Duke | Robert J. Margolis, MD Center *for* Health Policy

Pharmaceutical Compliance and Enforcement to Achieve Drug Quality: Establishing a Strategic Framework of Outcomes with Performance Indicators

Mayflower Hotel • Washington, DC
November 14-15, 2016

November 14th, 2016

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

9:00 a.m. **Welcome and Meeting Objectives**
Mark McClellan, Duke-Margolis Center for Health Policy
Gregory Daniel, Duke-Margolis Center for Health Policy

9:15 a.m. **FDA's Vision for its Drug Compliance and Enforcement Program**

Presenter
Richard A. Moscicki, U.S. Food and Drug Administration

9:35 a.m. **Session I: Overview of Strategic Framework and Its Development**
Mark McClellan – *Moderator*

Presenter
Caleb Michaud, U.S. Food and Drug Administration

10:00 a.m. **Break**

10:15 a.m. **Session II: Strategic Framework—Establishing Public Health Outcomes and Measures for Success**
Mark McClellan – *Moderator*

Presenter
Neil Stiber, U.S. Food and Drug Administration

Respondents
Joseph Famulare, Genentech
Jennifer Devine, U.S. Pharmacopeial Convention

11:45 a.m. **Lunch (off-site)**

12:45 p.m. **Session III: Timely Correction/Reduction of Identified Quality Risks (Part I)—Improving Timely Regulatory Decision-making and Enforcement Strategies**
Gregory Daniel – *Moderator*

Presenter
Alonza Cruse, U.S. Food and Drug Administration

Respondents

Keith Webber, Perrigo
Maxine Fritz, NSF Health Sciences, Pharma Biotech

1:45 p.m. **Break**

2:00 p.m. **Session IV: Timely Correction/Reduction of Identified Quality Risks (Part II)—Improving Identification of Quality Issues Posing a Risk to Patients**
Gregory Daniel – *Moderator*

Presenter
John Troiani, U.S. Food and Drug Administration

Respondents
Ted Fuhr, McKinsey
Francois Sallans, Johnson & Johnson

3:00 p.m. **Break**

3:15 p.m. **Session V: More Consistent and Reliable Quality Drug Manufacturing**
Gregory Daniel – *Moderator*

Presenter
Thomas Cosgrove, U.S. Food and Drug Administration

Respondents
Henry Grabowski, Duke University
Barbara Allen, Eli Lilly

4:15 p.m. **Next Steps and Closing Remarks**
Mark McClellan, Duke-Margolis Center for Health Policy

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

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November 15th, 2016

8:30 a.m. **Welcome**
Gregory Daniel, Duke-Margolis Center for Health Policy

8:45 a.m. **Session VI: Reduced Regulatory Burden on the Drug Industry**
Gregory Daniel – *Moderator*

Presenter
Ashley Boam, U.S. Food and Drug Administration

Respondent
Charles Cooney, Massachusetts Institute of Technology

9:45 a.m. **Break**

10:00 a.m. **Session VII: Minimize Shortages of Medically Necessary Drugs**
Gregory Daniel – *Moderator*

Presenter
Valerie Jensen, US Food and Drug Administration

Respondents
Andrew Gonce, Purdue Pharma
Karla Miller, Hospital Corporation of America

11:00 a.m. **Summary Discussion and Next Steps**
Gregory Daniel – *Moderator*

Remarks

Gregory Daniel, Duke-Margolis Center for Health Policy
John Troiani, U.S. Food and Drug Administration
Neil Stiber, U.S. Food and Drug Administration
Alonza Cruse, U.S. Food and Drug Administration

11:45 a.m. **Closing Remarks**
Gregory Daniel, Duke-Margolis Center for Health Policy

12:00 noon **Adjournment**

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