Mini-Sentinel: FDA's New Tool for Monitoring the Safety of FDA-Approved Medical Products

Melissa Robb
Project Director, Sentinel Initiative
Office of Medical Policy
Center for Drug Evaluation and Research
US Food and Drug Administration

What is Mini-Sentinel?

- A new safety tool for FDA
- Helps monitor drug and medical product safety after FDA approval
- *"Didn't FDA already find approved drugs to be safe?"*
- Yes, but no medical product is ever completely safe
- After approval, drugs and medical products are usually used by many more people than the number of people they were tested on prior to approval
- With so many more users, new safety issues can emerge
- This is why we constantly monitor for safety… even *after* approval

So how does Mini-Sentinel Work?

- Mini-Sentinel uses “active surveillance,” which adds to FDA’s “passive surveillance” ability
- Different than “passive surveillance” (AERS)
- Enables secure access to electronic health care data (such as health insurance claims and electronic health records)
- Data partners send information for FDA safety scientists to analyze
- 17 data partners, 126 million people

Mini-Sentinel Partner Organizations

America's Health
Insurance Plans

An Evolving Program

- Pilot (test) program for FDA's larger Sentinel System (under development)
- Congress authorized FDA in 2007 to create this kind of safety system
- A great opportunity to enhance safety monitoring for the American public!

How well is Sentinel Coming along?

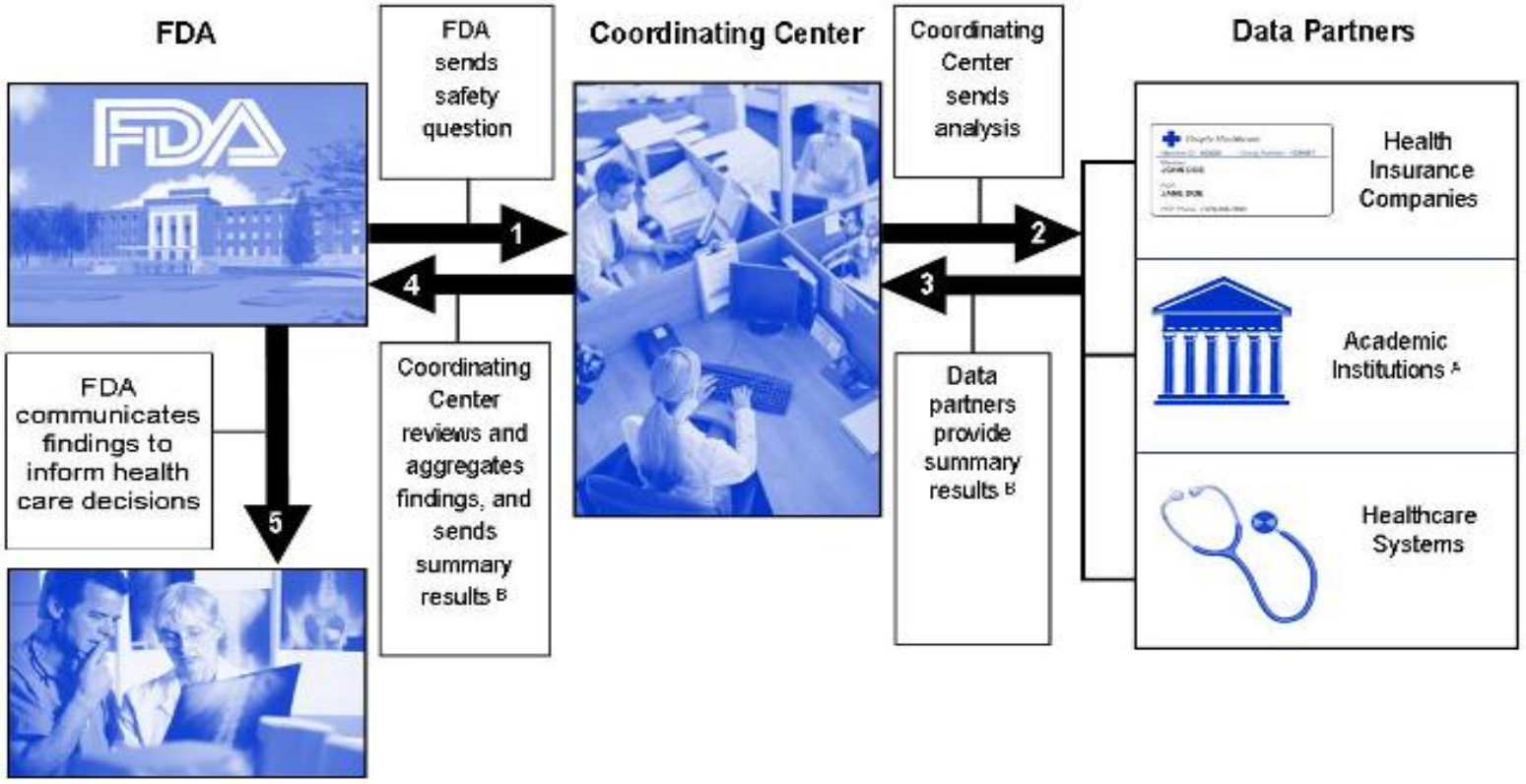
In 2007, Congress set a goal for FDA:

