

Off-Label Promotion of FDA Approved Drugs & Devices: *The Good, the Bad & the Ugly*

June 20, 2008

SETON HALL LAW

Program Agenda

8:30 a.m. – 9:00 a.m.	Registration & Continental Breakfast: Moot Court Room
9:00 a.m.	Welcome: Simone Handler-Hutchinson Director, Health Care Compliance Program & Faculty Fellow, Seton Hall Law School
9:15 - 10:15 a.m.	Session I: <i>Current State of the Law Governing Off-Label Promotion, FDA Warning Letters, Case Law and Pending Litigation</i> Kathleen Peterson, Epstein, Becker & Green Washington, D.C.
10:15 – 11:15 a.m.	Session II: Better Practices: Developing Controls for Dissemination of Scientific Information: An Update on the FDA's Industry Guidance on Good Reprint Practices Charles A. Bell, PricewaterhouseCoopers LLP New York, NY
11:15 – 11:30 a.m.	Break
11:30 – 12:30 p.m.	Session III: Risk Mitigation in Medical Education and Product Promotion John M. DeMarrais, KPMG, LLP, Short Hills, NJ
12:30 a.m. – 1:30 p.m.	Session IV: <i>Keynote Address:</i> Off-Label Investigations and Their Public Health Implications Paul Kalb, M.D., Sidley & Austin, Washington, D.C.
1:30 p.m. - 2:30 p.m.	Lunch: Faculty Library – 5 th Floor