AFTERNOON SESSION_II

(1:30 p.m.)

DR. SELIGMAN: My name is Paul Seligman. I'm the Associate Director of the Safety Policy and Communication, Center for Drug Evaluation and Research at the FDA. I'll be serving as this afternoon's Moderator for this session.

This afternoon, we're going to be focusing on the question of the role of rechallenging humans in assessing drug causality. This is a question that has already been broached by the many of discussions and questioners this morning.

Today we will tackle this question from clinical, mechanistic, experiential, and ethical perspectives, leavened by the viewpoints from industry and a regulatory agency. And although clearly the focus this afternoon will be on rechallenge and continuing challenge, a lot of what you're going to hear this afternoon and a lot that will be discussed clearly has value and relevance regarding issues related to clinical trials, assessing causality, predicting and preventing drug-induced liver injury.

So we've assembled two excellent panels. We're going to have our first panel up the first half of this afternoon, followed by some time for discussion, a break, and then we'll move on to the second panel and again follow that panel with some discussion.