



# **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

HealthCore® WELLPOINT



KAISER PERMANENTE®

hmo  
research  
network

Aetna®

Humana  
Pharmacy Solutions®

VANDERBILT  
SCHOOL OF MEDICINE

OUTCOME™



OPTUM™

Penn  
Medicine



Cincinnati  
Children's  
change the outcome®



DukeMedicine

CRITICAL PATH  
INSTITUTE  
Improving the Path for Innovative Therapies

UAB PARTNERS™  
HEALTHCARE

AHIP  
America's Health  
Insurance Plans

UIC

THE UNIVERSITY  
OF IOWA  
COLLEGE OF PUBLIC HEALTH

RUTGERS  
Institute for Health

# 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!

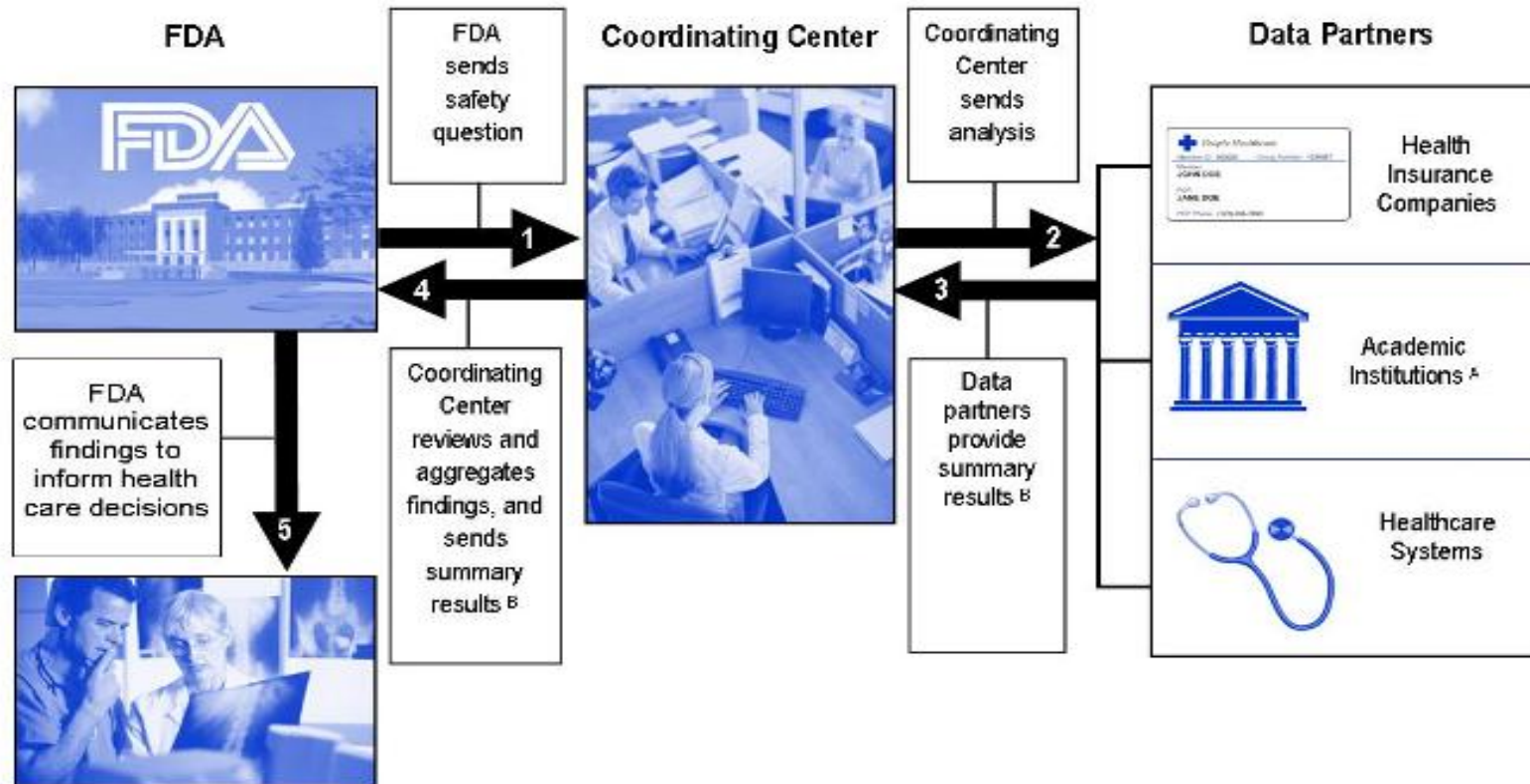
# How well is Sentinel Coming along?

