ENGELBERG CENTER for
Health Care Reform
at BROOKINGS

Modernizing Antibacterial Drug Development and Promoting Stewardship
The Brookings Institution • Washington, D.C.
Friday, February 7, 2014

Agenda

8:30 a.m. **Registration**

9:00 a.m. **Welcome and Introduction**
Mark McClellan, Health Care Innovation and Value Initiative at Brookings
Greg Daniel, Engelberg Center for Health Care Reform at Brookings

9:15 a.m. **Opening Comments**
Edward Cox, U.S. Food and Drug Administration

Facilitating Drug Development for Unmet Medical Needs

9:30 a.m. *Targeting Drug Development for Patients with Serious Bacterial Diseases and Unmet Medical Needs*
Overview of the systematic challenges in the development of innovative antibacterial drugs. Panelists will discuss how streamlined development programs and modernized regulatory approaches can address areas of unmet medical need, including through pathogen-focused drug development programs. Discussion will also explore the scope of pathogen-focused approaches and their relative advantages in supporting drug development and stewardship.

Panelists:
Mark McClellan – Moderator
Marco Cavaleri, European Medicines Agency
John Rex, AstraZeneca
Christine Murray, Achaogen
Cheryl Bettigole, CompleteCare Health Network, National Physicians Alliance

10:30 a.m. **Break**

10:40 a.m. *Evidentiary Considerations for Advancing Targeted Antibacterial Drug Development*
Discussion will focus on the evidentiary requirements to support targeted drug development, including pathogen-focused programs. Panelists will discuss the potential opportunities for diagnostics, PK/PD data, and clinical endpoints to support modernized antibacterial development programs.

Panelists:
Mark McClellan – Moderator
John F. Tomayko, GlaxoSmithKline
Karen C. Carroll, The John Hopkins University School of Medicine
Paul G. Ambrose, The State University of New York at Buffalo, Institute for Clinical Pharmacodynamics
Helen W. Boucher, Tufts Medical Center, Tufts University School of Medicine

12:00 p.m. **Lunch**

Promoting Prudent Use of Commonly Prescribed Antibacterial Drugs

1:00 p.m. *Stewardship and Benefit-Risk Considerations*
This session will examine approaches to combating the overuse of commonly prescribed antibacterial drugs in the ambulatory setting, with special consideration of acute respiratory infections. Panelists will discuss benefit-risk considerations for drug approval, and stewardship efforts in the ambulatory setting,

including the impact of guidelines, provider and patient education, and other strategies to change expectations and behaviors related to the use of antibacterial drugs.

Panelists:
Mark McClellan – Moderator
Joseph Toerner, U.S. Food and Drug Administration
John Powers, George Washington University School of Medicine
Lauri Hicks, Centers for Disease Control and Prevention
Stuart B. Levy, Tufts University School of Medicine, Alliance for the Prudent Use of Antibiotics

2:15 p.m. **Recap and Closing Remarks**
Mark McClellan

2:30 p.m. **Adjournment**