## Framing the Session

***Reed V. Tuckson, M.D. and Andrea Ferreira-Gonzalez, Ph.D.***

DR. TUCKSON: Thank you all very much. We are right on time. Before we move forward on today's session, it's worthwhile, I think, to recap where we are since things were left in November on this issue of oversight of genetic testing.

As you recall, Judy Yost and Tom Hamilton of CMS reported to us at our last meeting the notice of proposed rulemaking on a genetic testing specialty was not going forward as planned. Instead, CMS decided to explore other avenues for strengthening genetic testing oversight that would be faster to implement and, in their view, equally effective; i.e., improving their website, providing technical training to surveyors on genetic testing, and collaborating with CDC to publish educational materials. We've already heard some public testimony today about that issue, and I'm sure we'll be revisiting it in the course of our discussion.

To our great enthusiasm, Dr. Ann Willey, Director of Laboratory Policy at Wadsworth Center, New York State Department of Health, provided us with some insights that were very useful about the New York State program. She also conveyed some concerns about gaps in the oversight system. We invited her back today and we are very appreciative that she came. We just want to thank her for that. If you can find a seat at the table at some point, we'll have you come up and be a part of this. We're very glad you're here.

In November, we were briefed by Steve Gutman on two new draft guidances from FDA clarifying the oversight of certain types of genetic tests. The first draft guidance clarified that analyte-specific reagents, which are the active ingredients in genetic tests, marketed in combination with other products or with instructions for use in a specific test, are considered test systems and are not exempt from premarket notification requirements.

Let me just read that again because that's technical and complex, and I want to make sure that you all catch that. That's why it's complex because Steve did it.

So what Steve said was that the first draft guidance clarified that analyte-specific reagents, those which are the active ingredients in genetic tests, marketed in combination with other products or with instructions for use in a specific test, are considered test systems and are not exempt from premarket notification requirements.

The second draft guidance targeted a class of devices called in vitro diagnostic multivariate index assays or, as commonly known, IVDMIAs, that use an algorithm to calculate a patient-specific result. The IVDMIA guidance clarifies that these types of tests must meet pre- and postmarket device requirements appropriate to their level of risk, including premarket review requirements in the case of class II and class III devices. There will be a quiz on that in a moment.

Later this afternoon, we would like Steve to give us a brief update on the status of these documents and the public comments that FDA has received about them.

During our oversight session, we also heard conflicting perspectives from our presenters about gaps in the oversight of genetic tests, and we struggled ourselves to define the nature of the gap. I think it is fair to say that while a gap exists, we were all extremely frustrated at the lack of a clear understanding of the specific nature of the gap and who was responsible for filling it. At the end of the first day, we reached consensus about writing a letter to the Secretary that we had identified

an area of ongoing concern and we agreed to try to illustrate the oversight gap with a specific concrete example of a problem caused by the gap.

We also agreed that we needed to find out about the upcoming deliberations on the CLIA advisory committee on the matter of CMS's decision not to go forward with the augmentation of CLIA.

On the second day of our meeting, we also decided that we needed to probe these issues more fully and understand all the elements of the oversight system to pinpoint more precisely where the main gaps lie.

We appointed a task force to draft the letter and to organize a fact-finding session for today's meeting. To our great pleasure, Andrea was convinced, arm-twisted to serve as chair. And her group has met twice since the November meeting. By the way, it's a small group. Two people. Who's on it?

DR. FERREIRA-GONZALEZ: Cynthia.

DR. TUCKSON: Cynthia and who? You and Cindy. Wow. A meeting in a telephone booth. So it's you and Cindy.

DR. FERREIRA-GONZALEZ: Maybe the new members will help us.

DR. TUCKSON: There has been some negotiation going on behind the scenes. Certain people have had their arms twisted, and Marc, if he's going to sling, will let you know that somehow or another he was convinced to join the committee. We may need another one as well, so we'll be looking as the discussion goes on for the calling, Kevin.

(Laughter.)

DR. TUCKSON: Not you. You're on another one. We just want you to facilitate the process of the calling at some point for someone to get the spirit to join in. If not, I'm spirited.

But this wonderful committee has discussed the content of the letter. They concluded that since the committee planned to engage in further fact-finding about the oversight system, it was premature to send a letter to the Secretary. They focused their efforts on developing a framework for this session, identifying speakers, and following through on our interests in CLIAC's recommendations. I think that based on the conversation this morning, the one we had just before lunch, it's pretty clear that things are now moving forward in a very organized and assertive way. So I think that's good.

So let me just thank Andrea for your effort in convening such a complex committee --

(Laughter.)

DR. TUCKSON: -- and planning this session. If you'll now go ahead.

By the way, I did my job, which was to fill until the 30-minute moment where the people should be on the phone. Is anybody on the phone? It's a videocast? I didn't know we could do that. So Wylie Burke and who else?

MS. CARR: Wylie, and Al Berg at the end of the day.

DR. TUCKSON: And Al Berg at the end of the day. But Wylie is going to be on.

Andrea, I get to do all the hard work. So before you get started, we'll make sure that Wylie is there. So what do we do?

DR. FERREIRA-GONZALEZ: Do I start the overframe?

DR. TUCKSON: Okay. She'll do the overframe.

DR. FERREIRA-GONZALEZ: Let's move to our presentations. First, we will have an overview of the oversight roles of federal, state, and private sector entities concerning the analytical and clinical validity of genetic tests. This will be followed by more detailed presentations on New York and other state systems. Finally, we will learn about private sector responsibilities for clinical laboratory accreditation, standard setting, and the development of clinical practice guidelines for genetic testing.

Our first presentation will provide an overview of the approaches in various sectors to provide oversight of genetic testing. As many of you are aware, Dr. Wylie Burke is a noted expert on this subject. In addition to her work at the University of Washington School of Medicine, she served on the NIH National Advisory Council for Human Genome Research and was on the Secretary's Advisory Committee on Genetic Testing, which is the predecessor to this committee. And hopefully, we'll be able to connect with Dr. Burke to hear her presentation.