Center for Health Policy at BROOKINGS

**Risk Evaluation and Mitigation Strategies (REMS): Building a Framework for Effective Patient Counseling on Medication Risks and Benefits**

The Brookings Institution • Washington, DC

July 24, 2015

**8:45 a.m.** **Welcome and Introduction**

**Mark McClellan**, Senior Fellow and Director, Health Care Innovation and Value Initiative, The Brookings Institution

**Greg Daniel**, Managing Director, Evidence Development & Innovation, Center for Health Policy; Fellow, Economic Studies, The Brookings Institution

**9:00 a.m.** **Introduction to the REMS Integration Initiative**

**Claudia Manzo**, Director, Office of Medication Error Prevention and Risk Management, U.S. Food and Drug Administration

**9:10 a.m.** **Patient Benefit-Risk Counseling in REMS**

**Reema Mehta**, Acting Deputy Director, Division of Risk Management, U.S. Food and Drug Administration

**Gary Slatko**, Associate Director, Office of Medication Error Prevention and Risk Management, U.S. Food and Drug Administration

**10:00 a.m.** **Session I: Principles and Best Practices for Effective Patient Benefit-Risk Counseling and Shared Decision-making**

*Panelists:*

- **Michael Wolf**, Professor of Medicine, Feinberg School of Medicine, Northwestern University
- **Betsy Sleath**, Distinguished Professor and Chair of the Division of Pharmaceutical Outcomes and Policy, UNC Eshelman School of Pharmacy
- **Holly Witteman**, Assistant Professor, Faculty of Medicine, Université Laval
- **Nananda Col**, Principal, Shared Decision Making Resources

**11:15 a.m.** **Break**

**11:30 a.m.** **Session II: Translating Best Practices into a Benefit-Risk Counseling Framework: Key Challenges and Facilitators**

*Panelists:*

- **Gary Slatko** Associate Director, Office of Medication Error Prevention and Risk Management, U.S. Food and Drug Administration
- **Reema Mehta**, Acting Deputy Division Director, Division of Risk Management, U.S. Food and Drug Administration US Food and Drug Administration

- **Pamela Williamson**, Senior Vice President of Global Regulatory Affairs & Patient Safety, Alexion Pharmaceuticals
- **Paul Han**, Director of the Center for Outcomes Research and Evaluation, Maine Medical Center Research Institute
- **Theo Raynor**, Professor of Pharmacy Practice, University of Leeds

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

**1:30 p.m.** **Session III: Translating Best Practices into a Benefit-Risk Counseling Framework (Cont).**

**2:00 p.m.** **Session IV: Applying Best Practices to the Design and Implementation of a Benefit-Risk Counseling Support Tool(s) in REMS.**

*Panelists:*

- **Gary Appio**, Head, US Safety Risk Management, Global Drug Safety & Epidemiology, Novartis Pharmaceuticals Corporation
- **Nilay Shah**, Associate Professor of Health Services Research, Mayo Clinic
- **Charles Lee**, President, Polyglot Systems
- **Geri Baumblatt**, Executive Director of Patient Engagement, Emmi Solutions

**3:15 p.m.** **Break**

**3:30 p.m.** **Next steps**

**4:00 p.m.** **Closing Remarks**

**4:15 p.m.** **Adjournment**