



**Developing an Effective Long Term Strategy for
Post-Marketing Surveillance of Medical Products**

**April 11, 2007
Washington DC, 20004**

7.45 Continental Breakfast

8.15 The Future of Drug Safety: Recommendations of the IOM

Shiela Burke, Co-Chair, IOM Committee on the US Drug Safety System

**9.00 Strategies for Establishing An Effective Long Term Post Marketing Surveillance
Capacity: What, How, and Who?**

Scott Gottlieb, M.D., Resident Fellow, American Enterprise Institute

What are the major priorities for an enhanced post-marketing surveillance system? What are the key components of infrastructure required for an effective system? Which organizations should be involved in building and managing this system? Where would data collection and analytic capacity be located? How could disparate systems be integrated? What level of funding would be required to develop the system? What are the next steps for moving forward?

10.00 Break

10.30 Building Blocks for a Post-Marketing Surveillance System

Janet Woodcock, M.D., Deputy Commissioner, FDA

Arnold Chan, M.D., Sc.D., Senior Scientist, i3 Drug Safety

12.00 Lunch

**12.15 Lunchtime Panel: Strengthening the Food and Drug Administration: Priorities
for the 110th Congress**

Moderator: Stuart Altman, Ph.D., Professor, Brandeis University

Panelists: To be announced

1.30: Adjourn

Participation in this meeting is by invitation only. We are unable to accommodate substitute attendees.