at the appropriate time.

Thank you.

DR. EVANS: Let's see. I believe that Liz had a comment and then Andrea and then we really have to break. Liz, Rochelle, and Andrea. All right.

DR. MANSFIELD: So I obviously work for HHS. So I don't have an opinion on whether you're right or wrong, but I just wanted to bring up a couple points that I didn't hear necessarily addressed, although some of them overlap with what Marc and Mara just said.

I didn't see any traditional diagnostic industry input, I mean, on the committee for the report. Did I miss that or was it primarily laboratory-based?

DR. EVANS: I think it was laboratory-based. I would add that with regard to the representation, I think I would echo what Mara said, that to divide it kind of artificially between academic and industry is probably not the best thing.

DR. MANSFIELD: I agree.

DR. EVANS: I think if you look here, we've got people from the public health field, people from the legal profession, people from the laboratory side, clinicians like me, et cetera.

DR. MANSFIELD: I agree, but I just think there may be a distinct feeling among industry about whether it's reasonable to have the sole source or not. I mean, I think it's somewhat regrettable, from the FDA point of view, that

a lot of these patented tests, sole source, that you talk about are laboratory-developed tests.

What I want to actually segue into is, I'm in personalized medicine. That's my job right now, and as Marc brought up, there are going to be tests that go along that to say, this is how you should use this drug, and those tests are going to be required before you use the drug. Probably, a lot of them are going to be genetic tests, and FDA believes that those are tests that do not merit enforcement discretion and will probably require PMA, which is a fairly high bar in the regulatory world.

So I've heard from numerous IVD companies that they don't like the risk involved. If they get in and they put all the work into developing this diagnostic and go through the PMA and the second they're out the door, everyone else can knock them off, they're not going to do it.

So I'm a little -- I think you should take --

DR. FERREIRA-GONZALEZ: Well, then how do you explain KRS testing or treatment?

DR. MANSFIELD: KRS didn't need to go through a PMA process.

DR. FERREIRA-GONZALEZ: But it's going through the process and there are companies, there are commercial laboratories, academic laboratories, and there are IVD manufacturers.

DR. MANSFIELD: I'm not saying it won't happen. I'm saying I've heard from a lot of companies. They don't like the risk.

DR. FERREIRA-GONZALEZ: There's a slew of different laboratories in IVD that actually are going through the process of it and there's no patent for the KRS.

DR. MANSFIELD: Right, right.

DR. FERREIRA-GONZALEZ: I understand that you didn't go through a PMA process, but there is a company going through that. There is a cost associated with that.

DR. MANSFIELD: I'm just relating what I've heard. I'm not advocating one way or the other, but if this actually discourages companies from developing the tests that would get the drug on the market, it may have some unintended consequences. I don't know. You need to analyze that.

And the other thing is the size of the market I

think actually drives how many labs will do this. If it's a relatively small market, then there aren't going to be 10 labs doing it because they can't all make money off of it. So it's not just about patentability.

DR. EVANS: Rochelle, and then we'll stop for a break.

MS. DREYFUSS: I just have a couple of little things. One was on the comments that came from the universities. It's important when you think about the university comments to realize that universities are kind of strange. They're not like companies. The technology transfer office does a lot of licensing out but individual researchers do most of the licensing in, if they license in at all. So they're not seeing the entire picture and if they did, then they might have a very different view from the one that we saw and the comments that we made.

On the composition of the committee, the other thing that we didn't have is any antitrust people. So we keep talking about this as though these recommendations are making a huge change in the way that the world worked before, and I would like to point out that that's very much not true.

If you look at sort of the history of the world, patents are only one component of encouraging innovation. Competition is the other component of encouraging innovation. When you have a lot of competitors, then each competitor has to figure out ways to make the price lower, to make the quality better, to provide more information and so competition has in the past been a huge motivator of innovation, at least as much as the patent system has been.

Now do we have as much competition as we've had before? I would submit that in the last 10 years, 20 years, in fact that's what's changed, is the level of competition and it's changed in a number of ways.

First of all, in the last 10 years we got rid of research exemptions. So when we're talking about asking for research exemption, that's the way the world was until a court decided that there were no research exemptions and they did it on no information. So it's not like there are high burdens that were jumped when the law became the law that it is now. It happened in a particular case and in that particular case, it looked one way. The court wrote a very broad opinion and the question now is whether that very broad opinion is impacting on healthcare in a way that

was completely unforeseen by the court.

So this research exemption is not a new idea. It's returning to an old idea that was part of the law for 200-whatever years. In most cases, we had competition because people could invent around patents. So Jim started off by saying that patents are a limited monopoly. I cringed when he said that, with all due respect, because I think most patent lawyers don't think patents are monopolies. Patents are one way of accomplishing a particular result, solving a particular problem, but there are almost always ways to invent around it.

In this particular space with DNA, when you're trying to do diagnostic tests of people by looking at their DNA, there is no inventing around the DNA patent. That is something that is completely different from anything we have ever seen in history.

Third point, and it's the last one. The breadth of the patent system. The patent system used to be pretty narrowly directed at technological arts. It has expanded in the last 10 years, I would say, so that it covers business methods, including the methods of being a physician and treating your patients, but that is something

new.

So the fact that this committee wants to think about that not through the accretion of common law cases where the court did not have any evidence but by looking at evidence and thinking about how these past decisions are now affecting patient access seems to me to be not the incredibly revolutionary thing that several of the speakers have made it out to be.

So on the burden of proof, I don't understand the burden of proof. I don't understand why it's any higher for us than it is for the courts.

I have one more thing. That's this, that the patent system used to encourage leapfrogging. That is not cherry-picking the next most easy thing to do. It used to encourage people to really push the frontiers of science forward because it was hard to get patents.

In the last bunch of years, it's become easier to get patents. You don't have to have as inventive a step. The Supreme Court maybe pulled back on that. We have to see how that works out, but until now, it's not been that you could just go out and start sort of cherry-picking the things that are there, getting patent protection for it.

Things that were minor leaps, that were simply fairly easy to do, might require some work but fairly easy to do, people did because of competitive reasons, not because of patents.

DR. EVANS: I would just add I was reminded that regarding the composition of the committee, Emily Winn-Deen did represent the industry diagnostics, IVMDI-type perspectives.

So, all right, let's adjourn for 15 minutes and we'll start back at 3:20.

[Recess.]

DR. TEUTSCH: All right, everyone. Time to regroup here, and we've got to get down to brass tacks because we've got to get these recommendations reviewed and moved on. Clearly, we're hearing lots of different perspectives.

As I turn it back to Jim, what I think we'll be doing is, as we go through them, we're going to limit the discussions to some of the salient issues around the recommendations and then try to get a clear sense and vote on them as to where we stand, how close we are, since I know there's some people who are speaking a great deal and

others who are quiet and we need to know sort of are we on track as a group.

So, Jim, all right. Sultamonic Jim.

DR. EVANS: There you go. I'm not going to threaten to cut any babies in half, though, I promise.

All right. So we do need to get through these recommendations. We need to determine whether we are going to adopt them or not. This is certainly -- these are open for wordsmithing. They are open for adjustments, and if any of you have adjustments that make you feel like, okay, I could vote for it with this or that, by all means, bring it up, but we're going to try to move along relatively rapidly here.

The first three are going to be the toughest. All right. They're going to be the ones that evoke the most contentious debate, but we can't debate forever. You guys have read the report. We've been through a lot of this before.

So let's discuss this first one for a moment. The Secretary of Health and Human Services should support and work with the Secretary of Commerce to promote the following statutory changes:

"(1) The creation of an exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient care purposes."

Now, let me remind you of the Task Force's rationale. This is meant to address patient access problems and quality concerns, and to enable laboratories and test kit makers to offer multiplex tests and other innovations.

So let's have 10 minutes or so of discussion about this, and then let's put it to a vote. Who wants to talk?

DR. RODRIGUEZ: Laura Rodriguez from NIH, and I just wanted to ask -- well, I guess first going back to Marc's comment earlier about the technical members and contributions that were made during the Task Force committee, we were very much present and I was not speaking during the earlier discussion because we had shared our thoughts in that process and I thought that was the forum for the committee to have that and also to thank Jim, as well, for the process, as Mara said, that was there so that

different opinions could be heard in there and say that we do share many of the comments that came up before about actionability and some of the other scope questions.

But for this particular issue, coming back to the recommendation, I will apologize because I came on to the Task Force later in the development, but I did have a question about why the Task Force put forward this language that really was so open in terms of this exemption being available to anyone versus being more restrictive around the patient care issue.

DR. EVANS: Right. First off, it all funnels into patient care purposes, so that's meant to be the overarching issue. The reason that we had it say, for example, not just applicable to a physician ordering the test or doing the test was primarily, correct me if I'm wrong, other members of the Task Force, driven by Emily Winn-Deen, who, as an industry representative, who develops kits, et cetera, felt that it was unfairly privileging the academic university laboratory over others by allowing them the exemption.

So we were trying to broaden it to be inclusive of industry, as well, and it was really her advocacy that

got us to add the making. Otherwise using or ordering, right, or maybe offering for sale in the service lab would have been sufficient. All right.

Who's next? David.

DR. DALE: Well, I speak in favor of this statement or recommendation. I think the simplest way I could phrase it is I don't see why anyone could prevent me as an individual from asking a reliable source or laboratory to sequence my whole genome and tell me what they found. I think that's my personal right, and I can't see how the University of California could have sold that right to a company to deny me that access to information.

Thinking about it as an access issue, I would say the same thing to my patient, that I think they should have access to that information without obstacles as a part of general access to care.

So I would say this is the high ground in terms of what we're doing in terms of principles and that sets aside the issues surrounding the use of patented materials for product development or therapeutics, but it does improve access, and I think it's a modern thing to do because when we started down this pathway of patenting and

licensing of specific genes, it was in an era when it was a very unique thing to do and now we're certainly in a different era and to look ahead, I think to continue on the path we're on will be cumbersome and impair the health of the country.

DR. EVANS: Other comments? Mara.

MS. ASPINALL: This is a process issue both on Number 1. Have we ever heard from the PTO? Don't we have a representative from the PTO? Because one of the issues -
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DR. EVANS: PTO joined us on every conference call.

MS. ASPINALL: But are they here today to talk about some of the issues that we've brought up and discussed as to feasibility?

DR. EVANS: I mean, again, the PTO was represented at every single conference call that we went through.

MS. ASPINALL: And their comments on some of the questions? I don't remember anything.

DR. EVANS: They informed us all along the way about the recommendations, et cetera.

MS. ASPINALL: But on the specific questions about feasibility and viability, as we got close to the end of the recommendations?

DR. EVANS: I don't think that this, for example, recommendation, I don't think that PTO is particularly relevant to this particular recommendation. This would kind of take the PTO out of it. It would say --

MS. ASPINALL: Well, I mean, I would think that by definition of taking them out of it, they would have a strong opinion about it.

DR. EVANS: Again, they were there in every conference call.

MS. DREYFUSS: The PTO only decides whether there should be a patent. They have nothing to do with infringement or exemptions from liability. That just is not something that PTO does.

MS. ASPINALL: They have come out in various statements over the years and talking about what they believe on how infringements and how they structure patents and one of the things you talked about is the patentability of new claims and why --

MS. DREYFUSS: Yes. But this doesn't affect

patentability.

MS. ASPINALL: -- this is something -- as I said, this is both Number 1 and then more broadly. So I wanted to know if their representative was here and we could talk to them today.

DR. EVANS: Certainly, I mean, it doesn't look like at the table we have one now, but again I would assure that PTO has been intimately involved.

MS. DREYFUSS: When we added the last bit that Jim just described, we spent a lot of time talking about whether these patents would even be infringed by the kinds of things that are being sold. We spent a lot of time talking to them about it, but that was just because they're patent lawyers, not because they're the PTO.

MS. ASPINALL: On this comment in particular, was this the one -- and I don't remember -- Deb Leonard had some issues on?

DR. EVANS: Deb Leonard signed off on this. She was in support of it.

MS. CARR: I just wanted to clarify, I think. This may not be what you're getting at, Mara, but the agency experts were part of the Task Force to provide

technical information and it's important that we don't, I think, read anything one way or another into their participation in the Task Force. They're technical experts and providing information and technical corrections.

MS. ASPINALL: Speak for the agency with an opinion.

MS. CARR: Right. And whether they support one thing or another, if you were getting at the feasibility, the question of feasibility, John Legeider may have -- I don't know that we actually probed that with him, but he, as Jim said, was very much involved in the Task Force meetings.

MS. ASPINALL: I was moving it to the broader issue as opposed to on the committee, on the technical expertise that he and others gave us.

DR. EVANS: All right. I think Paul is next.

DR. BILLINGS: I just have a question, a point of clarification about this.

So does this have implications then for the next generation of patents on tests in the sense that a patent without an infringement capability or component is a different kind of patent than before?

DR. EVANS: Yes. I think that what this does is it tries to dissect out specific claims, right, and the claims that would be operative here would be claims that have to do with diagnosis. So this wouldn't affect claims on therapeutics, et cetera, but it would certainly -- yes, it would have an impact on diagnostic analysis of nucleic acids in the future.

DR. BILLINGS: Rochelle, do you not agree with that?

MS. DREYFUSS: This is just an exemption from liability for infringement of the patent claim on the genes. So if there were patent claims --

DR. BILLINGS: No, that's not what it says. It says tests. It's all tests.

MS. DREYFUSS: The patent claims on the genes that are involved in the test. So if you had invented some fabulous new test, you could get a patent on the test.

DR. BILLINGS: That's not what it says.

