

**Next Steps and Concluding Remarks**  
*Reed V. Tuckson, M.D.*

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DR. TUCKSON: Three minutes. I just wanted to review, if we can get it on the screen. By the way, what you'll miss, those who are leaving -- but it's going to be terrific, but we can get it to you -- is the update on the genetic discrimination because that's so important.

So with two minutes left, if you look on the board. What did we get done? I want to just review this real quickly.

So pharmacogenomics. Revise the report and recommendations based on the input received during yesterday's session. Send revised recommendations to SACGHS for review prior to seeking public comment. Lewin to seek input of 15 federal and non-federal experts and stakeholders on various issues. Seeking public comment on draft report and recommendations. Good. Does this, so far, look like reality?

PARTICIPANT: Right.

DR. TUCKSON: Gene patenting and licensing practices. We're going to revise the study questions, scope, and time table based on input received during yesterday's session, and initiate literature review and public consultation process.

Does that seem like reality? Jim? Jim, your reality is on the board there. You need to look real quick and make sure that you don't disagree with those summaries, the take-homes on gene patents and licensing. Revise the study questions, scope, and time table based on input received yesterday. Initiate literature review and public consultation process. Do you feel good?

DR. EVANS: Yes.

DR. TUCKSON: What is he going to say at this point?

(Laughter.)

DR. TUCKSON: Oversight of gene tests and testing laboratories in consultation with new work group. Prepare a letter to the Secretary expressing concerns about the adequacy of oversight, noting the forthcoming November meeting of CLIAC, but it will feature a case study illustrating the risks to the public's health due to current gaps in oversight. Oversight work group, which we have appointed, will do that proposal. The work group will also organize further fact-finding session for March meeting.

So notice that that assumes that even though you're sending the letter, you're going to put this on your March agenda, which I want to make sure everybody is comfortable with. You're going to get a report from the CLIAC, consultations with private sector organizations in New York State. We'll work with them in the interim. More in-depth discussion on FDA guidance. And folks may have some other things that will be fleshing that out as we get to that meeting.

Everybody, does it seem like it comports with reality? All right.

Large pop. Revise the report and recommendations based on input received during the morning session. Develop conclusion and executive summary. Circulate final report to SACGHS. Seek

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confirmation that the wording of the conclusion faithfully reflects today's sense of the committee from today's discussion.

But the real deal that you voted for was to transmit the report to the Secretary. So we're going to get it out the door. No fooling around anymore.

And lastly, these are some of the ideas that are being sort of proposed for the March meeting. Large pop update. Pharmacogenomics update. Gene patents and licensing practices session. Personalized health care initiative, AHIC. We talked a lot about all that integrated electronic data stuff, and we're going to have something more formal at the next meeting. Oversight informational session, question mark. To be determined. Possible presentations. Again, as we talked about, CLIAC. Also, I think CAP needs to be involved in this discussion.

So is the committee, in the last 10 seconds, comfortable? Are you all right? Do you feel like we got done what we needed to get done, and are you squared away for the interim?

(No response.)

DR. TUCKSON: Terrific.

For the three people only that are excused -- the rest of you are not. Just so everybody understands what's going on, we're gong to be able to have four -- Joe, you snuck in on this thing. So thank you all very much.

Last but not least, we do want to hear from Sharon Terry on the status. I'm sure you're going to have all kind of new insights because of the new Congress, and your predictions for all kind of new stuff. After that, we are done. So this is a good way to end up I think, and it really is a way to make sense.