

NEWS RELEASE

Janet Woodcock and Mark McClellan to Deliver Keynotes at 2008 Post-Approval Summit

Cambridge, Mass. – February 25, 2008 – The fourth annual Post-Approval Summit®, held annually at Harvard Medical School, today announced that Dr. Janet Woodcock, MD, Deputy Commissioner and Chief Medical Officer, The Food and Drug Administration (FDA), and Dr. Mark McClellan, MD, PhD, Chairman, Reagan-Udall Foundation, will both deliver keynote addresses at the Summit. The Summit, taking place in Boston at the Conference Center at Harvard Medical School on May 14-15, 2008, is the preeminent conference on the emerging role of post-approval research and the development and implementation of post-approval programs.

The Post-Approval Summit, has become a leading international forum to discuss strategies and best practices for demonstrating and improving the safety, effectiveness, value, and quality of healthcare products and services through patient registries, phase IV studies, risk management programs, and quality initiatives. This annual event attracts a broad mix of leaders from industry government, payer groups, and academia.

“The PDUFA reauthorization and the potential for surveillance methods to be used to evaluate the safety and effectiveness of therapeutics are critical issues that affect numerous stakeholders across the healthcare spectrum, including life sciences companies, payers, physicians, and patients,” stated Richard Gliklich, MD, Summit Director. “We are honored to have Dr. Woodcock and Dr. McClellan delivering the keynote addresses at the Summit. Their experience with and active leadership in the evolution of policies and strategies around post-approval safety surveillance, healthcare product risk minimization and comparative effectiveness is truly unique and will set the stage for a terrific conference..”

Dr. Janet Woodcock will discuss the Prescription Drug User Fee Act (PDUFA) in her address entitled “PDUFA Reauthorization and Post-Approval Research: What will it Mean?” She will provide the audience with an in-depth look at what PDUFA means for post-approval research and how it will impact drug safety surveillance and risk management efforts. Dr. Woodcock was previously the Director of the Office of Therapeutics Research and Review, Center for Biologics Evaluation and Research (CBER).

Dr. Mark McClellan will speak on the future of safety surveillance and will share his views on drug safety surveillance and whether the concepts proposed for safety might also be applied to effectiveness. He will also discuss initiatives with the Reagan-Udall Foundation. Dr. McClellan previously served as Administrator of the Centers for Medicare and Medicaid Services and Commissioner for the FDA.

The 4th Annual Post-Approval Summit agenda will cover topics including:

- Post-Approval Regulations and Expectations
- Risk Minimization, RiskMAPs, and Safety Surveillance
- Using Real-World Data, and Decision Making
- Strategies for Evaluating Safety, Effectiveness, and Quality



201 Broadway
Cambridge, MA 02139, USA
www.outcome.com

Phone: 617-621-1600
Support: 888-526-6700
Fax: 617-621-1620

Rte de Denges 28E
1027 Morges / Lonay, Switzerland
www.outcome.com

Phone: +41 (0) 21 321 3560
Support: +800 688 266 37
Fax: +41 (0) 21 321 3562

Honored guests and featured speakers represent organizations including the FDA; the European Agency for the Evaluation of Medicinal Products (EMA); the National Institute for Health and Clinical Excellence (NICE) from the United Kingdom; the Agency for Healthcare Research and Quality (AHRQ); Health Canada; India Ministry of Health; Biogen Idec; Medtronic; Novo Nordisk AG; Sanofi-Aventis; Wyeth Pharmaceuticals; Takeda Global Research and Development Center; Aetna; Harvard Medical School; and Harvard School of Public Health.

The Post-Approval Summit will take place from May 14-15, 2008 at the Conference Center at Harvard Medical School in Boston. For more information, visit www.postapproval.org or call 617-715-6882.

About The Post-Approval Summit

Held annually at the Harvard Medical School, the Post-Approval Summit focuses on strategies and best practices for demonstrating and improving the safety, effectiveness, value, and quality of healthcare products and services through Phase IV studies, Patient Registries, Risk Management Programs, and Quality Initiatives. For more information, please visit www.postapproval.org.