

Expert Workshop: Expedited Drug Development for Promising Therapies
The Brookings Institution • Washington, DC
December 15, 2011

Agenda

- 8:00 a.m. Registration, Continental Breakfast**
- 8:30 a.m. Welcome, Introduction, and Meeting Objectives**
Mark McClellan, Engelberg Center for Health Care Reform at Brookings
- 8:40 a.m. Panel 1: Existing Approaches for Expedited Market Access**
Gregory Daniel, Engelberg Center for Health Care Reform at Brookings – Moderator
Rachel Sherman, U.S. Food and Drug Administration
Margo Heath-Chiozzi, Bristol-Myers Squibb
- 9:30 a.m. Panel 2: Opportunities to Improve and Expand Existing Pathways**
Jeff Allen, Friends of Cancer Research – Moderator
Janet Woodcock, U.S. Food and Drug Administration
James C. Greenwood, Biotechnology Industry Organization
Jonathan Leff, Warburg Pincus LLC
Garry Neil, Johnson & Johnson
- 10:45 a.m. Break**
- 10:55 a.m. Panel 3: Focus Areas for Expedited Drug Development Informed by Patient and Public Health Needs**
Gregory Daniel, Engelberg Center for Health Care Reform at Brookings – Moderator
Daniel Perry, Alliance for Aging Research
Peter Saltonstall, National Organization for Rare Disorders
Naomi Aronson, Blue Cross and Blue Shield Association Technology Evaluation Center
Russell Katz, U.S. Food and Drug Administration
- 12:00 p.m. Lunch**
- 12:30 p.m. Panel 4: Innovative Methodologies for Expedited Evidence Development**
Mark McClellan – Moderator
Robert Califf, Duke University Medical Center and Duke Translational Medicine Institute
Donald Berry, University of Texas MD Anderson Cancer Center
Jeffrey Murray, U.S. Food and Drug Administration
- 1:25 p.m. Panel 5: Post-Market Considerations to Ensure Safe Use and Continued Evidence Development Following Expedited Development and Approval**
Mark McClellan – Moderator
Brian Solow, OptumRx
Ellen Sigal, Friends of Cancer Research
Richard Platt, Harvard Medical School and Harvard Pilgrim Health Care Institute
Kathleen Hewitt, American College of Cardiology
Louis Jacques, Centers for Medicare & Medicaid Services
- 2:20 p.m. Recap and Closing Remarks**
Mark McClellan
- 2:30 p.m. Adjourn**