

**Overview of Revised SACGHS Report *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests***

CHAIRMAN TEUTSCH: So we'll begin with a discussion of the gene patents and licensing reports. This was sent out to the committee in January so I hope that all of you have had a chance to review it.

Before we get into that I did want to let all of you know that we did have an opportunity to brief the Office of the Secretary, the U.S. Patent and Trademark Office, and the Office of Science and Technology Policy on the conclusions and recommendations on the revised report.

At our last meeting in October we voted on the recommendations individually and then collectively with a collective vote of 12 to one in favor. There was one abstention. We were advised to form a small subcommittee to work on the report to take care of a number of important issues. One of—and I want to go over those with you now because those represent the major changes that were in the report.

The subcommittee itself was composed myself, Jim Evans, Gwen Darien, Rochelle, Sheila and Paul. I think I got everybody, right? That's the group.

And this group did an incredible amount of work since the October meeting. You will see that the report was substantially revised and a dissent was incorporated since we could not get to unanimity on all the issues.

But the major things that we were asked to do were to strengthen the rationale and conclusions. Paul had advised us that somehow we weren't—we had a lot of material in there but we had not pulled it all together as strongly and coherently as we did, so you'll see that the conclusions and rationale that precede the recommendation has been added.

Paul Wise advised us that the timing of the report was not as tight and coherent as it should be with our main agenda item to enhance patient access and the quality of tests that are available. So thanks to Paul W., who undertook the task of making sure that we got that framed properly, that was then done.

The body of the report was changed

substantially, too. At the October meeting and really throughout the process we knew that there were substantial differences of opinion, and that we needed to incorporate as many of those perspectives as possible in the report, and so this report was substantially revised to do that. And I have got to say that that was a product of the subcommittee but the subcommittee could not have done this without the unbelievable writing, re-writing and re-writing again of Darren Greninger and the staff.

So the report that you all have had a chance to review is substantially changed and, I think personally, substantially better than the report that you saw in October.

So that's where we are.

I must say that although there is a dissent here that people who worked on that dissent did us all a tremendous service because it helped sharpen the points that needed to be made though, as I said, we could not bridge all of the differences, and hence the dissent is there. I think we should recognize that without that prompting and prodding and pushing we

would not have the report that we have today.

So I want to express thanks to the dissenters, particularly Sheila and Paul, but I also want to acknowledge the incredible work that the other members of the subcommittee, particularly Gwen, Jim and Rochelle, did because I cannot tell you the number of calls, emails, nightmares that we have had over the last couple or three months to get all of this together.

So, the report is complete. It's here.

Our task this morning is to move it forward to the Secretary.

With that, I will open it up for comments or motions on the draft report.

DR. WALCOFF: Steve?

CHAIRMAN TEUTSCH: Yes, Sheila?

I just wanted to point out that you are the only one that I can tell that has a chocolate heart in front of you this morning.

(Laughter.)

And I'm wondering who came in early to put it there for all of your dedication and hard work on this

because it certainly wasn't lost on me and I think on the rest of the folks that worked on this for years and years and years before I got here and then certainly in the last three months, and I just wanted to thank my colleagues on the committee for doing such a great job and working so hard because it was an interesting process but I think one that it's a better place now and I'm the only commenter, and you can eat your chocolate.

I will move to close the report and move it forward.

CHAIRMAN TEUTSCH: All right.

MS. ASPINALL: This is Mara and I'm going to shorten this. While I was involved in the second part of the report—the second part of the report more intensively than the first part of the report and the initial piece. I believe the process or the one that we came to was appropriate, effective, and we should move on to more important—the additional new work from the committee that will be important in the future, and look to have this as now a representative report of the majority of the committee and to have the dissenting

opinion.

I am very much appropriately really want to thank Steve and Jim and Sheila and Paul, and everyone for the opportunity to have in their representation of the other perspective but I think the process itself was one that was critical to acknowledge.

DR. : I just want to second that in the--from the atmosphere of this love fest here--

(Laughter.)

DR. : I want to second what everybody has just said. I think that the--while difficult at times--the dissent and the emergence of some degree of controversy really did sharpen all of our thinking about this. And I think it shows how good the process can work; how well it can work; and I also do want to second what Sheila said and really give an incredible thanks to Steve who remained incredibly calm during all of this and was able to keep everybody's passions channeled in a productive way. So thank you, Steve.

And I want to thank Darren who was unbelievable.

CHAIRMAN TEUTSCH: Thank you, all of you. It was a group process for sure.

So we have a motion on the table and that is a motion to move the--basically to approve the report as it is so we can move forward to the Secretary. Is there any further discussion on that?

DR. : There will be more chocolate hearts at the end for everybody else.

(Laughter.)

CHAIRMAN TEUTSCH: There will be more than chocolate hearts.

DR. : I didn't know--

(Simultaneous discussion.)

DR. : I was just thinking that he's the only one who didn't eat it yesterday.

(Laughter.)

DR. : I ate yours.

DR. : Okay.

(Laughter.)

CHAIRMAN TEUTSCH: All right.

Hearing no one else, all those in favor of moving the report forward, please signify by raising

your hand.

(A show of hands.)

MS. ASPINALL: Aye.

CHAIRMAN TEUTSCH: That's Mara.

How about you, Rochelle?

MS. DREYFUSS: Aye.

CHAIRMAN TEUTSCH: I think we have a unanimous vote of all of those who are here. So we will—

DR. : (Not at microphone.)

CHAIRMAN TEUTSCH: --approve the report to move forward and I again want to express my gratitude. This has been a long process. I think we've learned an incredible amount about the patents and licensing process, more than I ever imagined I would ever learn.

DR. : Or wanted to know really.

CHAIRMAN TEUTSCH: And I really want to thank the task force for all of its work again and for all of those of you who have spent an enormous amount of time and energy and really high level thinking to bring this to completion.

So thanks again to everyone.

