

- GENE PATENTS AND LICENSING -

Overview of Public Comments on the  
SACGHS Consultation Draft Report

James P. Evans, M.D., Ph.D.

[PowerPoint presentation.]

DR. EVANS: First, I want to express a huge amount of thanks to the taskforce members, who have spent a lot of time and who are now going to spend more time, now that the public comments are in. This has been a difficult process. I also want to thank the public because the response was very good. We got a lot of great comments.

The public comment period closed as of May 15th. We received a total of 77 formal comments on the draft report. They amount to 392 single-spaced pages. I have read them all and I'm going through them a second time now. They range from seven lines -- I think that is the shortest one -- in an Email, to 82 pages.

They come from a wide variety of sources. As you can see up there, there were 11 from professional associations, 16 from tech transfer officers. Industry organizations and life science companies represented 11 comments. Five were contributed by academic organizations,

nine from health care providers, four from laboratories and laboratory managers, and 12 from private citizens. They were virtually all clearly well thought out, methodical approaches to the subject.

The responses themselves ranged over a wide spectrum. Adjectives used to describe the report in general included terms such as deceptive and fear-mongering, to beautiful, thoughtful, diligent, and intelligent. I did a word search for erotic and exciting and could not find those adjectives anywhere. We obviously have a long way to go if we are going to really involve the public in this.

[Laughter.]

DR. EVANS: I would say that the range of opinions that were presented reflects the openness of the process. This was a very open process, as attested to by the fact that we got lots of comments that range all over the spectrum.

I was worried about what we would see. It is scary to spend all of this time and to really sweat over this kind of thing and then lay all 300-some pages out there for anybody in the world to comment on. I really was

very gratified once I got looking at them.

The report was obviously criticized, at times pretty harshly. Criticisms were leveled from really opposite ends, from both ends of the spectrum, from those who have little desire to see any changes whatsoever in the patent and licensing landscape, to those who would like to see a whole-scale dismantling of the genetic IP landscape.

We really find ourselves, I think, at this juncture in a good position. We have a report that has been criticized from both sides. I think that is a good thing. I think it reflects that we have likely achieved some measure of balance.

The hard part now is going to ensue. It is going to be an interesting and possibly a contentious process, given the wide divergence of both interests and philosophies that people on this committee and in the public at large have about this subject.

I also think, however, that the diversity that is represented on this committee that generates that kind of controversy is really our strength. It has lent the process the balance that it has, I think, thus far demonstrated.

The next steps are that we are going to review, analyze, and discuss the public comments. We are going to go through them. Each individual on the taskforce has been assigned a group of comments. I'm not sure who got stuck with the 82-page one.

One of the obvious and really, in some ways, easiest tasks is to correct any factual omissions or factual errors that arose. We will do that in consultation with the consultants to the process, et cetera.

We will discuss the policy options, of course. I will remind the taskforce that our first conference call to go over these things is going to be Monday. As we discuss the comments, we need to keep in mind what our final aim is. Our final aim is to bring the full committee a series of recommendations to be made to the Secretary in this final report.

We will review in October the final taskforce proposed recommendations. They will then be discussed and hopefully some consensus can be come to around this table.

The way we are going to approach this as we discuss it at the taskforce level is that we are going to go through each of those policy options that we threw out

there to the public and identify which ones had general support for adopting that recommendation and which ones for which there was general agreement that we should abandon that recommendation and not pursue it.

Those that will be the most difficult will be those that had majority support on the taskforce but for which there was some dissent, and those which there was minority support for but the advocates for those want it aired and discussed by the full committee.

I think -- and this would be to Sarah -- we are going to have to have sufficient time in October to talk about these things. I anticipate there will be some disagreement. This isn't going to be like genetic discrimination, which I think we all pretty much agreed was a bad thing. It wasn't a contentious kind of issue. This is going to be contentious. There will be people who don't agree with our final recommendations.

I would also remind you as you look through those that, unless you really want to, you don't need to read the whole report. Look at the range of recommendations. Some of those are mutually exclusive. If we adopt certain ones, it precludes others. We need to keep that in mind, too, as

we go forward.

There may be something where one person on the taskforce says, I want this aired by the Committee even though everybody else disagrees with me. I think we should do that. I don't think we should stifle any discussion.

I actually made a note to myself that that 82-page one is one I want to go back and scrutinize more. I think I can learn a lot from it. It was really neat to see the range of contributors to the public comments. They ranged from patients and people who take care of patients, to industry groups, et cetera. It really gives you a view of how important this question is to people out there. Therefore, we have an important set of tasks ahead of us.

DR. TEUTSCH: I think it is, in fact, one of the things that this committee is really designed to do, to try and look at the variety of thoughts and tradeoffs and how to represent societal interests as best we can.

Thanks to Jim and the committee and all the staff. You have a little work ahead of you.

DR. EVANS: A special thanks to both Darren and Sarah, who have been really instrumental in moving this along.

DR. TEUTSCH: Before we wrap up and I give you some final comments, any other items or comments?

[No response.]

### **Closing Remarks**

**Steven Teutsch, M.D., M.P.H.**

DR. TEUTSCH: As we come to the end of the day, it has been a productive one. Thanks, everybody, for all your attentiveness and participation. I want to particularly thank the staff, who, as always, labor long and hard behind the scenes frequently. Whatever good comes out of this is largely due to their efforts to make us look that way.

I always want to thank Abbey and her staff, who took care of all the logistics. I don't know if Abbey is still here. We want to thank her for doing all that work.

For those of you who are planning to come to dinner, hopefully you have signed up outside. It is at 6:30 at the Heart and Soul. It is near the hotel where many of us are staying, 415 New Jersey [Avenue].

I would also recommend, as I have mentioned once or twice, please read the report in Tab 5. That is the draft on DTC that Sylvia is going to be discussing with us

tomorrow. We would like to get to some conclusions so that we can move that forward.