DR. EVANS: A test developed under the patent --

MS. DREYFUSS: On genes.

DR. EVANS: -- for patient under the patent.

Okay.

DR. BILLINGS: What patent?

DR. EVANS: The exemption from liability for infringement of patent claims on genes.

MS. DREYFUSS: On genes.

DR. EVANS: Patent claims on genes. So let's say you invented some fabulous new test for something. So you could get a patent on the test, somebody else might have a patent on the gene. So, first of all, that's one of the problems this is trying to treat, is that somebody who wants to develop a brand new test should be allowed to develop the test. That's the second part.

This part says that if somebody does develop the test, they would -- somebody would still have to pay them royalties for the test, but they wouldn't have to pay royalties to the person who owns the patent on the genes for doing the tests.

DR. EVANS: Are you -- this might be a good point. Does there need to be a modifier test that says diagnostic test? I mean, is that necessary? Is that what you're advocating?

DR. BILLINGS: Well, I want to understand the

implications for patents on genes, patents on tests.

DR. EVANS: This says patent claims on genes.

DR. FERREIRA-GONZALEZ: You can develop a test and you can patent the actual process of the test. That's no different than we did in the whole report. So you can come out with a new PCR methodology to detect this gene and you can patent that methodology, but you wouldn't be infringing on the patent of the gene.

DR. EVANS: Gwen, I think you were next.

MS. DARIEN: So perhaps this is a naive comment, but if the entire reason to develop these diagnostic tests is to improve patient care, how could there be an objection to this recommendation?

DR. EVANS: Well, you're probably asking the wrong guy.

MS. DARIEN: It's a general comment, but the fact is, is that the entire basis of what we're looking at here is improving patient care and if you improve diagnostics, then you improve the treatment, then that flows into therapeutics and then that flows into --

DR. EVANS: And that's what I think the fear is. Here's the fear. You're going to harm patient care by

doing this. That's the fear. I don't think that's justified. I've enumerated those reasons over and over. The fear, though, by the people who object to it is that you're going to harm patient care. I'm dismissing those people who are worried simply about profits, et cetera, but that would be the legitimate response.

MS. ASPINALL: No, and I think the fear is not necessarily today because you'd say the gene tests are already out there. So you're saying anyone can infringe on the patents that we have. We have a patent system for a reason. We might improve patient care if all healthcare was free and we're debating that in a pretty broad way as to lowering the costs so there's more access for everybody all the time.

We have a process and what this says is the process of gene patents was nice, but we don't respect it and anyone can use the genes. I understand the issue about the test. Anyone can use the genes anyway and what I would say is does it -- for diagnostic purposes. I think it has broader implications than that, but I understand that's what it says and that what happens in the next generation when you need to be able to create something that has some

economic viability as the rest of the healthcare system looks at.

DR. EVANS: So what I would propose is that -- let me ask a very, very specific question. Does anybody have wording changes, specific wording changes that they feel would make this substantially better? I'm not talking about, yes, erase it all, right. I mean if that's the case, you'll just vote against it, right.

Yes, David.

DR. DALE: I just would insert the word "diagnostic" before "test." I think it adds clarity.

DR. MANSFIELD: I would just put the clarifying for infringement of patent claims on genes but not methods or whatever it is that you mean to exclude because I'm not sure I would have read this exactly that way about the health.

DR. FERREIRA-GONZALEZ: This was an issue that was brought in our conference call, that we needed to be really clear --

DR. EVANS: Oh, that's a good point, Andrea.

DR. FERREIRA-GONZALEZ: -- in the methodology.

DR. TEUTSCH: In the additional information.

DR. FERREIRA-GONZALEZ: Somebody brought it up during our discussions.

DR. EVANS: Okay. Is this what people suggest here? Andrea, is this a problem, given the issue of -- okay. So here's a potential monkey-wrench by inserting diagnostic. Many of these tests will be used to determine predisposition. That's not a diagnostic issue. So it makes me wonder whether diagnostic is --

DR. FERREIRA-GONZALEZ: Saying predisposition is not a diagnostic?

DR. EVANS: Well, I think a lot of people would construe it that way.

DR. TEUTSCH: I think diagnostic usually means for people who have a condition --

DR. EVANS: I'm not exactly -- when we do BRCA testing, that's not considered a diagnostic test. It's considered a predisposition test.

DR. FERREIRA-GONZALEZ: Actually, --

DR. DALE: I withdraw my suggestion.

DR. FERREIRA-GONZALEZ: -- I disagree with that, but I don't think that's the big issue here.

DR. TEUTSCH: You do what?

DR. DALE: I agree to take it back out.

DR. TEUTSCH: Okay.

DR. MANSFIELD: Under FDA's regulations, diagnostic doesn't just mean diagnosis. So we can look at the IVD definition.

DR. FERREIRA-GONZALEZ: So, for example, pharmacogenetic testing for 2D6 for metabolism is --

DR. MANSFIELD: Right.

DR. FERREIRA-GONZALEZ: -- screening and monitoring.

DR. MANSFIELD: Anything.

DR. FERREIRA-GONZALEZ: So we need to cover all.

DR. EVANS: And we need to cover it all.

DR. TEUTSCH: For some of these issues, like the genes and not methods, what we mean by diagnostic, there needs to be a paragraph or so that provides a little elaboration of those kind of details so people know what we mean.

DR. FERREIRA-GONZALEZ: But I don't think we can have a comprehensive list to all this, so some examples.

DR. EVANS: At this point, I think we should vote, and the Committee members vote.

Darren brings up an important issue. Here is what I would propose. I think we can wait and ask that question, so I would propose at this point that we vote on this and then proceed. Any last-minute comments before we vote?

[No response.]

DR. EVANS: All right. So all in favor of this recommendation, raise your hands.

[Show of hands.]

DR. TEUTSCH: Eleven.

DR. EVANS: All opposed?

[Show of hands.]

DR. TEUTSCH: Three.

DR. EVANS: All right. Oh, abstentions, good point. Abstentions or recusals, any abstentions or recusals?

DR. TEUTSCH: I think we're good.

DR. EVANS: Okay, Number 2. Let me go to the wording on the next point. The second statutory change is research exemption. It would enable test developers to conduct research to design new tests, and it reads as follows:

"The creation of an exemption from patent infringement liability for those who use patent-protected genes in the pursuit of research. Related healthcare and research entities also should be covered by this exemption."

So are there general comments and are there specific comments about how this could be improved, if you in general favor it?

DR. RODRIGUEZ: I just have a question on there because the term "research" isn't defined. So I thought it would be helpful, to better understand what the goals here are, to have a definition of that.

DR. WILLIAMS: I would add to that "related healthcare and research entities." I mean, this one, for me, is problematic because it's not adequately explicit about what we're really talking about.

DR. EVANS: Okay. So the reason that we initially cast a wide net with regard to research was that we wanted to not again privilege clinical research, basic research, transitional research, not only because we didn't want to privilege them, but it is often difficult to parse those definitions.

I would certainly be in favor of any clarifying language that people want to suggest that we can discuss.

Marc, did you have any ideas about how we might be able to gain more specificity without undercutting a research exemption?

DR. WILLIAMS: Well, I'm not sure I can come up with the solution to it, but I do think that we could create the same sort of a situation where we allow people to self-define what they're doing, much the same way that we'll be talking about with DTC, where they said, well, we're not doing health-related tests.

If there are existing definitions of "research" or what a healthcare entity is that we're really talking about here, I think we're obligated to use those definitions and to try and be as clean-cut about it as we possibly can. I just would be uncomfortable that it's just way too nebulous.

DR. EVANS: So one of the things we discussed in the Task Force was whether we could gain tremendous specificity by saying, "in the pursuit of NIH-funded research." That would be one option. I'm just throwing that out there. You're shaking your head. There are

problems with that, as well.

The other issue is "healthcare and research entities." There actually are very specific definitions for those.

Darren, do you remember? We talked about this in the Task Force call. I believe [it is] actually defined in Ganski-Frist, who a healthcare entity is.

There are specific recommendations or definitions of that, but let's tackle the research issue first. Do people feel that we should try to get more granular about what research is? I think Marc's point is a good one.

Andrea, you had some thoughts, I think, about, for example, if we were to say "NIH-funded research," is that problematic or health-related.

DR. FERREIRA-GONZALEZ: There is more to NIH-funded research.

DR. MANSFIELD: I mean, HMI, yes. What about "health-related research"? Gwen?

MS. DARIEN: I don't even know which one to use. I think "health-related research" is better, but just for an example, which is from our organization, we're the scientific partner for a major, major funding initiative on

cancer. Five teams were funded on this, and it's not NIH-funded.

The whole point of this project is that they are only funding team science. They are only funding people that are crossing institutions. So IP issues are huge to this. If the IP issues aren't solved, they aren't going to be able to work with each other.

So I think that it has to be "health research." Just to the second point, I would like Rochelle to comment on the history of research exemptions, because you started saying something about that earlier.

MS. DREYFUSS: Like in 1819 or something, Justice Story wrote this case in which he said that there is an exemption for people who are doing research for their own curiosity, and that has always been understood as meaning non-profit research, basically. There are very few cases on it, because it was generally understood that that was an exemption. Everybody in universities, for example, assumed that they had that exemption.

Then in 1998, I think, there was this case called Media v. Duke in which a professor sued Duke University for using what had been his patented laser-something or other,

and he won. The court said, well, anybody that is doing research in the ordinary course of whatever their business is isn't entitled to the research exemption. So then they said, well, what is the university's business? The university's business is doing research, and high-falutin' researchers, and encouraging fancy students to come to their school. So they decided that Duke didn't get the research exemption, and by extension nobody would.

Now, it's a strange case, because first of all, the facts are really weird. People don't usually sue their own universities.

PARTICIPANT: They should.

MS. DREYFUSS: Don't tell my dean. It was a kind of research tool. I can't remember what you did with it, but it was a tool and various judges of the Federal Circuit have since said, we really only meant that for research tools; we really didn't mean it for run-of-the-mill things, but they've never changed it at all.

The Supreme Court got a chance to look at it, but they didn't argue that issue. They argued, instead, the statutory research defense, which is only for doing research for FDA approval. So we have been living, in the

last 10 years, with people thinking that probably the research exemption does continue, but not really knowing, because we haven't had another case.

So in a way, this just clarifies what the law is, and clarifies it in a way that I think quite a few of the various judges on the Federal Circuit, informally, would agree with. Certainly, the dicta in the Supreme Court case, which looked at the statutory exemption, indicated the Supreme Court was kind of on the side of thinking that we should read patent law as having a research exemption. Now, that research exemption would be for non-profit research, so it would extend to universities, not to industry.

In Europe, they've had an exemption like that always, and it's a statutory exemption. It is clear what it is. They have actually had the kind of problem that you're talking about, of joint research projects, and also projects being done by for-profit companies but very, very far upstream. They say, if we're doing upstream research, why are we any different from a university doing upstream research?

So there has been a move in Europe to change it

to something more broad. This broadens what we thought we had, because it doesn't only apply to non-profit research but it broadens it in a way that it looks like other countries are moving.

DR. EVANS: I would also bring up another thing that is kind of interesting, and it gets to Marc's point and Rochelle's point, Gwen.

I am skeptical, to some extent, of claims by some of these new companies that we are going to be doing research in a new way, but they might be. They really might come up with new models that I don't think we should dismiss.

I think that also would drive me to advocate for the broad term and not put limitations on research. I think all of those reasons, to me, dissuade one from limiting it.

DR. WILLIAMS: Yes. I understand what you're saying. I'm more comfortable with, we can really be more definitional about the related healthcare and research entities, and if we do have some definitions that we can take from statute that seem to be applicable here, I think it would be appropriate to reference those.

I would just say, philosophically, I think this is really critically important, because to assume that a patent holder is going to have all of the novel ideas around a certain entity, I think that has not been the case in history.

So I could see this really impeding important science, particularly given the areas that we really, at the present time, have no clue around, like regulation of genes and this type of thing, where if you can't really look at the gene but you're interested in the regulation, how can you really answer those questions.

So I am philosophically predisposed to being in favor of this, but I also recognize the fact that there is potential for harm if we're not tight.

DR. EVANS: Mara, one more comment and then let's take a vote.

MS. ASPINALL: I think it is part of what Marc said, but I believe there is another Merck case around universities and the ability to do research. So, to me, this seems like a non-issue, because when people have rights, they have rights to commercial --

DR. EVANS: It's very much an issue. For

example, BRCA1 and 2 research, clinical research funded by the NIH was shut down.

MS. ASPINALL: I know I've heard that, and there have been some negotiations around that one in particular, but if you look at a number of the issues [the benefits] that you get are only on commercial rights, not on research rights.

MS. DREYFUSS: No. The statutory research exemption, which is the one that was at issue in the Merck case, applies if you're doing research in order to generate data that is going to be submitted to the FDA, to federal agencies.

So if you're doing research that is going to be submitted to state agencies, or that is not going to be submitted to any agency at all, you don't get the benefit of that.

It is a very narrow research exemption. It's written a little bit broader, but it was basically done so that generic drug companies could do research to prove bioequivalence. It is pretty narrow, and the Supreme Court broadened it a little bit, but you still have to have data. You still have to be generating data.

DR. FERREIRA-GONZALEZ: I think if you look at any of the diagnostic licenses that I've ever seen, it is not relevant in the current diagnostic licenses you get from universities today.

DR. EVANS: Let me just say that I think it's well established that those doing research do not have any kind of established exemption, except in narrow circumstances, like if they're going to submit.

