MS. PAULS: I'd like to introduce John Pears as our moderator for this morning.

DR. PEARS: Thanks, and good morning everybody. This is an auspicious and very sad day for the United States. You may or may not be aware that the invention of the Egg McMuffin was -- last night. I know what a cultural shock that one will be. (Laughter.) So my sympathies go -- I don't understand the addiction to it, but I recognize the issue.

It's a great pleasure and honor to be here. I also happened to send John Senior an e-mail at the wrong time, when he was looking for a moderator. So I guess that's why I'm here. (Laughter.) Despite all the interventions of the US Airways and Philadelphia Ground Control, I still managed to make it through and get here on time. It's a great pleasure to be here this morning to continue the discussion of this important and very timely draft Guidance document from the FDA.

We had a great discussion yesterday, and we're going to continue the discussion of some of the particular issues that were identified as potentially outstanding and needing further discussion this morning, and I'm going to moderate those two sessions.

I come from across the Atlantic. So if you think you need a translator, please let me know. (Laughter.) I was pleased to hear there were some foreign voices, even

some English voices presenting yesterday. Hopefully your ears have been attuned to that sort of stuff, and you won't have to see any of my spellings. So it won't be quite as offensive as it might otherwise have been.

My presence here reminds you that people do have livers and we do have drugs outside of North America. So perhaps that's a timely reminder that we're all living in a worldwide organization and working for the good of humanity generally. So don't forget us. Even though we look funny and speak funny, we're still -- we still want to be part of your gang if we can do that, or have influence you gave me, and I'm just glad to be part of.

So what we have this morning are three speakers who are going to introduce or give their views on the issue about whether we should be including patients with stable liver diseases in clinical trials. Where I'm going to push for by the end of the morning session is to try and get us to agree whether we should or not, what sort of patients should be included, how we should be including them, when we should be including them, what we would do with these people.

And then after the coffee break, we're going to talk about biomarkers. And biomarkers for liver disease is such an easy, straightforward issue that will be done in an hour and a half, which is we've given you so generously. Then, you know, we should be on track for lunch.

So let's get started. What we're going to do is

run through the first three presentations. I want to get the speakers up and then have a structured discussion like we did yesterday, where you all get an opportunity to throw things out and to discuss your points of view. I remind you that when you do come up to speak, please give your affiliation and speak clearly, because all of this is being recorded.

I should say for the record that while I'm an employee of AstraZeneca, and I lead AstraZeneca's teams that coordinate our hepatotoxicity efforts, anything I may say is the view of John Pears and certainly not that of AstraZeneca. I'll be saying things that are really meant to stimulate this debate and discussion, and hopefully everybody can join it. That's scary, hey. (Laughter.)