

Tenth Annual Sentinel Initiative Public Workshop

Bethesda Hyatt Regency • Bethesda, MD

Wednesday February 7, 2018

- 8:30 a.m. Registration**
- 9:00 a.m. Welcome and Overview**
Mark McClellan, Duke-Robert J. Margolis, MD, Center for Health Policy
- 9:10 a.m. Keynote Address**
Scott Gottlieb, U.S. Food and Drug Administration
- 9:20 a.m. The Sentinel Initiative: What does the next 10 years hold?**
Building on the keynote, FDA leadership will briefly comment on the Sentinel System's development over the past 10 years, and discuss strategic planning for developing new capabilities over the next 10 years.
Moderator: **Mark McClellan**, Duke-Robert J. Margolis, MD, Center for Health Policy
Panelists:
- **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
- 10:00 a.m. Updates from Sentinel's Network of Collaborators**
This session will feature remarks from key representatives of Sentinel's network of collaborators including the Sentinel Operations Center and Data Partners on recent developments to improve and modernize Sentinel's data, tools, and methods.
Moderator: **Mark McClellan**, Duke-Robert J. Margolis, MD, Center for Health Policy
Speaker:
- **Richard Platt**, Harvard Pilgrim Health Care Institute
- Reactors:*
- **Marcus Wilson**, HealthCore
 - **Vinit Nair**, CHI
 - **Kenneth Sands**, Hospital Corporation of America
- 11:00 a.m. Break**
- 11:15 a.m. Key Sentinel Achievements**
Sentinel leads from FDA's CDER and CBER will highlight Sentinel's top achievements over the past year impacting regulatory activities and demonstrating Sentinel's unique public health value. Reactors from the FDA and industry will build on these comments and discuss their experience using Sentinel and the value the infrastructure provides for their work.
Moderator: **Gregory Daniel**, Duke-Robert J. Margolis, MD, Center for Health Policy
Speakers:
- **Michael Nguyen**, U.S. Food and Drug Administration
 - **Azadeh Shoabi**, U.S. Food and Drug Administration



Reactors:

- **Brian Bradbury**, Amgen
- **Mwango Kashoki**, U.S. Food and Drug Administration

12:15 p.m. Lunch Break

1:15 p.m. The Evolution of the Sentinel System: Evidence, Engagement, and Expansion

Building on its success as an active post-market medical product surveillance system, the Sentinel System's data infrastructure could be leveraged for broader research aims. This session will highlight current examples of how extensions to this infrastructure are generating evidence for purposes beyond safety surveillance of drugs and biologics.

Moderator: **Gregory Daniel**, Duke-Robert J. Margolis, MD, Center for Health Policy

Panelists:

- **Allison O'Neill**, U.S. Food and Drug Administration
- **Chris Granger**, Duke University
- **Robert Platt**, McGill University
- **Beth Nordstrom**, Evidera
- **Claudia Salinas**, Eli Lilly and Company

2:30 p.m. Break

2:45 p.m. A Look into the Future of the Sentinel System

This session will explore how FDA is advancing Sentinel's agenda including strategic planning for further development of Sentinel System's data resources and analytic capabilities. While this session is future looking and seeks to build on comments discussed in earlier sessions by FDA leadership, presentations will be grounded in current challenges and opportunities that need to be addressed to improve Sentinel and continue its modernization over the next 10 years.

Moderator: **Mark McClellan**, Duke-Robert J. Margolis, MD, Center for Health Policy

Panelists:

- **Opening Remarks**
 - **Robert Ball**, U.S. Food and Drug Administration
 - **Richard Forshee**, U.S. Food and Drug Administration
- **Presentations**
 - **Alan Williams**, U.S. Food and Drug Administration
 - **Darren Toh**, Harvard Medical School
 - **Josh Gagne**, Harvard Medical School
- **Reactors**
 - **Marianthi Markatou**, University at Buffalo
 - **Joanne Waldstreicher**, Johnson & Johnson

4:20 p.m. Closing Remarks
Mark McClellan, Duke-Robert J. Margolis, MD, Center for Health Policy

4:30 p.m. Adjournment

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