MS. DREYFUSS: Some universities are following the nine points, and the nine points suggest that they reserve research rights either for themselves.

DR. EVANS: Some are and some are not.

MS. DREYFUSS: So most universities do that, or for other universities, but they're not reserving research rights in the kind of situation where there is a joint venture between the university and a for-profit company.

In Europe, you're seeing these cases being brought by for-profit companies who say they think they should have the same rights to do upstream research as anybody else.

DR. EVANS: With the understanding that we will explicitly define a healthcare and research entity using

established nomenclature, how many are in favor of this recommendation?

[Show of hands.]

DR. EVANS: Okay. And opposed?

[Show of hands.]

DR. EVANS: Okay, you're abstaining. Okay.

Now, the third issue is connected. We might have to have two votes on the third issue. There was some question in the Task Force as to whether, in those first recommendations, association patents should be folded in, reading something like liability for infringement of patent claims, including association patents.

The reason I did not address that at the time is that we have a separate recommendation that could stand on its own, all right, and this recommendation specifically addresses association patent claims. The rationale behind this was not that there was some discrete statutory function that the Secretary could advocate, not that there was some executive action she could carry out, but the reason the Task Force felt that association patents should be addressed is that they are an extraordinarily active area of debate and interest now in the field.

There are pending court cases that hinge, that revolve around association patents, and the courts pay attention to what bodies, such as ours, say. So we felt we should weigh in on it and what this would do is say the Secretary should use her powers to discourage the seeking, the granting, and the invoking of simple association patent claims. It is the committee's position that these claims represent basic laws of nature that cannot be invented around, and I would make two comments about this.

One is that again, as you can see, it's quite a general thing. It doesn't advocate some specific action. The word "simple" was one that we spent a lot of time on and the reason for the insertion of "simple" there is that there is, my understanding and Rochelle can speak, I'm sure, in a more knowledgeable way to this, there is question as to whether, once complex enough, would, say, an algorithm that associates two things rise to the level of an invention. That will ultimately be something that the courts will have to work out.

What we are trying to advocate for here is that we did not feel, most of us on the Task Force, that simple associations, say GWAS results that are now flooding the

medical literature, where we say this locus is related to a relative risk of 1.3 for this disease, it's a simple association, and we didn't feel that that association should be patentable.

We did not want to imply that there couldn't be such labyrinthic and complex algorithm that took tremendous inventiveness that we would want to preclude all options for patenting.

So I'll be quiet now. Any comments on this? I think we should have basically a discussion about whether this should, if we want, stand on its own or should we fold it into the first rec.

Marc.

DR. WILLIAMS: So I would have two comments. First of all, simple is just not adequately explicit. No one would know what simple means and everybody would define it differently.

DR. EVANS: Well, we do address it in the report.

DR. WILLIAMS: I know you address it, but it's not defined in an explicit way so that somebody reasonable could look at it and say this is simple, this is not, and so in some ways that's going to be problematic.

I think the more problematic thing here relates to the fact that in fact, as opposed to the first two instances where I think we do have a lot of challenge, a lot of unclarity, the fact is that there are cases that are going to provide clarity to this issue that are under adjudication.

I'm not sure that what you said, which is the courts pay attention to what bodies like this say, I'm not sure that that realistically is true in the sense of how the court would know that this is what we're saying, but it seems to me that if the court is actively considering this, that this may be premature.

DR. EVANS: Other comments? Rochelle?

MS. DREYFUSS: I don't think it is premature. The federal circuit is certainly struggling with that same question of whether all associations are patentable or not. They just handed down an opinion a couple of weeks ago struggling with exactly that question. That was one where you injected the patient with something and then you saw how it was metabolized. They said, well, that is not a law of nature, although somebody might say it is a law of nature. How you metabolize that thing is a law of nature.

DR. EVANS: That was Prometheus.

MS. DREYFUSS: Yes. That was Prometheus, but maybe we could do something like a direct association between a genotype and a phenotype, because that would narrow it to genes.

DR. EVANS: That's interesting.

MS. DREYFUSS: So we would be out of the rest of the Prometheus world.

DR. EVANS: That would be invoking direct association product claims between a genotype and a phenotype.

DR. FERREIRA-GONZALEZ: Yes. Because when you use the direct association between the phenotype and genotype, when you have to use multiple genes to do a calculation that you invented that form of the calculation, then that goes into the invention part. So I think that will actually help to motivate this.

DR. EVANS: That's interesting.

MS. DREYFUSS: Then you get out of using the words "association patent claims."

DR. EVANS: Yes. So, okay.

DR. WILLIAMS: Again, I want to make sure we all

understand what we mean by "direct."

DR. EVANS: Again, I think your points are well taken, and we talked a lot about this in the Task Force. At some level, you read the U.S. Constitution, there are all kinds of things that require interpretation. It's not completely clear, but you can't be so specific that you gut the intent. You have to let the process kind of define what those are.

DR. WILLIAMS: Well, the process will ultimately define what they are, but I'm saying that I think that we have -- this is not something like life, liberty, and the pursuit of happiness, which I think are very difficult to define in any reasonable sense of the term, but when we talk about a genotype and a phenotype, I think we can take a crack at that. I think we could have a reasonable definition of what we consider to be direct.

DR. EVANS: So give me some possible wording here: "Discourage seeking, granting, and invoking of association patent claims"? I mean how would you rephrase this to get that desired level?

MS. DREYFUSS: Would it be enough to define "direct" in the comments?

DR. WILLIAMS: That's fine, but we need to do that if we're going to vote on this. I mean, this gets at the point that was made, I think, in the previous one, which is, we can vote on it, but if we don't really understand or don't agree with what the definition of the comments are going to be, then it's problematic.

DR. MANSFIELD: Sheila.

MS. WALCOFF: I was just going to say I have -- well, you finish your thought because it wasn't totally done.

DR. EVANS: I was going to say, we could go so far as to say the association between a single gene's allele, a single allele and a phenotype. The problem I get to is that, okay, look at the prostate cancer situation. There are now really four well-established loci that result in an increased risk if you have the risk allele of prostate cancer. It doesn't take a rocket scientist or geneticist to figure out that, okay, I can just use all four loci. I mean to me, that's still a direct association.

So I tend to not want to get so granular that we start to name the number of loci, et cetera. I understand

that "direct" has some nebulousness associated with it, but I'm not sure we can do better.

Anybody?

MS. WALCOFF: I'm just going to make my comment and then my recommendation, and just back to the original point on the courts and what is happening, and what this committee's role is.

I mean, we get right back to it again. Our recommendation is for the Secretary. We're not making recommendations to a court, various courts, on any particular case. At the end of the day, when she receives these recommendations, she is going to have to reconcile those with whatever the current case law is and whatever the future rulings are from those pending cases. She will have to get advice from OGC on doing that.

And so, I was actually going to recommend, in terms of the recommendations, that some of these things be more couched as examples, which might get us past this definitional question, because I think it is going to be one that is somewhat going to depend on where the law is at that point.

We have, under Recommendation No. 7, "Licensing

policies governing federally-funded research to facilitate access." At the end of the day, Numbers 2, 4, and I think 6 -- I have listed out a number of them -- really could be tucked under this, because the Secretary's authority and power really rests, in these cases, with what she can and cannot do with federal funds.

And so, if we are going to be recommending that there be a more thorough legal review -- and that's some of the sticking points I have in this report, is I don't feel like I have enough information on exactly where the law is with respect to some of the claims we're making -- perhaps we tuck those in as examples, under the part about legal review.

DR. EVANS: So, again, I don't think you were here when we went over how we were going to approach this particular session. I think that I am in favor of going through these recommendations and deciding whether we want them or not.

I think that I would like to see us decide whether we want to say something about association patent claims. If we don't, then we can talk about, do we want to tuck it in as an example. I'm not sure exactly where that

would go.

In response to what the Secretary can do with this, I think we, on the Task Force, were very cognizant of the fact that this is a nebulous recommendation, but I think that is important for the following reason.

There is some attention paid to what we say, and as a body that has spent five years looking at this, I think it is not unreasonable to take a stand on certain things that may be for purposes that go beyond, simply, the Secretary should absolutely do this.

It's not unreasonable to say, well, we've spent five years, this is what we think, and we would like the Secretary to use her powers to discourage the seekings. See what I'm saying?

So what I think we need to do is, we need to decide whether we want to say this. If there are discrete changes to the wording that could make it better, I think we should do that. At this point, I have trouble finding a better modifier than "direct".

Any other ideas?

DR. DALE: Jim, if I could help. At least I would suggest deleting the second phrase "the committee's

position," and moving that phrase "if necessary" into the discussion. So then we are left with [choosing] the position [of] whether we should encourage her to use her powers, discourage her from using her powers, or say nothing.

I would favor leaving the phrase as it is, but simply better defining "association patent claims"; that is, have a modifier just to say what that is.

DR. EVANS: What kind of modifier do you think?

DR. DALE: I would say that is and put it into plain English.

DR. EVANS: I just heard Rochelle say a direct correlation between that. So what about something like this: "The Secretary should use her powers to discourage the seeking, the granting, and the invoking of direct association patent claims on a direct correlation."

DR. DALE: You need another word than "association". So the simple word is "link".

DR. EVANS: Muin.

DR. KHOURY: I don't know what the word "direct" means as opposed to "indirect". I mean, what we're talking about are genotype/phenotype associations or

genotype/phenotype correlations or linkages, whatever you want to use. I mean, if it's indirect, does it make it more patentable? I don't know what it means. Just genotype/phenotype correlation, why complicate it?

DR. TEUTSCH: Sometimes you have multiple polygenic things that really will be discoveries.

DR. KHOURY: But there are still genotype/phenotype correlations at multiple loci. I mean, if you put five prostate cancer SNPs together, it is still a genotype/phenotype association.

DR. FERREIRA-GONZALEZ: We're making a distinction between a genotype/phenotype, for example, of single genes versus expression of 21 different genes, where you have to run an algorithm that you have come up with, and where, through that algorithm --

DR. EVANS: That's what we're trying to parse.

DR. FERREIRA-GONZALEZ: So that is patentable, and we don't want it to be in here. So it's just the law of nature that you have these two findings, that you didn't have to come up with any mathematical computation for all the different --

DR. WILLIAMS: So maybe what we're talking about

as a difference here, or maybe I'm completely missing the point, is patenting an observation of an association as opposed to taking that observation and doing something with it.

DR. EVANS: It requires little in the way of sophisticated inference.

MS. ASPINALL: But don't you want to put single gene in, then, as Andrea just described?

DR. EVANS: Well, no. I definitely don't want to put single genes in.

DR. FERREIRA-GONZALEZ: It could be more than this. You might find 15 different genes.

DR. EVANS: For example, diabetes. It doesn't, again, take a great intellectual leap to say, there are 19 Type II diabetes loci that have been documented, and we're going to combine those. I mean, any first-year statistics class student can do that. I think that we certainly don't want to say "single gene".

Again, what we originally had here is invoking of association patent claims. We had "simple" in there, and, again, my initial view was, can I define precisely what simple is? No, okay. I think like Potter Stuart said, I

know it when I see it. In other words, the courts will --

DR. BILLINGS: That's not our role. We're here as experts to be clear.

DR. EVANS: Well, as clear as we can, as clear as we can.

DR. BILLINGS: We can be clearer than this.

DR. EVANS: Okay, how can we be clearer?

DR. BILLINGS: Well, we've just had a suggestion of cutting out the second half of this thing, which I think actually makes it clearer.

DR. EVANS: So we could put this in the report.

DR. BILLINGS: Of course. I mean, we're talking about clarity of language here.

DR. EVANS: So just for the moment, we can always back up on this, I'm going to delete that. Now it reads: "The Secretary should use her powers to discourage the seeking, the granting, and the invoking of direct association patent claims between a genotype and a phenotype."

DR. KHOURY: Jim, this can apply to multiple genes.

DR. EVANS: It can.

DR. KHOURY: It could apply to one gene. It could apply to whatever. Where things become a bit more complicated is when people put genes together, make an inference, develop algorithms.

DR. BILLINGS: But that's why people patent that. There are going to be access issues to that, too. I mean, the whole point, the whole argument you've just made about patenting, we're going to have the problem with algorithms put onto those things. There may be an access issue.

MS. DREYFUSS: Our argument is a two-fold argument. One is, you don't really need patents on these things; second, there is an access issue.

The problem with complicated algorithms is, you might actually need a patent on it because figuring it out isn't going to be very easy to do; verifying it is going to be very hard.

I mean, I do think maybe we have enough data to say some of the things that we're saying, but I don't think we have data to support that you get rid of patents entirely.

DR. BILLINGS: As I said before, the report is silent as to the quality of the data. That seems to be

glaring.

DR. EVANS: So again, bringing it back to this, the Task Force felt that we did not want to preclude the possibility that an association claim that relied on a sophisticated algorithm, that took tremendous inventiveness, would be disallowed. We did want to take the stand that simple association patents or direct associations were not legitimate.

I think at some point very soon, in the next few minutes, we need to just vote on this. To me, the remaining sticking point is the modifier: should we have "direct" there; should we have "simple" there; or should we have no modifier?

Marc.

DR. WILLIAMS: This is going to raise another sticking point, which is, the other part of this that is problematic is, how can the Secretary use her powers to discourage? Does the Secretary in fact have any ability to influence this at the present time?

If the answer is no, then we should get rid of this.

DR. EVANS: Well, there is another option here

that that raises, and that is to not have this as a formal recommendation but to put in the report that the Task Force feels that association patents are illegitimate. That's okay with me.

DR. RODRIGUEZ: You should do something with "NIH-funded research".

