

**Wednesday 8 April, 2009**

## **WELCOMES**

CO-CHAIR PAULS: I'm Lana Pauls, for those of you who don't know me, and I'm the co-chair of this conference, along with Dr. John Senior. I have a couple of logistical items for you. If you haven't checked in, please do so at the desk. In addition to that, they are going to be arranging shuttle service to the three airports for those people leaving today and tomorrow. Please sign up where you signed in to register because I need to return those sheets to the front desk this afternoon. If you need shuttle service, please go ahead and do that.

So I'm just going to go ahead and introduce John, who needs no introduction, for those of you who know anything about the drug-induced world out there. Dr. Senior.

CO-CHAIR SENIOR: Thank you, Lana. Well, I want to welcome everybody. We have so much more material this year than last, but our focus this year is on science, hard science. Last year we were talking about a lot of regulatory issues and guidances and all that sort of thing, which brings a lot of industry people out who want to know what the FDA is thinking.

So in order to tell you what the FDA is thinking, I am going to introduce Janet Woodcock, the Director of the Center for Drug Evaluation and Research. Neil Kaplowitz and Alan Goldhammer have graciously yielded part of their welcoming time to Janet so she can show you a few slides to give you the inside concept of what has been thought about. She spoke at the Institute of Medicine a few weeks ago, but she has modified that talk for us today. Janet?

[Link to Notes: Woodcock Slides](#)

CO-CHAIR SENIOR: Thank you, Janet.

About ten years ago, we had our first conference. It was an internal conference on DILI at the Center for Drugs, where we had an educational program for reviewers. Not just medical reviewers but the statisticians, pharmacologists, and all of the rest. We had about 325 show up for our first course in April 1999, which was just ten years ago, and another 75 at a re-run in November. At that time, we could not invite industry people. And so we had some protests from industry saying why can't we come and hear about all this stuff? So PhRMA became a co-sponsor of this program and today from PhRMA we have Alan Goldhammer. Where is Alan? Come forward and say hello. PhRMA has been a partner in sponsoring these conferences for the last eight years. This is the ninth one. Alan?

DR. GOLDHAMMER: I'm just going to take a minute to welcome everybody and then also indicate you will probably be hearing from me via email or some other kind of correspondence shortly. We are pleased to again co-sponsor this and see the attendance today.

I did talk with the Foundation for the NIH a couple of weeks ago. We have a couple of

programs that we are working on with the Foundation, collaborations with the FDA, and they have been asked by NIDDK to help raise a rather modest amount of money to help sponsor the DILIN work and a couple of experiments that are going on there. NIDDK is funding this something, I think, on the order of about 14 million dollars over five years but they need about another million and a half to get this done. We realize research budgets are tight. We are going to try to free up some money from our budget at PhRMA to help contribute to this. But I do have the proposal and so forth. So for the industry colleagues who are in the audience today, you may be getting a note from me to maybe request you to consider helping to fund this. So John, I wanted to give the rest of my time back to Janet, which I already did. So I will put it back to you.

DR. SENIOR: Thank you. And in addition, we added then the American Association for the Study of Liver Disease (AASLD) to be our academic partner. Neil, would you come forward and tell us about the wonderful world of the AASLD?

DR. KAPLOWITZ: Well, just very briefly. Hello. I am Neil Kaplowitz and I am the representative of the AASLD, the American Association for the Study of Liver Disease, which is, at least in the United States, the leading professional organization for the study of the liver and has something on the order of about five thousand members, mainly from academia, although there are many members from industry in the AASLD. Obviously, the membership of the liver society has recognized, especially through the work of FDA and PhRMA and this meeting and the DILIN network as well, have become extremely sensitized to the importance of drug-induced liver injury as both a common and often serious cause of very severe liver disease. So the organization is keenly interested in helping to support research and encourage research in this area. We are delighted to help. And I know the AASLD has contributed, at least in terms of the organizational aspects of this meeting and paying my way to come to this. So I am happy.

DR. SENIOR: Thanks, Neil.

We are going to start the regular program now. We are going to be starting right off with two examples of companies that did something about an unfavorable regulatory action. Their drugs were not approved by the FDA and that was quite a blow to them. Their stock analysts said, "Oh, my God." But instead of complaining to their congressmen, they said, "Well, let's do something about it. Let's try to find out why this happened." We're going to hear a little about that today. And of course, the FDA strongly supports this. To take over the morning session, Roger Ulrich is our moderator. Roger?