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

Twelfth Annual Sentinel Initiative Public Workshop

Zoom (Virtual)
October 14, 2020

Agenda

1:00 p.m. **Welcome and Overview**
Mark McClellan, Duke-Robert J. Margolis, MD, Center for Health Policy

1:10 p.m. **Keynote Address**
Patrizia Cavazzoni, U.S. Food and Drug Administration

1:20 p.m. **Session I: A Robust Sentinel System for the 21st Century**
Objective: In response to new legislative mandates and the desire to diversify scientific expertise and enhance core key capabilities in the Sentinel System, the Center for Drug Evaluation and Research (CDER) has awarded a new five-year contract that establishes a new organizational structure for the Sentinel Coordinating Center. This new contract builds on FDA successes integrating the active, post-market safety surveillance into regulatory decision-making. This session will feature key leads from each Sentinel coordinating center who will discuss plans on how to advance and transform Sentinel's data infrastructure into a national resource for evidence generation. Panelists will also discuss opportunities for collaboration to broaden stakeholder involvement, improve access to new data sources and analytic tools, and ensure more efficient and effective safety surveillance activities.

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

Panelists:

- **Robert Ball,** U.S. Food and Drug Administration
- **Richard Platt,** Harvard Pilgrim Health Care Institute
- **Sebastian Schneeweiss**, Harvard Medical School
- **Asif Dhar**, Deloitte

Moderated Discussion and Q & A

1:50 p.m. **Session II: Building the BEST Network and Establishing New Capabilities for the Surveillance of Biologics**
Objective: Launched in 2017, the BEST Initiative enacts the Agency's mandate to implement active surveillance for biologic products. This session will highlight key achievements of BEST over the last year enhancing its capabilities to execute safety and effectiveness surveillance and inform regulatory decision making. CBER representatives will discuss ongoing work to support the expansion of the BEST data network and methods infrastructure as well as specific studies utilizing the infrastructure.

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

Panelists:

- **Azadeh Shoaibi**, U.S. Food and Drug Administration
- **Richard Forshee,** U.S. Food and Drug Administration

Moderated Discussion and Q & A

2:20 p.m. **Break**

2:30 p.m. **Session III: Leveraging the Sentinel Initiative for COVID-19**

Objective: The U.S. FDA's Sentinel Initiative is engaged in numerous activities to protect and promote public health during the COVID-19 pandemic. This session will highlight key ongoing efforts across CDER and CBER to leverage Sentinel data infrastructure to describe course of illness, and evaluate the utilization, safety, and effectiveness of available COVID-19 therapeutics and vaccines under real-world conditions.

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

Panelists:

- **Gerald Dal Pan,** U.S. Food and Drug Administration
- **Vin Lo Re,** University of Pennsylvania
- **Steven Anderson,** U.S. Food and Drug Administration
- **Hui-Lee Wong,** U.S. Food and Drug Administration
- **TBD,** U.S. Food and Drug Administration

Moderated Discussion and Q & A

3:30 p.m. **RWE and Sentinel: Past, Present, and Future. A Fireside Chat with Amy Abernethy.**

- **Mark McClellan**, Duke-Robert J. Margolis, MD, Center for Health Policy
- **Amy Abernethy,** U.S. Food and Drug Administration

3:55 p.m. **Closing Remarks**

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

4:00 p.m. **Adjourn**

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