DR. WILLIAMS: That is another recommendation. I agree. I think I understand what simple is. I'm not sure anybody else would agree with what I think simple is.

I think that this is a problematic recommendation. I think it would be good to highlight this in the report and say we're very concerned about this. There are some ongoing cases. We need to be aware, and as appropriate, for the Department of Health and Human Services to respond as this landscape begins to change.

DR. EVANS: I think that gets to the issue, too, the very legitimate issue, [that] none of us are quite sure exactly what the Secretary is supposed to do with this.

So I would move, then, that we make a statement in the report that the committee feels, basically, this. We could elaborate a little bit on what "simple" means. I mean, we don't have to have the necessity for brevity there

that we would with the recommendation. So I think that would be a very reasonable option.

DR. RODRIGUEZ: I don't have a vote, so I just wanted to express my support for going in that direction because of the outstanding questions and the court cases.

DR. EVANS: All right. Other input before we take a vote as to that effect?

MS. WALCOFF: I might have a ridiculously basic question, but in terms of the position that these claims, which we're having a very hard time exactly defining, represent basic laws of nature that cannot be invented around, what is the basis of that, if we can't really define what we're talking about?

DR. EVANS: Well, if you look, for example, at Breyer's dissent to the rejection of their initial granting of certiorari in the Metabolite case, that, if I'm not mistaken, basically went to what he said, these are laws of nature; they should not be subject to patents.

We've taken that out, anyway. So that's the issue.

MS. WALCOFF: Okay. So we're taking the whole thing out?

DR. EVANS: Well, that is what we're advocating.

MS. WALCOFF: That's my point. Where are we putting it in the report?

DR. EVANS: We're going to put it in the report.

MS. WALCOFF: That's my point. If it's in the report, it's still part of the report.

DR. EVANS: It's a finding. It's something that the committee, and that's what we're going to vote on, I feel we've spent five years dealing with this. It is not out of bounds for us to express some conclusions.

MS. WALCOFF: That's not my concern. I don't understand the basis for it. Where did we talk about it? I mean, it's just Breyer's dissent, that's what we're relying on?

DR. EVANS: No. It's the question of whether simple associations are patentable material because, as we went through this morning in great detail, association patents between genotype and phenotype present tremendous potential obstacles to the use of multiplex tests, whole-genome sequencing, et cetera. So they're very germane.

MS. WALCOFF: Are we certain that you cannot invent around these associations that we are defining that

are not defined?

MS. ASPINALL: Let me just say something. I mean technology fundamentally changes. The things that we're calling simple associations now were not.

DR. EVANS: It's technology independent.

DR. FERREIRA-GONZALEZ: You cannot invent around them.

DR. EVANS: Absolutely. It is an association between saying, in the classic case, homocysteine levels are tied to B-12 levels. It has nothing to do with technology.

MS. ASPINALL: You go back 50 years, and these are supposed to last over generations. Things that are simple now and that we described are a direct influence.

DR. EVANS: No, no, Mara. Did you listen to what I said? It is an association between two things.

Okay, I'm going to make a proposal. We need to vote on it so we can move on. I'm going to propose that we eliminate this recommendation, and that we put in the report that the committee feels something basically along these lines. I know everybody doesn't agree, but that's why we're going to have a vote.

MS. WALCOFF: Two separate votes?

DR. EVANS: I think it's clear to me that there is a consensus it should not be a recommendation.

MS. WALCOFF: So the question is, should it be in the report?

DR. EVANS: Does anybody want to have a vote on that? We can have a vote on that. Who wants to keep --

MS. WALCOFF: I thought it's whether it's in the report.

DR. EVANS: Okay. So we're going to put it in the report. What are you asking me?

MS. WALCOFF: I thought I heard you say we're going to have a vote about -- I guess we're not having a vote about it being a recommendation.

DR. EVANS: Let's have a vote. Let's have a vote. Who wants this as a recommendation? Who's in favor of having this as a recommendation? Who's against it? Okay. So who abstains? All right.

So what we've decided then is that it's not going to be a recommendation. What I would move is that we at least address this in the report with wording that is substantially similar to this.

Now, I would say we should have a vote on that.

Who would vote for that option?

[Show of hands.]

DR. EVANS: Okay. Who's against?

[Show of hands.]

DR. EVANS: Okay. So we initially had removed the issue of law of nature, all right, from the recommendation which isn't a recommendation anymore.

My view is that in the report, we can be more expansive and I don't think there's an imperative to remove that language at this point.

DR. WILLIAMS: My recollection from reading the full report was that in the description about why this is a potential problem, we do have adequate detail there that does go into the issues relating to the law of nature. So my recollection of this discussion was that it actually was fairly broad. It was not just Breyer. There were a number of other examples that were presented, and I think that that stands on its own reasonably well and that people can take from it what they will.

DR. EVANS: Right. Okay. All right. I think we've done most of the heavy lifting, but I might be

surprised. The remainder of the recommendations are meant to -- there's going to be wording that says, and I think that was in the original wording this morning in the presentation, that says, okay, we recognize that evoking statutory changes is a complex, hard process, and you may not even choose, as the Secretary, to do this.

Because of the difficulties with that, we have come up with a number of other recommendations that we feel could address the issues that have been raised during the report and that's what most of these really focus on. So this one is concerning promoting adherence to norms designed to ensure access. It's kind of long.

The Secretary should develop mechanisms to promote voluntary adherence to the principles reflected in NIH's Best Practices for the Licensing of Genomic Inventions, the OECD Guidelines for Licensing of Genetic Inventions, the NIH Policy for Sharing of Data Obtained in NIH-Supported or Conducted Genome-Wide Association Studies, and in the public interest. Nine points.

The Secretary of Health and Human Services should also advocate that professional organizations involved in intellectual property policy and practice in this area work

together to build on those norms and practices as they relate to gene-based diagnostics by articulating more specific conditions under which exclusive licensing and non-exclusive licensing of uses relevant to genetic testing are appropriate. Professional societies should work cooperatively to forego consensus positions with respect to gene patenting and licensing policies.

B. The Secretary should encourage stakeholders, for example industry, academic institutions, researchers, patients, to continue their work of developing a code of conduct that will enable broad access to such technologies.

Now, as we discussed, one of the things that inevitably came up with was the question should these recommendations somehow have teeth. We're certainly all familiar with this litany of recommendations that say plain ice and should there be more in the way of teeth to this and, if so, how would we do that? So why don't we discuss those issues?

DR. TEUTSCH: I think the issue there, just to be clear, these were already out there as voluntary guidelines. So the question is what are we saying, besides

--

DR. EVANS: Besides these are good guidelines.

DR. TEUTSCH: If we think they're issues and the report provides some evidence, then we probably need to take out words, like "promote voluntary adherence" and say "promote adherence," and give them some more clout. I mean that's the question. Where do we want to go with this?

DR. EVANS: Right.

DR. TEUTSCH: But it worries me, frankly, to simply reiterate what's already out there as a recommendation.

DR. EVANS: I know. I share that.

DR. TEUTSCH: I mean, if we think that they're important.

DR. BILLINGS: I have a question and maybe we don't have the -- this has to do with payment and the Secretary's control of the purse strings.

But if the Secretary were to say something like laboratories that don't license broadly and thus cause all the problems that the report suggests that they might in terms of access and quality, the laboratories will not have access or entities doing business with them will not have access to federal dollars that are administered by HHS.

Wouldn't that have a rather strong impact on the situation?

DR. EVANS: So, actually, in a subsequent recommendation, we discussed that. There's also the issue of, for example, whether Bayh-Dole allows the Secretary, whether the law is such that that can be done, say, with funding dollars, et cetera.

So one way of trying to put more teeth in this, if we chose to do so, would be to, for example, get rid of voluntary and that simple change does, I think, do a little bit of work in communicating the frustration that Steve articulates.

B is pretty much kind of milktoast, and I don't know whether it makes sense to even have it. I mean, it does seem --

MS. WALCOFF: Maybe you can make it more direct in the way that Steve had suggested and instead of encourage stakeholders to continue their work of developing the code of conduct, I mean, you could make it a little less milktoast by saying develop a code of conduct by X or something, for review by something.

Then to the other point, there are also purse

strings without a doubt in terms of restrictions and limitations on federal funding of grants and whatnot, so long as it's not precluded by other statutory restrictions which I think is what we're getting to in terms of the evaluation of that.

DR. EVANS: So I guess we could -- okay. So let me -- we can always go back. I don't mean to ram anything through here.

DR. TEUTSCH: That's a pulse point. There's a variety of things you can use. You talked about several. One could be a contingent --

DR. EVANS: The whole recommendation went away.

DR. TEUTSCH: That they adhere to these things, if they're going to seek --

DR. BILLINGS: It would be very interesting for someone to tell us, this committee, what options for influencing this kind of phenomenon we have, yes, so we can make recommendations that then would be relevant.

DR. EVANS: What if we were to say that the committee supports these following things, the nine points, OECD, et cetera? Somebody help write this down, if it makes sense. That the Secretary should investigate ways of

promoting adherence that might include or that would include the use of funding as a deterrent or incentive.

Something like that?

DR. TEUTSCH: More than investigate is the point.

DR. WILLIAMS: I don't know. I don't know that I would -- I think again, within the recommendation that goes to the Secretary, I was thinking along the same lines that Jim was saying, that we think that these are good guidelines for how things should go. They are voluntary.

We, as a committee, do not know what avenues would be available to promote adherence, if you want to use those words. So we would recommend that the Secretary investigate or explore what are the options to promote adherence to these guidelines. I mean, I think that that's a reasonable thing to do.

DR. EVANS: Again, I'm just thinking out loud here. The committee supports guidelines and then we could insert in there such as OECD, nine points, et cetera, that encourage broad licensing and access to diagnostic and genetic tests.

Okay. Help me out here. We would request that the Secretary --

DR. WILLIAMS: I think technically we recommend.
We're advisory.

DR. EVANS: We recommend. Okay. We recommend
that the Secretary.

DR. WILLIAMS: Explore options that would promote
adherence beyond voluntary.

DR. TEUTSCH: I would go further and say because
you've got to explore them, you've got to identify them and
implement them.

DR. WILLIAMS: Explore, identify and implement is
what Steve just said.

DR. MANSFIELD: And implement such
recommendations in ways that go beyond simply --

DR. TEUTSCH: Adherence, that promote adherence
to those recommendations.

DR. MANSFIELD: Such recommendations. Oh, well,
we recommend the Secretary explore, identify and implement
such recommendations. Give me -- okay. What were you
saying?

DR. WILLIAMS: So that the Secretary explore,
identify and implement processes --

DR. MANSFIELD: And implement mechanisms.

DR. WILLIAMS: Mechanisms that --

DR. TEUTSCH: That promote adherence to those guidelines.

DR. WILLIAMS: -- promote adherence, right.

DR. MANSFIELD: That promote --

DR. WILLIAMS: Promote adherence beyond voluntary

--

DR. EVANS: To these guidelines that go beyond voluntary adherence.

DR. WILLIAMS: And then the second part of that would be, I think, whoever suggested that we recommend that the Secretary convene the group as opposed to just continue, that we change the verb to convene, so that there's an intentionality about bringing the people to the table to figure it out.

DR. EVANS: Should convene.

DR. WILLIAMS: Whatever the second part that you previously said.

DR. EVANS: The Secretary should convene stakeholders.

DR. WILLIAMS: Yes.

DR. EVANS: Yes, okay.

MS. ASPINALL: That's consistent with what we've done on previous reports. We've asked the Secretary to convene people.

DR. EVANS: It is, yes. The Secretary should convene stakeholders. We can worry about formatting later. Okay. Stakeholders, for example industry, academic institutions, researchers, to continue their work of developing a code of conduct -- yes, yes. To develop -- we'll have to wordsmith. To develop a code of conduct that will enable broad access to such technology. Okay.

Yes?

DR. RODRIGUEZ: I have a comment. So some of the comments that I had have changed now that the language has been altered a little bit and we're exploring things and looking further at these issues, but some of the power that the guidelines have had is the fact that they are guidelines and they're voluntary and they promote flexibility and by shifting to adherence, I think again that, as written, things would have to be looked at differently.

They weren't originally developed with the intent of being regulations or anything that was mandatory and so

that could change how some of it works and actually take away some of their power because the flexibility to look at the individual situation is helpful in moving some things forward, but as written and in terms of convening, I think that is something that's well within the scope of the Secretary to do and to bring stakeholders together and to have them go through these issues again and put something forward.

I think that could be very constructive, but another question that I had again is that all of this would only affect HHS-funded research.

DR. EVANS: Right. Absolutely.

DR. RODRIGUEZ: And so there's a question of impact overall.

DR. EVANS: Right. That's an acknowledged limitation of all these types of things. That's one of the reasons for Recommendations 1 and 2.

MS. DREYFUSS: First of all, I think the guidelines internally have some flexibility in them. So taking and making them more -- making it more required that you follow the guidelines doesn't remove all flexibility.

But I thought Paul had some ideas of ways to

broaden the teeth by saying the Secretary -- maybe I misunderstood you -- could also do things with funding of organizations that deal with these organizations.

DR. BILLINGS: Exactly. I mean, she has both direct and indirect influence on the environment in which these laboratories and the patent holders exist in nature and so --

DR. EVANS: So can you think -- so it sounds to me like a possibility to include that would be to have a sub-bullet that says something about the types of mechanisms, right?

DR. BILLINGS: She has authorities and influences. We don't happen to know all of them, but she does and we want her to -- the point here is that we want her to marshal them for this end.

