Session on Oversight of Genetic Technologies and Genetic Testing Laboratories
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DR. TUCKSON: We're now going to turn to the session on oversight of genetic technologies and genetic testing laboratories. There is an issue brief on oversight in Tab 6 of your briefing books. I think it's important that you take a chance, if you haven't yet, to study that. To set the stage for our presentations and discussions, I'm going to review a bit of the background on this important issue, particularly for the members of the committee who are new.

Oversight of genetic tests has been a public policy concern for over a decade. Both FDA and CMS have responsibility for regulating genetic tests and for regulating genetic testing laboratories. Currently, genetic tests developed in-house by individual labs are subject to less regulation than commercially distributed genetic tests. Most genetic tests that are currently available are in-house genetic tests.

By the way, we're using this word "in-house" because we have banned the use of the word "home brew."

DR. LEONARD: But it's still not a house. It's laboratory developed.

(Laughter.)

DR. TUCKSON: Today it's in-house. We'll keep trying. At least it ain't home brew.

DR. LEONARD: At least you stopped me brewing, but I'm still working from home, you know?

(Laughter.)

DR. TUCKSON: All right, with that modification.

In addition, as we know from Judy Yost's presentation in June, regulations governing clinical laboratories, the Clinical Laboratory Improvement Amendments, or CLIA, are currently lacking specific provisions for laboratories performing genetic tests. Ensuring the quality and validity of genetic tests has always been a high priority for our committee and for our predecessor committee, the Secretary's Advisory Committee on Genetic Testing, SACGT. SACGT issued a report in July of 2000 that concluded that a critical gap existed in the oversight of genetic tests relating to clinical validity and that a new multifaceted oversight framework was needed. There were three components of SACGT's recommended framework.

First, FDA should be responsible for the review, approval, and labeling of all new genetic tests that have moved beyond the basic research phase, and the level of review applied by the FDA should collate with the level of scrutiny warranted by the test.

Second, CLIA regulations should provide more specific provisions for ensuring the quality of the laboratories conducting genetic tests.

Third, a collaboration between the public and private sectors, coordinated by CDC, was needed to advance the collection and analysis of data on the clinical validity and utility of genetic tests.

In 2001, then Secretary of Health and Human Services, Donna Shalala, accepted these recommendations and indicated that HHS would proceed in a step-wise way, resources

permitting, to enhance oversight of genetic tests, including laboratory-developed tests. In 2003, SACGT's requested briefings from CMS and FDA about the status of oversight efforts, FDA reported that the agency had no plans at that time to regulate laboratory-developed tests. At the time, there were questions about whether FDA had statutory authority to regulate laboratory-developed tests. CMS reported that plans were underway to add a genetic specialty to the CLIA regulations. At our meeting in March of this year, however, we heard public comments questioning why CMS has not moved forward with the proposed rule amending the CLIA regulations. In June we invited Judy Yost to update us on those plans. Ms. Yost indicated then that the rulemaking process was proceeding, that proposed regulations have been developed and were in clearance within CMS and that if all went well, we might see proposed amendments by early 2007.

At the end of the meeting in June, we decided to revisit the oversight issue at this meeting to have a more in-depth discussion about whether any gaps in oversight persist, and I would indicate any gaps in oversight persist that we think are important enough for us to be attentive to. Today we'll be updated, first by CMS and then by FDA, and then have a focused discussion on whether SACGHS should undertake further activity in this area. What I mean by that is should we move beyond a monitoring role and undertake some deeper fact-finding and analysis.

So let's be clear. What we are saying that we want you to do is to listen carefully to whether or not there are significant gaps in oversight but not just to discover that there may be gaps but to discover whether or not those gaps, in our role as representing the interests of the public, whether those gaps deserve further attention. So it's not just saying that there's a gap; it's is that gap worthy of further effort and attention by this committee. So those are the two things we're going to do.