- at least 25,000,000 patients by July 1, 2010
- at least 100,000,000 patients by July 1, 2012

We're ahead of schedule

(126 million by December 2011)

Figure 1: Overview of the Mini-Sentinel Safety Question Evaluation Process



A. Only those academic institutions with electronic healthcare data will receive safety questions for evaluation.

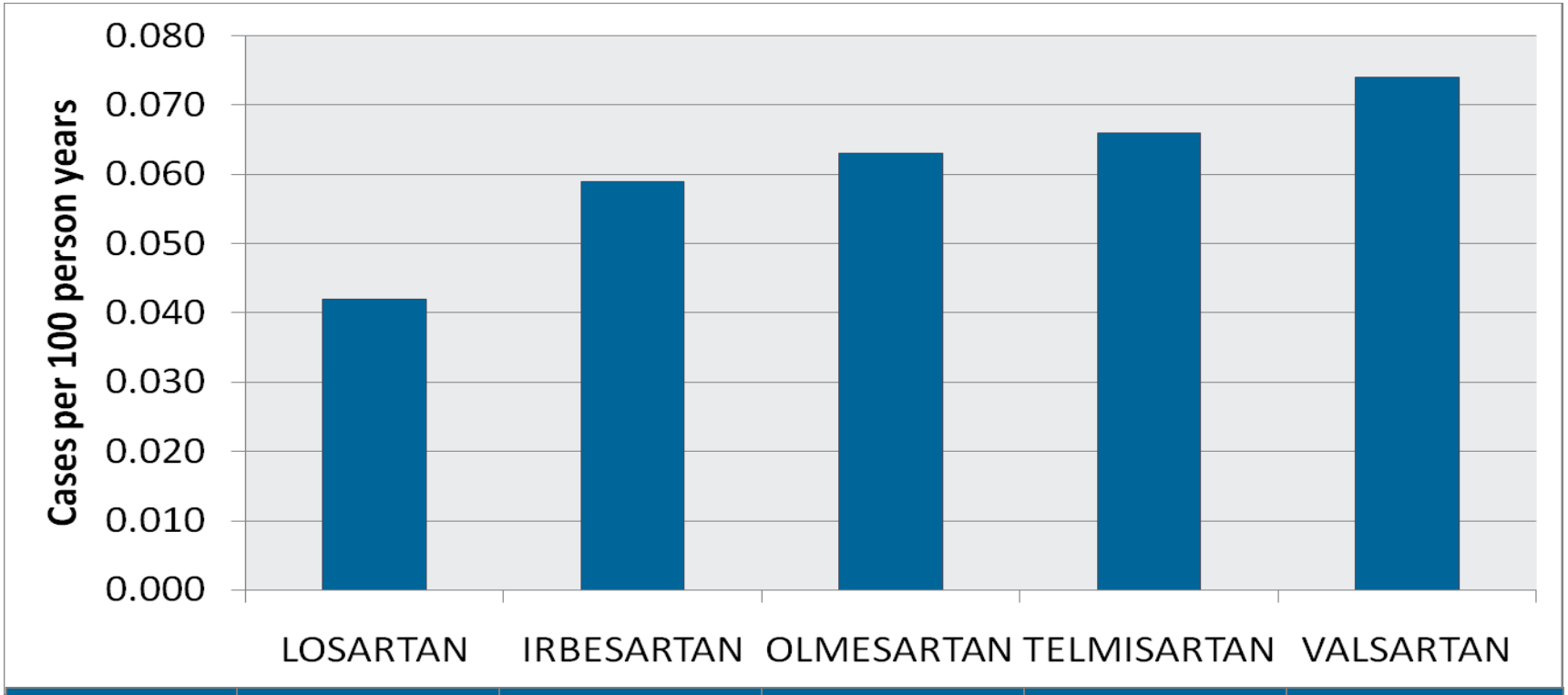
B. Data partners will provide summary results from analyses conducted within their secure data environments. Those summary results will not include directly identifiable health information.