DR. EVANS: And implement mechanisms using her authority and resources?

DR. BILLINGS: Yes.

DR. EVANS: Mechanisms, using her authority, and what was the other thing? Resources. Thank you. Resources, in order to promote adherence to these guidelines in a way that goes beyond voluntary adherence.

Okay?

All right. Other suggestions? Which point? I mean, the one point is you can't get around it, right? It's only going to impact NIH-funded research.

DR. RODRIGUEZ: Right. And may actually in some ways be a disincentive to interact with HHS-funded research if this is a problem and so that companies may just not --

DR. EVANS: For most people it's the only game in town.

DR. RODRIGUEZ: I don't know. I don't know that really most -- again, talking about all of the research that goes on in the private sector.

MS. ASPINALL: For lots of private sector companies and the research and early developmental stage, NIH funding is a very big piece of it.

DR. EVANS: So that actually is a good thing for the potency of this.

All right. So we'll do some wordsmithing and find some time tomorrow or something to circulate things.

DR. TEUTSCH: I think from a process point of view, if we can get a sense that these are now directionally correct, we should wordsmith them tonight and

bring them back to the whole committee, not the ones that we've already voted with, but the ones that we're still extensively rewriting, and get some final approval on those tomorrow. We'll find some time.

DR. EVANS: Okay. That's right, and I'm going to now move this one.

DR. TEUTSCH: So I think what you should probably take a vote on those two that were basically correct.

DR. EVANS: Yes, okay, right. Okay. I'm just putting that at the end, so we'll still have it as a model.

All right. So let me just go over it again. This is for promoting adherence to norms designed to ensure access.

The committee supports guidelines, and we'll fill in the litany, that encourage broad licensing and broad, I think we should probably have broad, modifying those, as well, access to diagnostic genetic tests. We recommend that the Secretary explore, identify and implement mechanisms, using her authority and resources, in order to promote or that will, I guess that would be, that will promote adherence to these guidelines in a way that goes beyond voluntary adherence.

The Secretary should convene stakeholders, for example, to develop a code of conduct that will enable broad access to such technologies.

So all those in favor.

[Show of hands.]

DR. TEUTSCH: 14, one abstention.

DR. EVANS: All right.

DR. TEUTSCH: Any opposed?

DR. EVANS: All right. Let me get rid of that.

Okay. Enhancing transparency in licensing, and the reason for this was, okay, there was some dissent here. Gee, imagine that.

The Secretary should encourage holders of patents associated with genetic tests and their licensees to make information about patent licenses readily available, either by making the signed licenses publicly available or by disseminating information about their technology and licensing conditions, including any terms that pertain to the type of license, field of use, and scope of the technologies that are still available.

And B. As a means to enhance public access to information about the licensing of patents related to gene-

based diagnostics, the Secretary should direct NIH to amend its Best Practices to 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, including such factors as type of license, field of use, and scope, in order to encourage next generation innovation.

Comments?

DR. WILLIAMS: So I guess I would like to understand if there was dissent about this, what the nature of the --

DR. EVANS: That's what I'm trying to remember.

DR. WILLIAMS: -- dissent was and probably better for someone that --

MS. ASPINALL: I think that several of the universities also dissented to this in the letters and just saying they did not want their financial information on good, bad, or indifferent business practices public information.

DR. WILLIAMS: So this is -- I don't want to make this a pejorative sense of the term, but the issue is then less about the fact that there could be challenges relating

to discovery of IP or things. It's more related to public perception of what it is we're actually doing with --

MS. ASPINALL: Disclosure on financial terms in the effort to not say you negotiated a good deal or a bad deal with this type of company or other university and they did not want that information public.

DR. WILLIAMS: Do we say anything about financial terms here? I mean, my reading of this, and maybe again I completely missed the boat, but my reading of this was really the idea was to know who was involved so that people that are looking to actually be engaged would at least know what the landscape looks like, that it's not necessarily disclosing all financial information or anything else like that, right? It's just who --

DR. FERREIRA-GONZALEZ: It's who has been licensed to whom for what application and what it covers, not what money or how. I mean just to know there's already a license out there, so I don't have to try to do this because there's already a license.

MS. ASPINALL: I think you have to make that clear because terms and fields of use to many who had read it said that's the term sheet, that's all the conditions

for which we're licensing.

DR. WILLIAMS: I would certainly favor clarifying that because I don't think that that information needs to be made public. I think then if that's the case, if people are concerned that that's what we're saying, then we need to modify the language to make it clear that we're just trying to identify who's actually involved and if licenses are out there.

MS. DREYFUSS: I thought that was the only information we were requiring, but my impression was that some people considered that trade secrets. What deals they had, not the nature of the deal, the simple fact that they had deals, they wish to regard as trade secrets.

MS. ASPINALL: That was the second level that was absolutely voiced by industry as well as research and academia.

DR. EVANS: Brian Stanton was a dissenter on this. I think he was the major dissenter and what he says here is that he doesn't believe the evidence supports the need for this.

First, patent information is readily available from USPTO, the European Patent Office, the Japan Patent,

private sources, such as Google, and others.

So I think that, for example, the individuals who pursued the case studies would argue that actually this information is very hard to come by and I think most of us would agree with that latter point.

So how could we change this then to address the points that Mara and Marc, Rochelle were talking about?

MS. DREYFUSS: I think Brian was thinking of finding out whether there were patents you could Google, first of all, but that isn't so easy either, but what Bob Keegan said was that it was very hard to find out who you'd go to to even get a license and that just seems to me to be the kind of information that ought not be regarded as a trade secret.

I agree about the financial information. That seems like really important information that people might want to withhold. So I would try to change it so it's clear it's not financial information but that people would be able to find out who they need to get licenses from if they want licenses because that's an important part of getting access.

DR. WILLIAMS: The other point I would make, as I

read through both of those, is that the operative verb for the Secretary in both of those cases is encourage which implies voluntary and so that would also then raise the question that we brought up previously which is are we really looking just to enhance voluntary reporting or do we really want to --

DR. EVANS: Should we use her authority? Again, we could use the same wording here, that the Secretary explore, identify and implement mechanisms using her authority and resources, so that holders of patents associated with genetic tests, blah-blah-blah, and then have a clause that, for example, excludes the financial aspects. Does that make sense? Well, in a way this does it, right?

Here, let me go back to the full screen. I mean what this is is about technology and licensing conditions, including any terms that pertain to the type of license, field of use, and scope. So that isn't financial, right?

MS. WALCOFF: Are we trying to identify -- you say we're trying to identify where licenses are. Does that necessarily follow that because a company that holds a patent has licensed it to another entity, that they would

naturally license it further? I mean, aren't we trying to figure out who the patent holders are?

DR. EVANS: Well, what we're really trying to do with this, I think, is find out who it's been licensed to for what fields of use, right, because that proves to be very hard and it's going to be a big deal as multiplex testing becomes the norm.

DR. FERREIRA-GONZALEZ: For example, I want to set up a new test and I want to, first of all, you try to figure out if the finding of the gene, there's a gene patent. You normally go to the first original publication and you try to contact the authors there or the university there or whoever is the entity and sometimes you can't find them and you don't know where to go and then from there, they might already have licensing or they might not be willing to tell or not. So it's very hard to find that information.

MS. WALCOFF: If you identify the licensee, just that, I mean that's --

DR. FERREIRA-GONZALEZ: Also what they have been licensed for.

DR. EVANS: Right. The terms of use, the field.

MS. WALCOFF: I was trying to think of a way to get around the fact that people would be sensitive to however we define the use.

DR. FERREIRA-GONZALEZ: Just finding the licensee might be compromised.

MS. WALCOFF: Right. That's what I'm suggesting because then you could easily identify just their contact information and then that entity could seek to clarify the terms under which they could use --

DR. FERREIRA-GONZALEZ: They might decide not to do that and then I try to set up a test and then they contact me to send cease and desist letter.

MS. WALCOFF: Right. So you'd avoid a cease and desist because you actually have a clear contact beyond the original patent, but if it doesn't make people nervous about all these other things, they may be required to disclose beyond this is the licensee.

MS. ASPINALL: Well, I don't agree with it, but I think that's closer because when you put in any terms that pertain to the type of license, then it says you need to be able to do this much research at this time and keep it exclusive. I mean, there are all sorts of terms that

relate to licenses and I did not believe it was the -- well, actually, I wasn't sure what the full intention was, but I think when you have the way it's phrased initially as any terms that go to scope of technologies in the broad second sentence, I think it's very easy to say I've got to make public all the information regarding this license and I did not think that was the committee's intention.

DR. EVANS: Okay. I'm trying to make this bigger so that we can --

DR. FERREIRA-GONZALEZ: Is there a way to dissect all these different terms? I'm doing research for this amount of time or do this data support? That part is not - - but do you still know what you're using the test for, why you're licensing it for? For diagnostic, prognostic and clinical scenario and so forth.

DR. EVANS: Okay. So what the heck happened? All right. So trying to work our way towards this, trying to put a little more teeth into it. One way of achieving that would be to use the same wording we did in the last one.

We recommend the Secretary explore, identify and implement mechanisms, using her authority and resources,

that will make information about patent licenses readily available either by making the signed licenses publicly available or by, and here's where we have to do some wordsmithing, disseminating information about their technology and licensing conditions, including, and you felt like any terms was too broad.

What if we said including the type of license or just get rid of any?

DR. WILLIAMS: What I would probably do with this is to not be as -- I mean, the first part of it is we're asking her to explore and then we're telling her exactly how to do it in some ways.

I would almost say, and it's just at the bare edge of my readability here, so that will make information about patent licenses readily available, period, and then say the information that is necessary because of the concerns referenced in the report are around the field but would not constitute financial.

So, in other words, you wouldn't have to articulate everything in the recommendation. You could basically say we're interested in this. We're not interested in that and then expound on it in the report.

DR. TEUTSCH: Or just indicate that she should develop the elements of the following type.

DR. WILLIAMS: Right.

DR. EVANS: So something like information needed for greater transparency due to concerns articulated in the report include information about their technology and licensing conditions, licensing conditions, terms that pertain to the type of license, field of use, and the scope of technologies. What about that?

DR. DALE: Jim, that phrase at the end, though, "that are still available," doesn't make sense.

DR. EVANS: Yes. I just took it out because it didn't make sense with the change there.

Now in B, as a means to enhance public access to information about the licensing of patents related to gene-based diagnostics, the Secretary should direct NIH to amend its Best Practices for the Licensing of Genomic Inventions to encourage licensors and -- encourage again, to include in their license contracts a provision that allows each party to disclose information about its licenses.

So should we say here the Secretary should direct NIH to amend its Best Practices for the Licensing of

Genomic Inventions to require?

DR. WILLIAMS: Would it be appropriate just to ask the Secretary for the NIH to revisit its recommendations to specifically address this point and then bring those forward, I mean, as opposed to saying this is exactly what should be done? Are we absolutely certain that that's exactly what should be done or should we give NIH -- let them use their expertise.

DR. EVANS: Or we could say the Secretary should consider directing the NIH to require blah-blah-blah.

DR. RODRIGUEZ: I was just wondering, actually, since, in the first part of this, it's been changed to explore all of the authorities, then I would think that this becomes a little bit moot in terms of that would be done in the course of doing the first part and so again I think that it needs to be explored and there would be a lot of questions that the NIH would have about doing that.

So certainly changing it to a consider, if it's going to go beyond encourage, I think there are definitely --

DR. WILLIAMS: So B would move to the report as part of the explication about the different opportunities

that could potentially be looked at and, yes, I agree, I think it is redundant. I would just take B out and move it to the report.

DR. EVANS: So, okay, we're talking about then moving this sentence maybe with exactly or close to that wording to the report in the context or in the discussion of this recommendation, right?

DR. RODRIGUEZ: Right. Because I don't know that there is existing authority to do this.

DR. EVANS: Right. And that you have to explore that which we kind of say. Okay. All right.

So other comments about this? All right.

DR. WILLIAMS: So B is out then?

DR. EVANS: B moves to the report. So the vote then would be, unless somebody -- here, let me get it up here.

We recommend that the Secretary explore, identify and implement mechanisms, using her authority and resources, that will make information about patent licenses readily available. The information needed for greater transparency due to concerns articulated in the report include information about technology and licensing

conditions, terms that pertain to the type of license, field of use, and the scope of technologies.

Okay. So all those in favor.

[Show of hands.]

DR. EVANS: Okay. All right. Moving on, we can get rid of that. All right.

Advisory board. All right. To assess the impact of gene patenting and licensing practices. The Secretary should establish an advisory board which would be available to provide ongoing advice about the public health impact of gene patenting and licensing practices.

This advisory board would also be available to receive any reports of problems in patient access to genetic tests from the public and medical community. The board then could review new data collected on patient access and assess the extent to which access problems are occurring.

One of the board's missions would also be to recommend what information should be systematically collected through iEdison so that iEdison can be used to research questions about licensing, including whether the licensing of genomic inventions has been conducted in

accordance with NIH's Best Practices for the Licensing of Genomic Inventions.

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

Basically what this is saying is -- this arose because there seemed to be frustration that there was kind of a vacuum there, that if people perceived problems, they didn't know where to go. There wasn't any mechanism and this would take care of that.

Barbara.

MS. McGRATH: I think, just to make it simple, I would keep the first sentence and then cut out everything and then go down to the last sentence, the advisory board also should provide, and then just have that be the recommendation and then in the text, since there's a lot of discussion about who should be at the table on this committee and other places, maybe specify a list of potential stakeholders that would be part of that advisory board.

