ENGELBERG CENTER for Health Care Reform at BROOKINGS

Enhancing the Development and Use of Patient-Reported Outcomes in Drug Development

Embassy Row Hotel • Washington, DC
Wednesday, July 16, 2014

9:00 a.m. **Welcome, Overview, and Meeting Objectives**
Mark McClellan, Engelberg Center for Health Care Reform at Brookings
Greg Daniel, Engelberg Center for Health Care Reform at Brookings

9:15 a.m. **Opening Remarks**
Theresa Mullin, CDER, FDA
Elektra Papadopoulos, SEALD, FDA
Ellis Unger, CDER, FDA

9:30 a.m. **Session I: Experiences with the FDA Guidance on PROs: Evidentiary Standards**
Mark McClellan, moderator
Ethan Basch, UNC Chapel Hill
Ari Gnanasakthy, RTI Health Solutions
Tara Symonds, Pfizer
Cynthia Bens, Alliance for Aging Research
Amylou Dueck, Mayo Clinic

11:00 a.m. **Break**

11:15 a.m. **Session II: Experiences with the FDA Guidance on PROs: Standardizing Communication Processes**
Mark McClellan, moderator
Nancy Leidy, Evidera
Deb Silberg, Shire Pharmaceuticals
Katarina Halling, AstraZeneca
Donald Patrick, University of Washington
Pat Furlong, Parent Project Muscular Dystrophy

12:30 p.m. **Lunch**

1:30 p.m. **Session III: Identifying Other Issues Related to the FDA Guidance on PRO Development**

2:15 p.m. **Session IV: Challenges to Capturing the Patient Voice Across the Drug Development Continuum**
Mark McClellan, moderator
Stephen Joel Coons, PRO Consortium
James Witter, NIH/PROMIS
Deb Gipson, University of Michigan
Chad Gwaltney, ERT
Marc Boutin, National Health Council

3:30 p.m. **Break**

3:45 p.m. **Session V: Next Steps in Promoting the Development and Qualification of PROs**

4:15 p.m. **Closing Remarks**

4:30 p.m. **Adjournment**

Convened by the Engelberg Center for Health Care Reform at Brookings and supported by a cooperative agreement with the U.S. Food and Drug Administration.