Overview of Pharmacogenomics Session and Update on Efforts of the SACGHS Pharmacogenomics Task Force
Emily Winn-Deen, Ph.D.

DR. WINN-DEEN: Okay.

(Slide.)

Well, today I wanted to give an overview of what the pharmacogenomics task force has been up to and what we're trying to accomplish at the meeting today.

(Slide.)

So in the session today the first thing we're going to do is review the activities that we've done to date. That's going to be followed after my short introduction and review here. We're very, very pleased and privileged to have Janet Woodcock from FDA here to give us a briefing on the Critical Path Initiative and we also hope that she can stay for a little bit and participate in a Q&A session at the end of her talk.

After that, we're going to have about four hours during which we can discuss the draft background report that is in your briefing books, as well as the recommendations that we're considering making to the Secretary.

(Slide.)

So for the benefit of the folks who are just joining the committee, the task force really was formed in response to pharmacogenetics being identified as a high priority issue during our original vision setting activity. In June 2005, we had our first informational session and then that was followed by another session in the October meeting. In March 2006 we went through a very detailed review of what all the HHS agencies and other federal groups were doing with regard to pharmacogenetics since there is a lot of activity in this field and began a discussion of what things we could recommend going forward.

(Slide.)

So today you've gotten a report outline. Right now the Lewin Group, which was commissioned to write this backgrounder for us, has completed the draft report. What will be done with that is that it will be slightly reorganized and our recommendations will be interspersed into it at the appropriate places so there will be a discussion on the topic and then recommendations that go with that topic will be interspersed much the way we did with the coverage and reimbursement report. So that is the plan moving forward.

(Slide.)

The task force has looked through this report and given sort of the first set of feedback through a series of conference calls. We certainly would like feedback from the rest of the committee if there's anybody who has comments on the report. Either of things that aren't in there that should be in there or things that are incorrect that are in there. We definitely would like input from all the committee as well as the ex officios so that we can continue to revise and refine this report.

(Slide.)

Since the March meeting the task force has been working with the staff to further refine the draft recommendations that we discussed in March. We've held several conference calls and we now have our intern who is working with us to help work on some additional recommendations. Those are the 13 new recommendations that will be discussed today. They are in your table folders, I believe.

(Slide.)

So just for reference, the literature review is at tab 4 of your briefing booklet and the original recommendations are also at tab 4 right in the beginning, and then the new draft recommendations are in your handouts that are at your place today. These include a number of straw man recommendations. Some of them are just sort of a topic and several options for what we might want to say on that topic. There's no meaning to the order in which those things are presented. They are just there as thoughts for what the committee might want to say from maybe a very mild response to a much more strong recommendation. So that will be the basis of some of our discussion later today.

(Slide.)

The next steps are really to try and pull this all together to use the literature review as a basis for what will become our pharmacogenomics report, to refine the recommendations so that they fit into that report, and of course to take all the input that we receive in the discussion during this meeting and use that as well to refine the draft recommendations.

The plan for the task force is to organize a day long session for just the task force in early September and then to really have finally put together a draft report and recommendations which we hope the full committee will give its blessing to at the November meeting and will then at that point be set out for public comment.

I should remind you that up till now the drafts that are in your book are drafts for internal discussion. They are not ready for going out to the public.

As part of our normal process, we'll have a public comment period and we'll take the additional feedback from the public comments and then try and finalize a report, hopefully, some time in 2007. I'm not sure exactly what the timing will be.

As Reed mentioned, I will be rotating off of the committee and Jim Evans will, fortunately, be taking over the helm of the task force. So he will be the person that you can direct all your comments, good and bad, to in the future.

DR. EVANS: Only the good.

(Laughter.)

DR. WINN-DEEN: Okay.

(Slide.)

Well, with that said, I'd like to now give Janet Woodcock a chance to come up and do her presentation on the Critical Path Initiative. This is a very important initiative that the FDA has

undertaken to really try and move in the direction of understanding what the roadblocks are and trying to overcome some of those roadblocks.