DR. EVANS: I'm all for simplifying because my eyes glaze over when I see a recommendation like this. So

tell me again your specific --

MS. McGRATH: I just end up with two sentences, the first and the last.

DR. EVANS: So the Secretary should establish an advisory board which would be available to provide ongoing advice about the public health impact of gene patenting and licensing practices. The advisory board also could provide input. Is that what you're saying?

MS. McGRATH: Exactly.

DR. EVANS: And then what we could do, if this makes sense, is we could try to incorporate in the report these other things.

MS. McGRATH: As well as making explicit that the composition of the advisory board would be reflective of all the groups that we've sort of mentioned.

DR. EVANS: Okay. So in the report, then insert a discussion along the following lines which also includes suggestions about the composition of such a board and then put --

MS. WALCOFF: So would this be an advisory committee, in addition to SACGHS, or also --

DR. EVANS: Yes. I don't think this would be

SACGHS.

DR. WILLIAMS: I was going to -- I think I'm going where you are, which is advisory has a very specific meaning, I think, in the context of the Secretary. So I had that question which was would that in fact be us.

The second question is whether there would be expertise from -- would it somehow be an interdepartmental board because we've already acknowledged that there are different people that hold different pieces of this puzzle.

And the third point is that in our recommendation, I think it was Number 3 maybe, we do establish or recommend establishing another group to explore best practices. So in some sense, could we look at folding this into that? Would that be a potential -- because again, I don't think we should necessarily have recommendations for 15 new committees or boards, et cetera.

DR. EVANS: Right. So that makes sense.

MS. WALCOFF: And also, I like your idea of the interdepartmental workgroup to continue to look at these issues.

DR. EVANS: So what we could do -- so this now is something --

MS. WALCOFF: Your five-year tenure will end.

DR. EVANS: That's right, that's right. Exactly, exactly. So what we could -- in this wording, which we'll figure out, that will go in the report that won't be in the recommendation, help me out here.

You're saying we could discuss the need for interdepartmental membership. We could also --

MS. WALCOFF: I think it would be an advisory board then. I think it would be more of like an interdepartmental workgroup or committee. I mean, there are technical terms for those.

DR. EVANS: Okay.

MS. WALCOFF: Maybe we could just find those out.

MS. CARR: Are you suggesting feds only? An internal working group?

MS. WALCOFF: Are we suggesting feds only? That's what I was thinking, but I don't know.

MS. CARR: This was outside, I think, outside advisors.

MS. WALCOFF: Okay. I guess when you mentioned the point about needing advice from the other implicated departments, my mind went to feds only, but maybe so.

I mean, is there something between a departmental working group and an advisory board because the chartering of an advisory board just kind of looks like we're duplicating ourselves.

DR. EVANS: Yes.

MS. DARIEN: Can't you just call it an advisory body and then allow it to be constituted the way that it should be constituted?

DR. EVANS: As long as we discuss like whether it should be interdepartmental advisory body, which would be more intentionally vague, and let her --

MS. CARR: It could be inside or outside. You're not going to specify your wishes in that regard.

DR. TEUTSCH: You need to talk about who it's advisory to. This one was advisory to the Secretary.

MS. CARR: But if it's interdepartmental, then it may have more than one advisor.

DR. TEUTSCH: Right. Well, here because Number 8 refers to a group that's advisory to the Patent Office.

DR. EVANS: Yes. I mean, my assumption with this would be that it was an advisory body that would report to her. Do we need to say that?

MS. CARR: I think you're focused on the public health impact here, so perhaps you could have interdepartmental but still reporting to the Secretary of Health.

DR. EVANS: Do we need to say that? That's the question. Should such an advisory board or body be reportable to her or do we need to get there? At this point, I'm going to leave that off for a moment.

I was going to mention, I was going to put down here -- I'm sensitive to the idea that, oh, go ahead and create another board, another advisory body, when think about what our committee does, right. It's supposed to address issues of genetics, health, and society. We're talking about gene patents here.

It does seem to me that it might not be illogical to suggest that there could be a role for this committee as this. I mean, we've got interdepartmental input, et cetera. Does that make sense?

MS. WALCOFF: Sadly, it does.

DR. EVANS: Sadly, it does, yes.

MS. WALCOFF: Maybe we're just thinking of ways -

PARTICIPANT: Still not fully representative.

DR. EVANS: Right. So we could discuss interdepartmental membership. We could even say that others could be brought into it. We could also suggest it might be a role.

MS. WALCOFF: Is it an advisory group that really would be advising the SACGHS?

DR. EVANS: No. I mean, my reason for bringing it up is the idea that it seems a rather natural function of this committee, not a group that would advise this committee, but kind of a function of this committee.

MS. WALCOFF: Are you still trying to get into the broad -- some way to enable broader membership in terms of views that we might --

DR. TEUTSCH: Is this where public/private partnership can look at these issues and bringing recommendations on technologies and changes to the appropriate public or private bodies?

MS. WALCOFF: Right. Because then we could vet it.

DR. TEUTSCH: We've done that in some of the other things when we've talked about --

DR. WILLIAMS: In the oversight report, we recommended constituting that.

I mean, I didn't want to necessarily substitute one buzz word for another, but I think I'm envisioning that it needs to have representation from within the federal government and then it needs to have outside representation, as well, and again I'm going to reflect back just to try and simplify things, that if we're recommending we create whatever this body is, that we task it to do several things.

This. We task it to look at the best practices, which was represented, I think, in Recommendation 3, that that should be pulled into this, and if there's any subsequent recommendations that talk about forming a group, that they be given charge over all of this.

DR. TEUTSCH: And 8, the one that deals with the PTO.

DR. EVANS: Right. So, okay, now this is -- just bear with me because I'm trying to piece together these various ideas. So again, the recommendation, as we've got it now, is just this very first part, per Barbara's recommendation or suggestion.

In the report, we would then discuss those issues, like iEdison and all, and then to try to get to what we're talking about here, we could discuss the need for interdepartmental membership, representation from a broad array of experts and stakeholders, and the nature of membership. We could also suggest it might be a role for SACGHS.

Does that get what we're talking about?

DR. DALE: Jim, another structural way would be that there become over time, as this field evolves, standing subcommittees of this committee.

DR. EVANS: That's a good point, and we could discuss that in the report.

DR. DALE: And then we wouldn't spend quite as much time around this table talking about details but rather receive reports.

DR. EVANS: Right. And we can include in that verbiage, we'll figure out in the report, and there might be a role for standing subcommittees of the SACGHS.

DR. WILLIAMS: Chaired in perpetuity by Dr. James Evans.

DR. EVANS: No, thanks. I think I have some kind

of conflict of interest or financial impropriety or something.

All right. So let me read the actual recommendation.

The Secretary should establish an advisory body which would be available to provide ongoing advice about the public health impact of gene patenting and licensing practices. The advisory board also could provide input on the implementation of any future policy changes, including the other proposed recommendations in this report, and then within the report, we would talk about the composition, the need for interdepartmental membership and a broad array of experts. We could suggest the possibility that it's an appropriate role for SACGHS perhaps with the standing subcommittee.

Oh, okay. Gotta change the boards to bodies.
All right. This is body. All right.

All in favor of this recommendation and the attendant insertions into the report.

[Show of hands.]

DR. TEUTSCH: 13, one abstention, one no.

DR. EVANS: Okay. Federal efforts to promote

broad licensing and patient access.

"The Secretary shall encourage federal agencies within the Department of Health and Human Services to undertake the following actions: (a) federal agencies should promote wider adoption of the principles reflected in the best practices and OECD guidelines, both of which encourage limited use" -- is this redundant? -- "and (b) federal agencies should encourage wider use of the nine points to consider in licensing university technology."

Points 2 and 9, including their explanatory text, are particularly relevant. For example, 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 and/or control."

So the question would be, as I read these again, are these redundant?

DR. WILLIAMS: Yes. Fold it into the previous one.

DR. EVANS: All right. So the motion is to fold this into the recommendations, or to fold it into the

discussion that refers to the recommendation?

DR. WILLIAMS: Into the discussions first.

DR. EVANS: That's what I would think, too.

Okay, good. So the consensus, if people agree, is fold this verbiage into the report's discussion of Rec 3.

Yes, okay. Are people okay with that? I don't think we need an actual vote on that.

Federal efforts. This is continued, and I think it's going to be the same thing: "Federal agencies should explore whether approaches to addressing patent thickets" - - okay, this is a little different. This might be a separate recommendation -- "to explore patent pools, clearinghouses and cross-licensing agreements to facilitate the development of multiplex tests for whole-genome sequencing."

DR. WILLIAMS: So to me, this would fall under the purview of Recommendation 5, where we create this group that is exploring it. This is a really important issue, I think, that we need to explore in much greater detail. This would be one more thing I would task that group to explicitly explore.

DR. EVANS: So the suggestion, then, is to fold

this into the report where we discuss the advisory body, right? Are people okay with that? I mean, I like the fact that we're making this simpler.

Licensing policies governing federally-funded research to facilitate access. So this is now a shift and a totally different issue. Because it is unclear whether the Bayh-Dole Act gives agencies authority to influence how grantees license patented inventions, the Secretary should seek clarification about this legal question.

"If it is determined that such authority exists, the Secretary should 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 should also be allowed if a grantee can show that an exclusive license is more appropriate in a particular case. For example, because of high costs of developing the test.

The Secretary should also direct NIH to make compliance with NIH's Best Practices for the Licensing of Genomic Inventions an important consideration in future

grant awards, and let me see. There was something -- okay.

And the question was should the below sentence from this recommendation be deleted, modified, or left the same, and that is that last sentence.

DR. WILLIAMS: The last sentence really relates to what we were talking about in terms of exploring different options. So that should go into the report relevant to, I think, Recommendation 3.

DR. EVANS: I agree. So I think what Marc is saying is that this should be inserted into the report where we discuss Recommendation 3, okay, and this stands on its own as a recommendation that basically calls for a clarification of legal question. Does that make sense to people?

MS. WALCOFF: I just want to make sure I'm clear. So in terms of the clarification of the legal question, but then we had discussed earlier, and this is what you just said, Marc, folding the rest of that into the earlier -- or are you still saying --

DR. WILLIAMS: Actually just referring to the last sentence be folded, but I think that, as I was listening to this again, we're sort of presuming in the

recommendation that we think we know what they're going to find and here's some things that you could do.

I would basically limit the recommendation to just say seek clarification on this and then you could put again in the text of the report here are some of the specific issues that are coming up that we need clarification about. So I don't think we need to clutter the recommendation per se with all the rest of it.

DR. EVANS: So you're saying --

MS. WALCOFF: It's really just the first sentence?

DR. WILLIAMS: Yes

DR. EVANS: Yes. So you're saying take this and fold it into the report, as well.

DR. RODRIGUEZ: I would just agree with that because I think otherwise that language is premature before we have --

DR. EVANS: That makes sense. Okay. All right.

DR. RODRIGUEZ: I also just a question on the last sentence that was suggested to be moved under the discussion for Recommendation 3 because again that's directive in the sense that the committee's stating that

this should happen with regard to making the best practices a condition related to grant award, and we're saying, as it goes into under 3, it will be something that's explored.

DR. EVANS: I'm sorry. I was preoccupied. Say that again.

DR. RODRIGUEZ: The sentence that Marc suggested be moved under Recommendation 3 about where the committee states that they should direct NIH to make compliance with the best practices related to consideration for future grant awards, that would now be more conditional under Recommendation 3 where there's --the actual recommendation is to explore the authorities that are possible.

DR. EVANS: Right.

DR. RODRIGUEZ: So this response statement would not be there.

DR. EVANS: As a condition of that discussion of Recommendation 3. Is that what you're saying?

DR. RODRIGUEZ: Right. So that I think there's a question to be asked and answered with whether or not that authority exists.

MS. CARR: May I just ask you, though, could you not also put it under -- as part of what's left of this

recommendation because isn't one of the issues here whether NIH or the Secretary has authority to --

DR. RODRIGUEZ: Right. I think it's related to clarifying.

MS. CARR: It is. So it would stay here with this recommendation.

DR. WILLIAMS: I'm not sure, Sarah, because this is really -- as I understand it, this is relating to that we're suggesting that we explore whether this should be an element that would be part of the grant review and scoring process in terms of -- that's how I read this and if that's the case, that's not Bayh-Dole, is it?

DR. EVANS: Well, yes, I think that the question is does Bayh-Dole allow her to use that information, right, and, if so, what we're saying is then she should direct the NIH to make compliance with it a condition of granting.

So I actually do think this probably belongs in the discussion of this recommendation.

DR. WILLIAMS: Okay. All right.

DR. RODRIGUEZ: It's relevant to both recommendations because it will depend on the answers in exploring her authorities under Recommendation 3 and the

analysis of Bayh-Dole.

MS. CARR: Actually, isn't this, the first part of this, of Number 7, like the most overarching thing for what's now Number 3?

DR. WILLIAMS: That was the question that I was wondering now, too.

DR. EVANS: Yes.

DR. WILLIAMS: In some sense, as we look at the ordering of the recommendations, that this may proceed because that may well define what is within purview and what isn't.

DR. EVANS: Yes. So maybe we need to --

MS. CARR: I think this falls after 3, I think, because 3 has the possibility of affecting people that interact with fundees. So 3 might affect more people than --

DR. EVANS: So we can discuss this. Okay. I'm pointing on the computer. You guys probably can't see that. Okay. So we could discuss this in relation to this, but we could also emphasize its relevance to 3 and put them together, yes, yes, and so put 3 and current 7 adjacent. I don't want to make a mistake and think we're fusing them.

