FDA-PhRMA-AASLD Hepatotoxicity Steering Committee Meeting
Rockville Civic Center ("The Mansion"), Rockville, Maryland
Friday, January 28, 2005

8:00 AM	**CONTINENTAL BREAKFAST**	
8:30 AM	Welcome/Introductions	Lana Pauls (*FDA*)
8:45 AM	Recognizing Drug-Induced Liver Injury in Exposed Populations	John Senior (*FDA*)
9:15 AM	Update on the Acute Liver Failure Study	Will Lee (*UTsw*)
9:45 AM	Methods for Attributing Liver Injury to a Drug	Bob Fontana (*UM*)
10:15 AM	Case study: ximelagatran hepatotoxicity	Mark Avigan (*FDA*)
10:45AM	**BREAK**	
11:00 AM	Use of the DILIN Registry and Tissue Bank for Research	Paul Watkins (*UNC*)
11:30 AM	Genomic Approaches to the Prediction of Drug-Induced Hepatotoxicity	Allen Roses (*GSK*)
12:30 PM	**LUNCH**	
1:15 PM	Hepatotoxicity: A Common Challenge for the DILIN and the Pharmaceutical Industry	Jose Serrano (*NIH*)
1:30 PM	Update on the Hepatotoxicity Nomenclature Document and Manuscript	Vic Navarro (*TJU*)
2:00 PM	Mechanistic vs. Predictive Genomic Biomarkers of Liver Toxicity	Federico Goodsaid (*FDA*)
2:30 PM	Nonclinical Hepatotoxicity Testing: State of the Art and Limitations	Jim Sanders (*Aventis*) Vince Meador (*Lilly*) TBD (*Gene Logic*)
3:15 PM	Hepatic Safety: Risk Assessment and Risk Management during Drug Development	Holly Read (*Lilly*)
3:45 PM	General Discussion, New Business, and Wrap-up	All
4:00 PM	**ADJOURN**	