Pharmaceutical Regulation and Product Liability

Venue: Lovells, Atlantic House, Holborn Viaduct, London, EC1A 2FG

21 APRIL 2006

9.00 - 9.15 Welcome: Mr Justice Underhill, Chair.

9.15 - 9.40 Keynote Speech:
"Recent Developments in US Pharmaceutical Regulation: Update on FDA Physician Labeling Rule"
Paula M. Stannard, Acting General Counsel, U.S. Department of Health & Human Services

9.40 - 11.15 Future challenges of pharmaceutical regulation

- "The importance of dialogue between regulators": Prof Vincenzo Salvatore, Head of Legal, European Medicines Agency (EMEA).
- "The changing shape of pharmaceutical risk": Dr Peter Feldschreiber, Medicines and Healthcare Products Regulatory Agency (MHRA).
- "The PREP Act: Liability Protection to Ensure Public Health Protection Against Pandemic Flu": Jeffrey Bucholtz, US Department of Justice.

Questions from floor.

11.15 - 11.40 Morning Coffee

11.40 - 12.40 Pharmaceuticals, Investors and the Media
In the Chair, Dr Sarah Houlton, Global Correspondent, Pharmaceutical Executive magazine.

- "Regulation under the scrutiny of the Media": Simon Gregor, Director of Communications, MHRA
- "The financial impact of pharmaceutical regulation and litigation": Andrew Baum, Managing Director, Co-head European Pharmaceutical Research, Morgan Stanley.

Questions from floor.

12.40 - 13.40 Lunch

13.40 - 16.15 Pharmaceutical litigation on a global playing field

- "Obstacles to access to justice in pharmaceutical cases": Martyn Day, Leigh Day and Co and Nicholas Diamand, Lieff, Cabraser, Heimann & Bernstein, LLP, New York.
- "A worldwide forum?": Ina Brock/Joe Cyr, Lovells.
- "European trends in pharmaceutical litigation": Dr Duncan Fairgrieve (BIICL) / Stefan Lenz (BIICL/Lovells) / Prof Marco Bona (Università Bocconi di Milano).
- "Liability arising from clinical trials": Leigh-Ann Mulcahy, 4 New Square.
Questions from floor.

16.15 - 16.30  Afternoon Coffee

16.30 -18.00  Parallel panel discussions: The coming years

"Global regulation of pharmaceuticals: dialogue, efficiency, safety"
Chaired by John Meltzer, Lovells.

Panellists:-
Dr Grant Castle, Covington & Burling.
Ian Dodds-Smith, Arnold Porter.
Arundel McDougall, Ashurst.
Hervé Tainturier, General Counsel, Sanofi Pasteur SA.

"Challenges of a world-wide pharmaceutical law suit"
Chaired by Jeremy Stuart-Smith QC, 4 New Square.

Panellists:-
Jalil Asif, 4 New Square.
David Body, Irwin Mitchell Solicitors.
Eric Duranson, Legal Affairs, Sanofi Pasteur SA.
Gregory Loss, Chadbourne & Parke LLP.
Simon Pearl, Davies Arnold Cooper.
Anne Ware, Covington & Burling.

19.00  Dinner