Right? Okay.

All right. So are people okay with this? This then would be the recommendation.

Because it is unclear whether the Bayh-Dole Act gives agencies authority to influence how grantees license patented inventions, the Secretary should seek clarification about this legal question.

Then in the report, we would discuss this issue of using that authority to influence funding decisions as we discuss this recommendation and then we would take this information where we discuss Recommendation 3 about promulgating regulations that enable the department's agencies to limit ability of grantees to exclusively license.

All right. All in favor.

[Show of hands.]

DR. EVANS: Okay. All right. I know. We have 6D, right. I'm aware of that. All right. Let's just keep going and then we'll go back. Okay. So you think we're on the last slide but we're really now. We have to go back to one more.

8. Providing needed expertise to USPTO. This is

something we asked the USPTO representative about. As I recall, the comment was we'll take all the advice we can get. I don't want to put words in their mouth, but I don't want to overstep bounds either.

I don't want to say -- I don't want to force an advisory kind of board on USPTO if they don't want it or don't need it, but that was not my sense from the Task Force, just to get that out there.

So this says that the Secretary should recommend that the Secretary of Commerce advise the USPTO to establish an advisory committee to provide advice about scientific and technological developments related to genetic tests and technologies that may inform its examination of patent applications in the realm of human genes.

The committee believes experts in the field should 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.

DR. WILLIAMS: So again, it seems to me that this would be a role that could be defined under that previous

group.

DR. EVANS: Yes.

MS. DREYFUSS: I thought that this group is really about scientists, that it's the scientific advice that we're wanting to give the PTO rather than the stakeholder kind of advice.

DR. EVANS: That's a good point.

MS. DREYFUSS: I mean maybe we want to do that other thing, but --

DR. EVANS: Because we are talking about scientific and technological development.

MS. DREYFUSS: I thought it was that, but maybe a bigger role would make some sense.

MS. WALCOFF: Does OSTP advise USPTO, at the risk of using a billion letters there?

DR. EVANS: I'm confused.

MS. WALCOFF: The White House Office of Science, Technology, and Policy advise the USPTO.

DR. EVANS: I don't know.

MS. WALCOFF: The Patent and Technology Office. I mean, I'm wondering if that already exists and maybe there just needs to --

MS. DREYFUSS: I was at a National Academy's committee once and we explored this question of who gives advice to the PTO and the PTO at that time was saying that they really would like more advice than they actually get, that they're left sort of on their own quite a bit, but that was about avenues for finding out more scientific information rather than information about sort of the economic value of patents and things like that.

I mean, if you think about a broader committee, it would be about the economic place of patents in the overall system of promoting innovation, but that's not what I know the PTO wants. What the PTO has said it wants is more actual science, scientists who actually understand where the technology is right now, how much this new advance really is different from something that a person of ordinary skill in the art could have done, how broad is the technology, how broad are the claims, and really science-type questions.

MS. WALCOFF: Right. It seems like, I mean, they can certainly ask the White House for that kind of information and that kind of focus, I know, for OSTP. So I'm wondering in terms of recommending to another Secretary

to do something, I'm just thinking is there a possible way to alert to existing resources and suggest that those be drawn upon or that they expand what OSTP is currently looking at.

MS. DREYFUSS: OSTP is more science policy. It's more science policy role than what's the actual science of this widget technology.

DR. EVANS: My initial reaction, as we were discussing this in the Task Force, was kind of, I thought, well, you know, this probably exists and do they really want the advice, but as we queried the USPTO, that didn't seem to be the case. So this did seem, kind of to my surprise, as something that would be welcomed.

DR. BILLINGS: But do we want them to establish an advisory committee or do we want them to take heed of these issues that we've raised and change patenting policy?

DR. EVANS: Well, we're trying to help them do that. I mean, this, I think, actually is not designed to change patenting policy. This one. I mean, we certainly have ones in there that are, but this one, I think, is saying, look, it's a rapidly-moving field, both technologically and legally. It would behoove the

Secretary or it would behoove everybody if the Patent Office had some technical experts that were on call to --

DR. BILLINGS: But we're not the only field that has this issue, right?

DR. EVANS: That's what I said. That's what I said when we were discussing this and to my surprise, and it sounds like Rochelle got the same reaction, the USPTO is like, yes, we'll take that. So this surprised me and I don't want to put words in their mouth, but I understand your reaction, I had the same reaction, but it sounds like -- and what we could say, we could use Gwen's recommendation. We could leave it looser and say an advisory body.

DR. BILLINGS: How about advisors?

MS. WALCOFF: Making it so siloed, I mean maybe this should be something where USPTO and the science advisors are all with this interdepartmental, whatever we decided to call that earlier, group and then everyone's talking to everyone, instead of creating a lot of independent bodies that do exactly what we do.

DR. EVANS: Yes. Again, that's interesting. The only issue with that is that, as Rochelle points out, the

intent of this was to try to really hone down on the technical issues in this rapidly-changing field in light of -- things like non-obviousness are a very technical issue. Is it obvious to a person versed in the art?

So the only problem with kind of folding this into that previous body is that that has all this membership of policy people and we're talking here about science.

MS. DREYFUSS: Part of the problem the PTO has is that for each new science, they really need new advisors. So you can't have like a standing committee that's going to help them because the next science, the next new thing, we have no nano technologists here, even though who knows what nano technology could do for genetics. So they really need the kind of people that will help point them to the right people to ask about new things because if they just chose somebody, they could choose the right person, they could choose the wrong person. If a stakeholder tells them to choose somebody, you always wonder whether that's a biased person. So sort of a neutral advisory committee to help them kind of ferret out who the right people to talk to is more along the lines of what I was thinking about, the way

I understood what they wanted.

MS. WALCOFF: You want to identify experts?

DR. EVANS: No. Advisory committee to provide advice. So I think what we would want to say is perhaps establish a body of scientists or technical experts to provide advice about scientific and technological developments.

MS. WALCOFF: Rochelle said we don't want a standing committee.

DR. DALE: I was going to suggest something a little short of that and that is, that the Secretary explore a liaison relationship with this committee, with the Patent Office, on issues related to genetic technologies and then see where that goes.

DR. EVANS: Yes. I like explore because I think there's enough uncertainty around the table here that we're not sure we want to say you gotta do this. So help me out. Something like this.

Advise USPTO to explore the establishment of a -- and now you're going to see my horrible spelling.

MS. CARR: We actually already have a representative. Michael Amos is from the Department of

Commerce. He sits on this committee. He's from NIST.

DR. EVANS: Between this committee and USPTO.

MS. CARR: Were we thinking of something more than that?

DR. DALE: It could be more specific. We could leave that to the Secretary and the Patent Office.

DR. EVANS: What if we say the Secretary and the Secretary of Commerce should explore? Can we say that?

DR. FERREIRA-GONZALEZ: Do we have an idea how often they would need this advice? I mean, is it something that we need? So that's what I mean. Do we need a different kind of advisory group?

MS. DREYFUSS: Think about this. The USPTO's granting these patents on gene sequences long after sequencing was really easy to do and they were still granting them up to, what, last year when the federal circuit finally said wait, maybe not. That's a kind of a problem and at the same time as our committee's doing this, there's also a committee exploring how much the PTO should be owed deference by the federal circuit so that when the PTO says something is obvious, the federal circuit would then pretty much have to say, unless there's some clear

reason to think it's wrong, we're going with the PTO's decision.

So that kind of thing happens fairly often. Technology is patenting, patenting, patenting. Nobody's saying wait a minute, everything in this field has changed. There's now 10,000 machines that do all of this automatically. You don't need patenting anymore. So that's the advantage of a continuing relationship. So I like the liaison idea.

DR. EVANS: Look. I spelled liaison right.

MS. DREYFUSS: The second time around.

DR. EVANS: With Spell Check. Okay. So what about this? Again, just throwing this out there, I don't know if I've captured what people want. Let me get it here.

The Secretary should explore with the Secretary of Commerce, because that's necessary because of the USPTO, a liaison relationship between this committee and the USPTO which would provide advice about scientific and technological developments related to genetic tests and technologies that may inform its examination of patent applications in the realm of human genes.

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 are --

MS. DREYFUSS: How about provide advice or that would recommend advisors?

DR. EVANS: Okay. So you're saying that this committee would recommend advisors?

MS. DREYFUSS: If the PTO is having trouble identifying people.

DR. EVANS: Forget the liaisons?

MS. DREYFUSS: "Provide advice and identify advisors."

DR. EVANS: "Would provide advice" --

MS. DREYFUSS: "And recommend."

DR. EVANS: -- "and recommend technical advisors" -- I'm losing it here -- "and recommend technical advisors who would provide" -- say what? -- "would provide input about scientific and technological developments related to genetics." Okay.

DR. BILLINGS: You could take the second sentence

out.

DR. EVANS: This might go in the report. Okay, so in the report's discussion of this rec.

So what we've got, at this point, is: "The Secretary should explore, with the Secretary of Commerce, a liaison relationship between this committee and the USPTO, which would provide advice and recommend technical advisors who would provide input about scientific and technological developments related to genetic tests and technologies that may inform its examination of patent applications."

It could use a little tweaking, which, we can tweak this so it doesn't sound like William Faulkner on drugs. One bestial sentence, then in the report we would discuss those things.

Do we have approval for this? Approved? Okay. So 6D is the last one. We really are about there. Somehow I spaced this out. Are we done with that?

[Recommendation] 6D, all right. "Federal agencies should provide more detailed guidance regarding the licensing of patents associated with genetic tests. In particular, this guidance should encourage the use of terms in licensing agreements, particularly those with

exclusivity, increasing the number of insurers that reimburse for the test or improving the specificity and sensitivity, or examples of milestones that a license could be required to meet, or to earn or to maintain license rights."

So what this is saying is that there should be more guidance about the kinds of milestones that need to be adhered to in terms. Does this rise to the level of a recommendation? Is this something that should be in the report?

MS. DREYFUSS: A different question. What about the recommendations that Sheila started with, about more ways of getting funding for sole-source tests or for poor people?

MS. WALCOFF: I'm reading this differently, as increasing the number of insurers that reimburse for the test; whose responsibility would that be.

DR. EVANS: Yes.

MS. WALCOFF: That's a milestone for the company.

DR. EVANS: Well, that came up with discussions. Again, look what Myriad's done. They've been able to steadily increase the number of payers

that --

MS. WALCOFF: I think everybody would like to have more payers.

DR. EVANS: Right, right.

MS. WALCOFF: But all those individual contract negotiations, and I am not sure that we're not reaching, a little bit, into that with something like this.

DR. EVANS: Yes.

MS. WALCOFF: I think what you were thinking of, Rochelle, was related but different on the other side. We don't have a reimbursement recommendation, and that seems to be, to me, the biggest crux of this report.

DR. WILLIAMS: I would say two things. One is, this specific recommendation isn't specific enough to what the Secretary can and can't do and includes some things that I think the Secretary really does not have. I mean, federal agencies. The only federal agencies would be the ones that are actually under Department of Health and Human Services.

MS. WALCOFF: Which would mean CMS.

DR. WILLIAMS: The other issue is that the report that we have issued on reimbursement, there is no reason

why we couldn't include language, as we have done in other instances, that says we have addressed a number of issues relating to reimbursement of genetic tests. The patenting issues that are outlined in this report are another impediment to this, but an overall solution to reimbursement reflecting these previous recommendations is still needed.

MS. WALCOFF: Isn't it direct to the whole patient access issue? I mean, it seems like a lot of this report talked about reimbursement and the resulting challenges in reimbursement on patient access.

DR. WILLIAMS: I'll speak for Sam since he can't speak. He is not fully vetted. I think I'm vaccinated against what he's not vetted for, but I'm not sure.

The issue from the payer perspective is that they would not equate reimbursement with access. They would say that patients always have the ability to access services if they're willing to pay out of pocket. So then it refers to issues of health and equity, and then you say, well, yes, we understand the healthcare system is inequitable in the way it's currently configured.

Is it our job to solve all the problems of the

healthcare system, or are there specific issues here that are very narrow that do in fact impact access and reimbursement?

MS. WALCOFF: It sounded like Medicaid was that issue.

DR. WILLIAMS: I didn't bring this up because I really didn't want to muddy the waters, but the reality with Medicaid is that each state defines its benefits. In the State of Utah, the benefit package says, we do not cover genetic tests. It's not a contracting issue.

DR. EVANS: In many, many states, it is.

DR. WILLIAMS: But in other states it is. I'm just saying that we shouldn't delude ourselves into thinking that somehow the Secretary can do something in the Medicaid system that is going to fix it.

The other point I would make is that, while Myriad has in some ways solved the Medicare problem, the way they solved it was in a very unique way. They are located in Utah. They went to the Medicare carrier for the State of Utah, and that carrier issued a local medical decision that covered that testing. What they have told every other Medicare carrier is that, because we're located

in Utah, this is covered by all Medicare.

DR. EVANS: Well, and I think also what was on their side was that it became more and more clinically useful.

DR. WILLIAMS: Well, I'm not disagreeing with that, but I'm saying that the mechanism by which that reimbursement was accomplished was basically by playing some of the little funny issues about how Medicare's actually administered at the state level. So again to presume that somehow this happened because of a national fiat is delusional.

DR. EVANS: So we've got to get back to 6D. The question is is there a role for a recommendation, that there is a need for more detailed guidance regarding licensing of patents, about terms in licensing agreements, et cetera, and, if so, does that rise to the level of a recommendation or should this be basically a part of the report?

