Comments from Kathy Hudson, Ph.D.
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DR. TUCKSON: So in addition to those centering comments, we are very excited that Kathy wanted to come and present some comments. We know that the areas of her comments are germane to where we are getting ready to go. Therefore it seemed to make sense to stop what we are doing here and get those comments as we now proceed through in an orderly way the rest of our agenda.

So, good. Thank you.

DR. HUDSON: My name is Kathy Hudson. I'm the director of the Genetics and Public Policy Center at Johns Hopkins, and I was honored to be asked to serve on the Oversight Taskforce. I really want to commend the Committee for its expeditious work in moving through all of the issues that were included in the final recommendations, and I appreciate your endurance today as you work through all that.

I particularly want to acknowledge the incredible work of Sarah Carr and Cathy Fomous, who have worked tirelessly to pull this together.

I would like to comment on three issues that are raised in the recommendations and comment on those. First, the recommended enhancements in the CLIA, the Clinical Laboratory Improvement Amendments; secondly, the recommendation for a registry; and third, say just a word about direct-to-consumer genetic testing. I recognize that the revised recommendations haven't yet been discussed, so this is a little bit of a challenge.

In the draft report for public comment, the taskforce recommended an expansion of proficiency testing and not the creation of a genetic testing specialty. You heard from some of the public this morning that there are still a number of people who are interested in the creation of a genetic testing specialty.

A specialty is a framework that was created by CMS in order to implement CLIA, and currently, it is really the only way that CMS has of putting in place new proficiency testing requirements. But the statute certainly doesn't require that, and it is not the case that the creation of a specialty necessarily would require that laboratories perform PT.

Previous advisory committees have attempted to work within the existing CLIA specialty structure and have made recommendations over the years to create a genetic testing specialty. I think the taskforce was correct in ascertaining that the thing that we really want is more proficiency testing and therefore let's just move outside of this framework and get to what we really want, which is PT.

It has also been clear over the last year that CMS does not want to create a specialty, so banging your head on that particular wall again may not make much sense.

We strongly support the revised recommendation that requires that laboratories that are performing tests for which a CMS-approved PT program exists should be required to enroll. The key issue there is going to be what PT programs does CMS in fact approve, and there may be some devil in the details there, but I think this will go a long way. There will be a market to create PT programs for tests that are offered on a widespread basis.

Implementing this recommendation will require changes to CLIA regulations, which will of course be subject to public comment before they are finalized. We believe these changes are straightforward. In fact, we have drafted a model regulation that would fulfill both the requirements of the report and we believe avoid concerns about genetic exceptionalism that have been expressed in public comments. We would be happy to share that model MPRM with the Committee.

DR. TUCKSON: Excuse me. Before you go further, just so we are hearing you clearly, who is "we"?

DR. HUDSON: "We" is the Genetics and Public Policy Center.

DR. TUCKSON: Genetics and Public Policy Center.

DR. HUDSON: Is "we," yes. I'm speaking of my role as a member of the taskforce but also as --

DR. FERREIRA-GONZALEZ: When you are here, you are here as a member of the taskforce.

DR. HUDSON: Okay. I will try to differentiate between me and "we" and "they" and "us."

[Laughter.]

DR. HUDSON: The second issue I would like to address is the recommendation to create a genetic testing registry. The draft report included a recommendation for the creation of a voluntary registry, perhaps as an extension of gene tests. As Mark Smith of the California Healthcare Foundation has said, there is no such thing as a voluntary universal anything.

The taskforce and the steering committee clearly reviewed those comments, where a majority of the people who made a comment about this issue recommended that the registry be mandatory. I think the taskforce has responded to those public comments. So that is an important addition.

Several commenters have urged that the registry be housed by and managed by a federal regulatory body, and in considering what agency should have lead responsibility, a number of key issues have been raised. I think this is where, probably if the taskforce had had more time, we could have gone into these issues in greater detail.

What functions are going to be carried out by the registry. Will they be facilitating data submission. Will they be involved in any quality control. Will they have a stick with which to demand that data be submitted, and will there be penalties for non-compliance. These are issues that still remain but certainly that the Secretary has the authority to put in place.

The other question that has been discussed is whether the various agencies or the Department in total has sufficient authority to require the kinds of information that are envisioned to be within the registry. It is important to recognize that many of the authorities that the agencies have are actually authorities that are held by the Secretary and he delegates them down. So it may be possible for him, the Secretary, to use some creative redelegation of authority to get the job done.

In the discussion of the taskforce of what agency would be the most appropriate home, there was lively conversation. In one iteration, CMS was indicated to be the appropriate home for this registry because they already do collect some information, although as somebody mentioned, it is difficult to retrieve that information.

It is certainly possible for the Secretary to figure this out and for this Committee to punt to the Secretary and not name a specific agency, but I think wherever this registry is housed we should look for an agency that has documented experience and expertise in creating and running publicly accessible registries.

So FDA certainly has lots of experience in maintaining publicly accessible and useful databases. CDC maintains a number of registries. NIH manages huge numbers of publicly accessible databases that allow timely and easy access to trillions of pieces of interlinked information.

If I am speaking as a taskforce member, I might not then be able to share comments on DTC, some of which grew out of the conversation that just preceded, so I will take guidance from the chair.

DR. FERREIRA-GONZALEZ: You are here as the taskforce member.

DR. HUDSON: Fine. I will withhold my comments on DTC. I would like to make one point, though, that in the map that was put up where it had a separate line for DTC non-CLIA certified, that the CLIA statute applies to laboratories that are providing assessment of health irrespective of how they are marketed. So I don't think there is a distinct pathway there. I think that may be misleading.

DR. FERREIRA-GONZALEZ: That line is specific, and maybe we need to be more clear. It is for direct-to-consumer advertising by laboratories that claim they are not under CLIA regulations and they can directly market these tests or offer the tests to the public.

DR. HUDSON: So that is a problem in enforcement. There is no permissible pathway.

DR. FERREIRA-GONZALEZ: Exactly. That is why some of our recommendations are going to deal with that specific issue.

DR. TUCKSON: Great. First of all, thank you for your comments. They are very helpful, and we are going to move right on. If you will sign up for the public testimony part so we can get your DTC stuff in, that would be great, Kathy. Thank you.

All right. Let's move right into the next section. We are going to really move.