

Expert Workshop: Facilitating Antibacterial Drug Development

The Brookings Institution • Washington, DC Wednesday, May 9, 2012

Agenda

8:30 a.m. Welcome and Overview

Mark McClellan, Engelberg Center for Health Care Reform at Brookings

8:45 a.m. Remarks from FDA: Current and Future Status of Antibacterial Drug Development

Janet Woodcock, U.S. Food and Drug Administration

9:00 a.m. Existing Paradigms for Antibacterial Drug Development

Mark McClellan - Moderator

Brad Spellberg, Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center

George Talbot, Talbot Advisors LLC

Thomas Fleming, University of Washington School of Public Health

John Powers, National Institutes of Health and George Washington University School of Medicine

9:50 a.m. Pharmacokinetics and Pharmacodynamics (PK/PD) in Antibacterial Drug Development and

Bayesian Methods in Clinical Research

Rob Califf, Duke Translational Medicine Institute, Duke University Medical Center – Moderator

George Drusano, University of Florida College of Medicine

Scott Emerson, University of Washington

10:40 a.m. Break

10:50 a.m. Novel Approaches to Further Antibacterial Drug Development: New Approaches to the

Clinical Development Program

Rob Califf – Moderator

John Rex, AstraZeneca Pharmaceuticals and University of Texas Medical School at Houston

Daniel Beniamin, Duke Clinical Research Institute, Duke University School of Medicine

Richard Platt, Harvard Pilgrim Health Care and Harvard Medical School

Edward Cox, U.S. Food and Drug Administration

12:00 p.m. Working Lunch

12:50 p.m. Outlining the Path Forward

Mark McClellan – *Moderator*

Helen Boucher, Tufts Medical Center and Tufts University School of Medicine

Barry Eisenstein, Cubist Pharmaceuticals and Harvard Medical School

Louis Rice, Warren Alpert Medical School of Brown University, Rhode Island Hospital and

The Miriam Hospital

Rachel Sherman, U.S. Food and Drug Administration

2:20 p.m. Recap and Closing Remarks

Mark McClellan

2:30 p.m. Adjournment