Mini-Sentinel Example

- Potential "signal" identified from FDA reports that olmesartan might cause more celiac disease than other drugs in its class

Mini-Sentinel question: How many patients taking olmesartan had developed celiac disease compared to those taking other similar drugs for high blood pressure?

Cases of Celiac Disease



Cases	63	10	17	5	50
New users	235,630	40,071	81,560	24,596	153,159

ARBs: New users after ≥365 day washout; Celiac Disease: 1st dx code after >365 day without diagnosis.

What does FDA do with Mini-Sentinel Information?

- We add it to our OTHER information to help us reach decisions (we would rarely if ever reach a conclusion or make a decision based on one source of information)

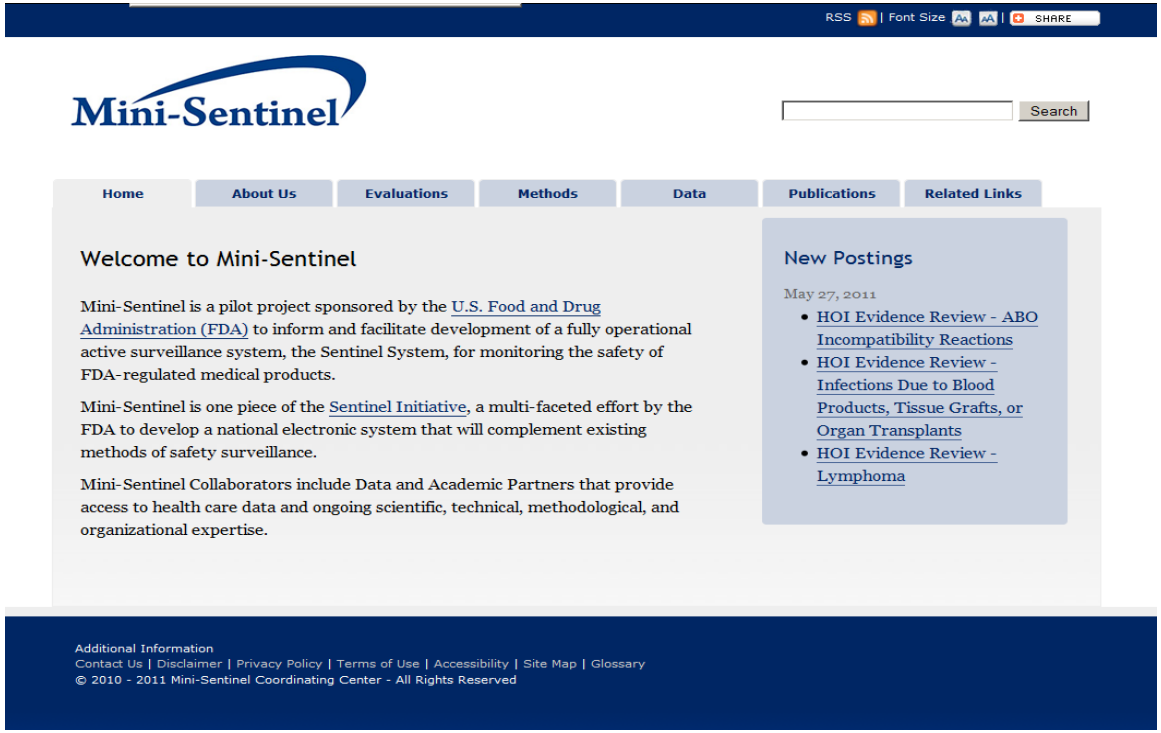
Mini-Sentinel does NOT replace our existing tools… it gives us one more tool in our "tool box"

What are FDA's other tools to assess safety after approval?

- Premarket Development Program
  - Clinical information
  - Preclinical information (animal, laboratory)
- AERS Reports ("passive surveillance")
- Medical Literature
- Postmarket Trials and Studies
- Foreign postmarket Experience
- And now Sentinel

How can I find out more?

www.mini-sentinel.org



Mini-Sentinel Web Site

IMPORTANT

- Results are posted to inform the public of FDA's work with Mini-Sentinel.
- The fact that a drug or other medical product was investigated does NOT mean there is a safety issue with that product.

Communicating Findings

- Remember: FDA typically COMBINES information from many sources before we reach safety conclusion or make decisions

- If our Mini-Sentinel findings help us reach a safety conclusion, we will communicate it through our existing channels
  - FDA's press announcements
  - MedWatch Alerts
  - Drug Safety Communications

Summary

- Mini-Sentinel is a new FDA safety tool
- Working model of Sentinel
- It does not replace other tools
- We combine Mini-Sentinel findings with other information to make decisions
- Posted findings from Mini-Sentinel do not indicate confirmed safety issues
- FDA will communicate safety issues through existing channels

Thank You!

Questions?