Life Sciences College

Pharmaceutical Regulatory and Compliance Fundamentals

Tuesday, February 26, 2013

9:00	**Welcoming Remarks by Life Sciences College Co-Chairs** • **Simone Handler-Hutchinson, Executive Director, Center for Health & Pharmaceutical Law & Policy, Seton Hall Law** • **Jim Stansel, Partner, Sidley Austin LLP (Washington, DC), Former Acting General Counsel of the U.S. Department of Health & Human Services**
Key Risk Areas for Biopharmaceutical Manufacturers	
9:05 – 10:00	**Civil Litigation Risks. Product liability remains the most significant civil litigation threat, but changing economic conditions point to commercial litigation as a growth area. Alternative dispute resolution techniques continue to provide useful alternatives to litigation.** • **Julie Coletti, Vice President, Bayer HealthCare LLC and Chief Legal Officer, MEDRAD, Inc.** • **Becky Wood, Partner, Sidley Austin LLP (Washington, DC)** • **Marc Palay, Partner, Sidley Austin LLP (Geneva)**
10:00 – 11:00	**Risks Arising From Regulatory Paradigm. Biopharmaceutical manufacturers are heavily regulated by FDA in all their operations, but the Department of Justice is the more important locus of government enforcement, particularly in False Claims Act cases with predicate violations premised on FDCA, GMP, AKS, government program pricing and other violations. Federal regulatory officials have begun to increase their cooperation with state attorneys general, heightening the need for effective risk management programs.** • **Maureen Ruane, Chief, Health Care & Government Fraud Unit, U.S. Attorney's Office for the District of New Jersey** • **Heidi Wendel, Assistant United States Attorney, U.S. Attorney's Office for the Southern District of New York** • **Kathleen Boozang, Professor Of Law, Seton Hall University School of Law** • **Paul Kalb, Partner, Sidley Austin LLP (Washington, DC)** • **Jaime Jones, Partner, Sidley Austin LLP (Chicago)**

11:00 – 11:15	**Coffee Break**
11:15 – 12:15	**Anti-Corruption Laws. Perhaps the single most resource-intensive growth area among all key risk areas for biopharmaceutical companies, allegations arising under the Foreign Corrupt Practices Act and analogous measures in the UK and other key jurisdictions often require sustained and focused investigative attention and self-reporting, with complex implications.** • **Michael Bosworth, Chief, Complex Frauds Unit, U.S. Attorney's Office for the Southern District of New York** • **Jeffrey Eglash, Senior Counsel, Litigation & Legal Policy, General Electric Company** • **Timothy Treanor, Partner, Sidley Austin LLP (New York), Former Assistant United States Attorney for the Southern District of New York** • **Moderator: Joe Tompkins, Partner, Sidley Austin LLP (Washington, DC), Former Deputy Chief of the Fraud Section of the Criminal Division of the U.S. Department of Justice**
12:15 – 1:00	**Lunch**
1:00 – 1:30	**Guest speaker on Health Care Reform** **Dora Hughes, Senior Policy Advisor, Sidley Austin LLP (Washington, DC)** ***Former Counselor for Science & Public Health to Secretary Kathleen Sebelius at the U.S. Department of Health and Human Services,*** ***Health Policy Advisor to former Senator Barack Obama, Deputy Director to Senator Kennedy on U.S. Senate Committee on Health, Education, Labor & Pensions***

Topical Deep Dives		
1:30 – 2:30	**Modern Compliance. An effective compliance program reinforced by regular training and thoughtful engagement with key external stakeholders (e.g., OIG) can provide significant risk-management advantages for biopharmaceutical companies.** • **Frank Bigley, Chief Compliance Officer, Novo Nordisk** • **Kristin Koehler, Partner, Sidley Austin LLP (Washington DC)** • **Susan Roberts, Executive Vice President, Chief Compliance Officer, Bausch & Lomb** • **Moderator: Kathleen Boozang, Professor of Law, Seton Hall University School of Law**	
2:30 – 3:30	**Health Care I** • **AKS Issues in Payor and Chain Contracting** • **Related Price Reporting** • **Coverage & reimbursement** **Michael McCulley, Former Assistant General Counsel, Johnson & Johnson** **William Sarraille, Partner, Sidley Austin LLP (Washington, DC)**	**FDA I** • **Updates on Good Clinical Practice** • **Working Effectively with Contract Research Organizations** • **Drug Approval Issues** **Judy Braun, Legal Consultant, Sunovion Pharmaceuticals Inc.** **Jordan Paradise, Associate Professor of Law, Seton Hall University School of Law** **Lauren Silvis, Partner, Sidley Austin LLP (Washington, DC)**
3:30 – 4:00	**Coffee Break**	

4:00 – 5:00	**Health Care II** • **Data privacy and security** • **Sunshine Act** **Kathleen Boozang, Professor of Law, Seton Hall University School of Law** **Meena Datta, Partner, Sidley Austin LLP (Chicago)** **Anna Spencer, Partner, Sidley Austin LLP (Washington, DC)**	**FDA II** • **Post-market regulation** • **Enforcement basics** **Jordan Paradise, Associate Professor of Law, Seton Hall University School of Law** **William McConagha, Partner, Sidley Austin LLP (Washington, DC), Former FDA Assistant Commissioner for Accountability and Integrity**
Landscape Assessment: Emerging Risk Areas		
5:00 – 5:45	**Panel Discussion: Regulatory and Enforcement Issues That Keep You Awake At Night** • **Freddy Jimenez, Assistant General Counsel, Johnson & Johnson** • **Geoffrey Levitt, Associate General Counsel, Pfizer Inc** • **Michael McCulley, Former Assistant General Counsel, Johnson & Johnson** • **LaDonna Steiner, Associate General Counsel, Purdue Pharma L.P.** • **Moderator: Jim Stansel, Partner, Sidley Austin LLP (Washington, DC)**	
5:45	**Closing Remarks by Life Sciences College Co-Chairs** • **Simone Handler-Hutchinson, Executive Director, Center for Health & Pharmaceutical Law & Policy, Seton Hall Law** • **Jim Stansel, Partner, Sidley Austin LLP (Washington, DC)**	