

Ninth Annual Sentinel Initiative Public Workshop

The Barbara Jordan Conference Center at the Kaiser Family Foundation • Washington, DC

February 2, 2017

- 8:30 a.m. Registration**
- 9:00 a.m. Welcome and Overview**
Mark McClellan, Duke-Robert J. Margolis, MD, Center for Health Policy, Duke University
- 9:10 a.m. Keynote Address**
Richard Moscicki, U.S. Food and Drug Administration
- 9:20 a.m. The Sentinel Initiative: Perspectives from FDA's Leadership**
Moderator: *Mark McClellan*
Presenters:
- *Gerald Dal Pan, U.S. Food and Drug Administration*
 - *Steven Anderson, U.S. Food and Drug Administration*
 - *Gregory Pappas, U.S. Food and Drug Administration*
 - *Richard Moscicki, U.S. Food and Drug Administration*
- 10:00 a.m. Updates from the Sentinel Coordinating Center**
Presenter:
- *Richard Platt, Harvard Pilgrim Health Care Institute*
- 10:15 a.m. State of Sentinel Safety Surveillance Activities**
Moderator: *Mark McClellan*
Presenters:
- *Robert Ball, U.S. Food and Drug Administration*
 - *Mwango Kashoki, U.S. Food and Drug Administration*
 - *Scott Proestel, U.S. Food and Drug Administration*
- 10:45 a.m. Break**
- 11:00 a.m. Overview of CBER's Current Sentinel System Activities**
- *Azadeh Shoaibi, U.S. Food and Drug Administration*
 - *Maria Said, U.S. Food and Drug Administration*
 - *Richard Forshee, U.S. Food and Drug Administration*
- 12:00 p.m. Lunch Break**
- 1:00 p.m. Overview of CDER's Current Sentinel System Activities**
Moderator: *Greg Daniel, Duke-Robert J. Margolis, MD, Center for Health Policy, Duke University*



Presenters:

- *Andrew Mosholder*, U.S. Food and Drug Administration
- *Christian Hampp*, U.S. Food and Drug Administration
- *Efe Eworuke*, U.S. Food and Drug Administration
- *Mark Levenson*, U.S. Food and Drug Administration
- *Tiffany Farchione*, U.S. Food and Drug Administration
- *Jennifer Pippins*, U.S. Food and Drug Administration
- *Mary Ross Southworth*, U.S. Food and Drug Administration

2:00 p.m. Engagement in the Sentinel System

Moderator: *Greg Daniel*

Presenter: *J. Stephen Mikita*, Sentinel Planning Board Member; Patient Advocate

Panelists:

- *Sally Okun*, PatientsLikeMe
- *Vinit Nair*, Humana

2:45 p.m. Break

3:00 p.m. Moving Beyond Surveillance: Sentinel as a Component of the National System for Evidence Generation

Moderator: *Mark McClellan*

Presenters:

- *Melissa Robb*, U.S. Food and Drug Administration
- *David Martin*, U.S. Food and Drug Administration
- *Robert Reynolds*, Pfizer
- *Rachael Fleurence*, Patient-Centered Outcomes Research Institute
- *William Murray*, Medical Device Innovation Consortium
- *Catherine Meyers*, National Institutes of Health

4:15 p.m. Closing Remarks

Mark McClellan

4:30 p.m. Adjournment

Funding for this conference was made possible in part by a cooperative agreement from the U.S. Food and Drug Administration Center for Drug Evaluation and Research. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsements by the U.S. Government.



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