

Update from the SACGHS Task Force on Pharmacogenomics
Emily S. Winn-Deen, Ph.D.

MS. BERRY: With that, it's time to turn to our pharmacogenomics session. Emily Winn-Deen, chair of our Pharmacogenetics task force, will lead that session for us. She will provide an overview of what will be discussed, and a review of the task force's work since our June meeting.

Emily?

DR. WINN-DEEN: So what I wanted to do to open this session today on pharmacogenomics is to just give you a quick overview of what the session is going to be and what the task force has been doing since we last met as a committee.

We have a very broad representation of committee members, as well as ex officios on the task force. I'm not going to read everybody's name here, because it's just too long to list, but I want to say that most of these people have been very active participants, and that we really have appreciated all of the viewpoints and the inputs that we've received.

Today's session is designed to continue the fact finding on some of the issues that we identified at the June meeting, and then to proceed with our work plan in terms of trying to develop a recommendation on what this committee should or shouldn't do in regards to this subject.

So in the June meeting, we identified a number of key issues, and those are summarized in your briefing books, so I hope everybody had a chance to just quickly review that. We also identified some areas where we felt we still had some gaps in our factual knowledge where we wanted to get a little bit more education and input.

In the R&D area, there were several areas we wanted to get some more input on, particularly on the drug diagnostic co-development. This is both happening on the industry side as well as the FDA side, and we'll hear a little bit about the FDA side today, as well as some of the pharma perspective, how the whole concept of pharmacogenomics is impacting the way research is done, the way evidence is collected on effectiveness and safety.

There are issues particularly on existing drugs of how one might fund pharmacogenomic studies, and who should be the right funding source for that. And then sort of a topic that's just out there waiting for us to decide how we want to address it is to what extent does genetics segmenting of a disease or response to a drug lead to some kind of orphan disease status or orphan drug status potentially.

In the infrastructure area, we'll hear a little bit from FDA about their attempts to create some kind of data standards for pharmacogenomic data, at least as it comes into the FDA. There has been a lot of very active work done in consultation with the pharmaceutical industry to come together on kinds of data and how it should be submitted. We'll hear a little bit about progress and regulation, and also a little bit of feedback on how the first pass at trying to implement this is going.

One of the key issues of course is it is all nice to have all this stuff going on at the R&D level, and cool new science kind of level, but our real goal is to integrate this into clinical practice. That raises several issues. We talked a lot yesterday about some of these issues. I don't know if I need to go through them again, but we definitely need to deal with the access and education issues.

The specifics of pharmacogenetics or pharmacogenomics lead to a need to develop some kind of standards for evidence and guidelines on how this data should be used in clinical practice, and inevitably when you get to some kind of a clinical practice guidance, you lead yourself down the road of if you're not following the guidance, what kind of liability does that leave for the physician?

There is also in this area, again, a large number of ELSI issues. I think they are really in several sort of big lumps. One of which is there going to be some kind of stratification that happens, unintentional stratification that happens based on social economic status, or, you know, access to insurance, access to physicians, that will instead of improving health, will actually create more health disparities.

You, again, with all genetic tests, have the issue of informed consent. But in this case, for a test that is really only going to tell you about your response to the drug, does that informed consent need to be at the same level of both education and consent that you would if you had a, you know, very severe genetic disease that you were talking to someone about, and how do you deal with those sort of nuances of levels of both education, as well as informed consent.

Of course anytime you're going to be doing genetic analysis on someone, you get into the whole issue, as we just heard, about patient concern about having their data in a medical record, and what that might lead to in terms of any disclosures which they feel would violate their privacy or confidentiality, or whether they might be discriminated against.

I think it's less likely you'd be discriminated against if you're a poor metabolizer for 2D6 and if you're likely to come down with Huntington's. But still, we have to make sure that we have these kind of protections in place.

The issue of race I think comes into play here, particularly because of the recent approval of BiDil. It is the first drug approved for just a subsegment of the population. The question I think arises whether we could do a better job of segmenting the population based on a real genetic marker as opposed to what I think right now is really more a surrogate marker, and how can we move that ahead. We don't want to do any unintended harms. We want to make sure that the psychosocial consequences are minimized.

Then sort of outside of that, we have the issue of patents and intellectual property. This becomes extremely important when you get into the pharmaceutical side where the pharma industry commits a lot of money to developing a drug, and pretty much feels that they can't make that commitment without some kind of intellectual property position.

So how do we deal with that in terms of that influence on access and availability of health care? So the task force had one intervening conference call since the last meeting. The goal of that call was to basically plan today's session.

We asked the staff as well to survey basically all the HHS agencies to identify what ongoing federal efforts are already in place related to pharmacogenomics, and a summary of that survey was also in the briefing books. Then we discussed how we would develop a framework for committee recommendations. We didn't actually try and frame any recommendations at this point, but just sort of talked about the process.

So today we are going to have sort of a two part thing. Before the break, we're going to hear an update from FDA, both the diagnostic side and the pharma side, to understand a little bit about

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what is going on, what's new in the ever changing world of FDA. There has been a lot of developments I think since the last meeting.

We are going to take a pause in the pharmacogenetic session to do public comments, and then we'll come back with some presentations that address the economic and financial issues surrounding how this is implemented in both drug development, as well as clinical practice.

Then finally to finish the session with the talk by Wylie Burke on ELSI issues, and particularly on how drug responses in different ethnic groups, what are the ELSI issues surrounding that particular subsegment of the global scope of pharmacogenomics.

So in terms of the federal efforts, I think I mentioned this already, the task force requested a review, and the goal of that was to inform an analysis of basically are there places where there is the same test being done by multiple agencies so you have overlap, or are there areas that we have identified as important for HHS to be working on, but no agency appears to have sort of picked up the ball and run with it.

I think that was, again, designed to help us with our recommendation to HHS about how the HHS agencies can best participate in this field.

We have developed an outline of a comprehensive report. Basically this came from all of the things that we have discussed over the last couple of meetings as issues. We got very good feedback I think from the public, although the folks that have had a chance to look at the coverage and reimbursement report are feeling that it was useful to have both a sort of state of the state summary, what things are, definitions, you know, the basics of the field, and it provided us with a framework to make some specific recommendations. So the task force at least at this point is thinking that we could do something similar in this area. With that, I will close my opening remarks.