DR. WILLIAMS: I mean, it seems to me that this is one more part of exploration of what can we do around this and is there guidance needed? So in some ways, doesn't this reflect a general exploration of this that we

referenced under Recommendation 3 or whatever? I mean, I'm not seeing anything necessarily unique or new here.

DR. EVANS: That's kind of my feeling. I mean, my feeling is that this is not too different from the previous recommendation, that it could be folded into the discussion of that recommendation.

MS. DREYFUSS: And also, actually, the Recommendation 7 where you're asking for clarification around Bayh-Dole of what licensing terms you can do, so we don't even know yet whether or not we can put forward or we can take forward guidance in this regard.

DR. EVANS: Right. In fact, what that leads me to feel like is that perhaps this should be folded into the report where we discuss Recommendation 7.

How do people feel about that? All right. Sam?

DR. NUSSBAUM: First, I will speak. Marc did a beautiful job in representing a viewpoint of the health insurers, but there is a fundamental issue here that I think needs to be addressed, and that is that if these tests, sole-source or others, become very expensive and they're not covered as benefits, then I think it's important for us to recognize that we have an access issue.

While coverage decisions are generally based on science and on clinical results, I think it would be important, somewhere, to write in a review of whether these tests are being offered to communities, to citizens. I think you can do that without trying to mandate what insurers or what Medicaid or Medicare --

DR. EVANS: Within the report?

DR. NUSSBAUM: I think so.

DR. EVANS: Give me some wording. What would you say?

DR. NUSSBAUM: I think one would want to look into these. When genetic tests are proven of clinical merit, we would want to be sure that they're provided broadly in insurance policies and in Medicaid/Medicare as payers.

I think one of the debates can be that people can write out preventive services. They can write them out, just as we talked about, and I think you would want to be sure that that is not occurring in a drive for affordability.

DR. EVANS: Yes. So as genetic tests are incorporated into medical care, it will be important to

ensure that they are included in --

DR. NUSSBAUM: Benefit structures and coverages by governmental and non-governmental payers and this could be reviewed in a responsible --

DR. EVANS: Governmental and non-governmental payers.

DR. WILLIAMS: And the other thing we could reference in there is in our letter to the Secretary regarding the reimbursement issues, to kind of update that report and highlight new issues.

One of the things that we did specifically talk about was the opening of the Medicare National Coverage Decision and the Medicare Advisory Committee to evidence-based assessment and so some reference to saying that we've mentioned genetics in this context before and this would be another place where this could be -- again, just reinforcing what we've said in numerous other situations.

DR. EVANS: Okay.

MS. ASPINALL: Can we add a piece here that I had mentioned earlier which is streamlining the process for diagnostics to be able to -- for diagnostic providers to be able to provide -- I don't know if we call it free testing,

but testing available to -- well, free testing, for lack of a better word right now, and simplify and streamline that process because right now, as I've heard from physicians at all sorts of institutions, it is considered a kickback. You can't do it and as you described earlier, it's a very cumbersome process today that needs to be streamlined so companies would have the ability to do it.

DR. TEUTSCH: Help us focus. What would the Secretary -- what are you advising that the Secretary should do? What would our recommendation be? I think the issues --

MS. ASPINALL: The recommendation in the same context of this and reimbursement is to consider -- to explore, understand, and streamline the process for indigent testing.

DR. EVANS: I'm not sure if it rises to the level of a formal rec, but what if, in this discussion, in the report, we put as genetic tests are incorporated in medical care, the importance of ensuring they're included in benefit structures covered by governmental and when -- I guess when not covered, that the mechanisms for providing -

-

MS. ASPINALL: Well, you can include in there review the relevant mechanisms for --

DR. WILLIAMS: Examine the barriers is what I'm hearing, right?

MS. ASPINALL: Yes. To approval, because it's not only one issue and it's, quite frankly, bigger than genetic tests, patented or not, but this is something that has become more of an issue, particularly -- and this was two of the letters that came in to say there's been perceived criticism directly here, saying they're too expensive.

One of the ways to deal with access is to allow this to happen.

DR. TEUTSCH: Can you write some language?

DR. EVANS: That would be great. Could you write something that could go in the report, because I'm not sure how to do that right now.

MS. ASPINALL: Yes.

DR. WILLIAMS: It fits within the exploration piece, because there are a number of different pieces that roll into this. It has to do with STARK and STARK II.

MS. ASPINALL: That's exactly the issue.

DR. WILLIAMS: It has to do with the statutory things. I know it's statutory for its rules within Medicaid, that to say, here is what you can or you can't do in terms of discounting.

DR. EVANS: I mean, this sounds like a laudable goal. The thing I wonder about is, is it at all unique to genetic testing? It sounds like a very overarching thing.

MS. ASPINALL: Well, several of our recommendations are not unique. We talked about genetic exceptionalism, I think, three days ago when we got into this room.

DR. EVANS: Come up with something.

MS. ASPINALL: Not specific, but it's relevant to the reimbursement piece.

DR. TEUTSCH: It's related to the sole sourcing issue, right?

MS. ASPINALL: I used it as a sole sourcing issue because it's often used as an example of why sole sources can't do it, but, quite frankly, it's relevant more broadly when you have an indigent patient and you have a test you want to get done.

DR. TEUTSCH: So help me here.

DR. EVANS: Are we talking about charity care?

MS. ASPINALL: I would describe it more broadly and I know patient advocates would not call it charity care. It's for people for whom, for whatever reason, whether they're insured or not, do not have access to the test and for the companies and laboratories, academic, university and otherwise, to have a streamlined process to do it, and to make people aware of what that process is, because unanimously they all complain about that.

Sole-source test is one area, but if the test is \$500 at everyone's lab and they can't afford it, it doesn't have to be sole sourced.

DR. EVANS: Okay. So Mara will address streamlining the mechanisms by which labs/companies can provide testing when not covered. Is that right?

MS. ASPINALL: We can work on the language. I think it's just laboratories. It doesn't matter where they are.

DR. EVANS: Got you. Okay.

DR. TEUTSCH: Paul.

DR. WISE: Paul Wise from Stanford. The last two issues relate to more generic equity issues, and I've kept

my mouth shut pretty much all day because, as somebody who focuses on disparity reduction, I was content with the conversation focusing specifically on patent issues.

The fact that we're bringing in more generic issues diminishes the equity arguments because it makes it a peripheral clause within a subcategory on one of the less exciting recommendations.

If we're going to include this, which I think would be fine, then I would suggest in the recommendation a preamble that says this is merely one component of this committee's concern, or set of recommendations for ensuring equity in the provision of genetic-related tests and services and therapies, period.

We would remind the Secretary that earlier reports, like the reimbursement report and other components of equity issues, that have come up in prior things that have not been acted upon are also relevant to this conversation. Then, in an appendix or someplace, list the recommendations that came through the relatively recent reports that address the issue of inequitable provision. Otherwise, my concern is that we're really peripheralizing this issue merely by putting it in in this small way.

So my general suggestion would be to have an intro or a preamble.

DR. EVANS: So we need to go back and rework the wording of the recommendation here?

DR. WISE: Not the recommendation but the set-up of the recommendations, to ensure that the context for this report and its recommendations is really part of a much larger commitment from this committee to equitable provision of relevant tests and services, and reference, if you will, the other relevant recommendations from prior reports that speak to this issue.

Closing Remarks

Steven Teutsch, M.D., M.P.H.

DR. TEUTSCH: I think the hour is late. It seems to me there are a few things.

One is that Jim is probably going to have a busy evening.

Sam, did you want to say something first?

DR. NUSSBAUM: Just again it's because of my newness to the committee and clearly this has been a five-year journey, Jim, that you have led so many of our colleagues on and congratulations, and I would have been

voting largely with you, but having said that, at the very beginning there were some really substantive issues, and it seems to me that a minority of the committee and what we heard from public comments are strong views and they're not nuanced views. They're 180-degree viewpoints that are different.

I guess the question that I have, since these are complex legal issues that are going to be determined in many ways, perhaps in courts, is there room, in past deliberations by this group, in the body of succinct minority representation, to say, here are some concerns that did exist?

Because I think that, while voices have been heard -- we've heard a little bit about balance, we've heard a bit about the evidence -- these are case studies, but the evidence, perhaps, isn't as strong as we would all like, and I just wonder if that's something that would happen or not.

DR. EVANS: I guess this is probably a very long discussion. My feeling is this, we don't issue minority reports in this committee, we hash things out. We try to produce as balanced a report as possible that includes

various issues.

I am not in favor of some kind of minority report that then dilutes what we have had a hard-fought battle to achieve consensus on, and I would say have done so with a relatively decent proportion of the committee that endorses these things. So, no, I'm not in favor.

DR. BILLINGS: Is there a precedent?

DR. TEUTSCH: I mean, the report can talk about some of the challenges and some of the --

DR. EVANS: I think we do. I have been told on numerous occasions that this especially has brought balance, et cetera, et cetera. So I think the place for trying to discuss the controversies is the report.

MS. WALCOFF: Has there been a report before, where you have not had unanimous agreement?

DR. EVANS: Oh, yes.

MS. WALCOFF: Which one? I don't remember one.

DR. WILLIAMS: Oversight was clearly not a unanimous report.

MS. ASPINALL: I thought, in the end, there were no 'no' votes.

DR. NUSSBAUM: I certainly understand that.

Perhaps, then it's just writing the final document to include some of those issues in a more direct way.

DR. EVANS: I'm very sensitive to that, and we will do that.

DR. WILLIAMS: Of course, all of the comments and all of the written public comments, the oral public, they are all available in the public record, and they are all associated with the report.

Now, we all recognize that not everybody will read those.

DR. EVANS: But, look, that's the way it goes. I mean, I think we have accommodated diverse viewpoints. We have had an extraordinarily open deliberation process. We have had abundant public comments and we've had time for discussion. I think that you can't make everybody happy, and I think you dilute the purpose of the report if you now start issuing alternate minority reports.

MS. ASPINALL: Jim, I have to disagree with that. I mean, at least what I heard Sam say is not alternate minority reports in any way, shape or form, because the vast majority of the information and the discussion is there. I was parts of much of it, and part of the team was

much of it.

I think that there are a couple things. One is, to acknowledge the dissenting views.

DR. EVANS: I think we do that in the report.

MS. ASPINALL: It was not just one, and I think that that's important. I don't see that in the report today. I didn't see it in the summary slides today.

I made a comment earlier that I didn't see the summary slides today truly represent the breadth of view from the public comments, in addition to some factual changes which are relatively small on the piece of it.

I think we need to acknowledge that to ensure that that is represented because, while all of this is public, it's not going to get out and people are not going to read the 101st letter, or even the first letter in there.

DR. EVANS: I certainly think that we can look at the report to try to make sure again, as we've done the whole process through, to make sure that minority opinions are represented. All right? But they are minority opinions and I do not think that we should delay approval of this entire report --

DR. TEUTSCH: Jim, I'm going to step in here because I'm not hearing people say that we should delay approval of the report or the recommendations.

What I'm hearing is that some people do not feel that some of these perspectives are represented as well as they might be, not that they need to carry the day -- we've had the discussions -- but as we go through and finalize the report, that we make sure that some of these perspectives are clear and incorporated.

I would ask those of you who hold those minority reports to provide us the specific places where you think they don't come out clearly enough --

DR. EVANS: With specific wording.

DR. TEUTSCH: -- so we can do that, because at the end of the day, we do want people to feel like their voices have been heard and are recognized.

And so, I would ask you to please help us with that because I know Jim, to the best of his ability, has listened to this committee, the Task Force, to try and do that. If it is not coming through clearly, please help us do that in specific ways so that we can move it forward.

MS. ASPINALL: I appreciate that, because I think

Jim has listened, but it was written as the majority, which is the intention.

DR. EVANS: This also gets very convoluted because the insertion of certain statements can then change the entire thrust of the report, which then makes the recommendations paradoxical. We have to be very careful.

DR. TEUTSCH: No, no, no, no.

MS. ASPINALL: Let's issue a majority opinion. That's what holds is a majority opinion, but you see what is the logic that says there's a different way to think about it. We're not saying changing the sense of the report. It is pages and pages and pages.

DR. EVANS: As long as we can do it without making the report a disjointed and self-contradictory entity, that's fine.

DR. TEUTSCH: No. I think we can do that and I hope we can.

MS. ASPINALL: I think therefore having it almost separate is actually a better way to do that, but we can do it as an integrated one.

DR. TEUTSCH: There may be notes at the bottom. The committee took note of other opinions. There are ways

that we can do that.

DR. EVANS: Right. And these were discussions we had at Task Force meetings over and over.

MS. ASPINALL: I recognize there was much discussion about it. I acknowledged at the beginning it wasn't that there wasn't much discussion. It's just that the final report, if anything, as one of the public comments made, had hardened in a position that had fewer broader issues discussed.

DR. NUSSBAUM: It strikes me that critics and criticism will be muted if in fact the issues are shared.

DR. EVANS: I completely agree. I would maintain, and I've had a lot of feedback, that it is balanced. Now, if we can achieve greater balance, that's great. I'm all for it, but I just don't want to gut the report or, essentially, start over.

DR. NUSSBAUM: Jim, let me be straight. Again, I read this with a fresh set of eyes, not the five years of intense -- I think it's extremely well done. As I said, there's clarity. Look at the way the vote has come down on the recommendations.

I think from what I've heard from the public

comment, and as I read it, I thought there could be, particularly since it was case study method, not pure science, there could be a reflection of other viewpoints in it, not mitigating at all the impact of the final discussion.

[Whereupon, at 6:02 p.m., the meeting was recessed to reconvene the following day.]