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

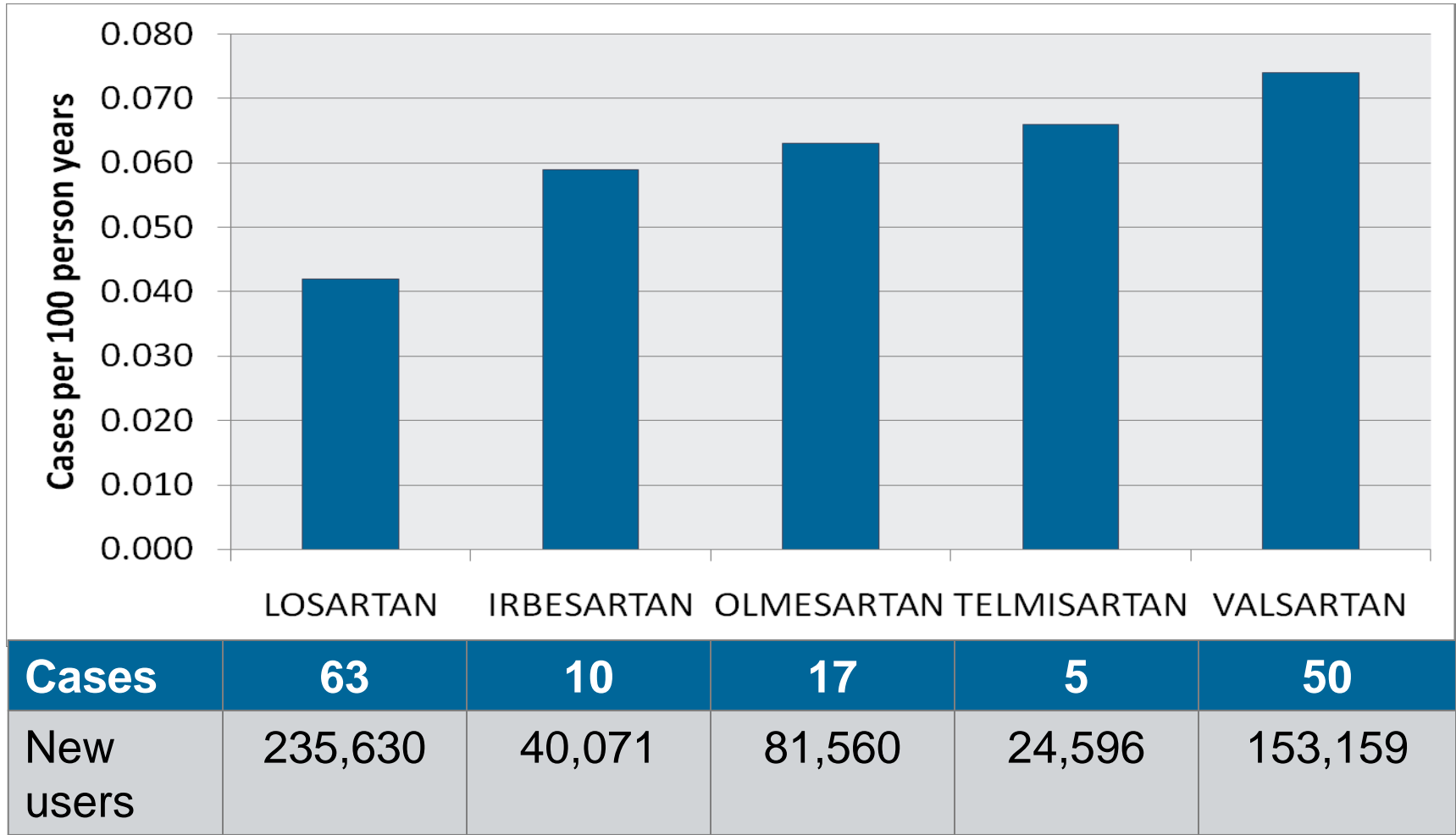
- Potential “signal” identified from FDA reports that olmesartan might cause more celiac disease than other drugs in its class

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



\_ARBs: New users after  $\geq 365$  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](http://www.mini-sentinel.org)

The screenshot shows the Mini-Sentinel website homepage. At the top right, there are links for RSS, Font Size, and a SHARE button. The Mini-Sentinel logo is on the left, and a search bar is on the right. A navigation menu includes Home, About Us, Evaluations, Methods, Data, Publications, and Related Links. The main content area features a 'Welcome to Mini-Sentinel' section with three paragraphs of text. To the right, a 'New Postings' section lists three articles dated May 27, 2011: 'HOI Evidence Review - ABO Incompatibility Reactions', 'HOI Evidence Review - Infections Due to Blood Products, Tissue Grafts, or Organ Transplants', and 'HOI Evidence Review - Lymphoma'. The footer contains additional information, contact links, and copyright notice for 2010-2011.

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### Welcome to Mini-Sentinel

Mini-Sentinel is a pilot project sponsored by the [U.S. Food and Drug Administration \(FDA\)](#) to inform and facilitate development of a fully operational active surveillance system, the Sentinel System, for monitoring the safety of FDA-regulated medical products.

Mini-Sentinel is one piece of the [Sentinel Initiative](#), a multi-faceted effort by the FDA to develop a national electronic system that will complement existing methods of safety surveillance.

Mini-Sentinel Collaborators include Data and Academic Partners that provide access to health care data and ongoing scientific, technical, methodological, and organizational expertise.

### New Postings

May 27, 2011

- [HOI Evidence Review - ABO Incompatibility Reactions](#)
- [HOI Evidence Review - Infections Due to Blood Products, Tissue Grafts, or Organ Transplants](#)
- [HOI Evidence Review - Lymphoma](#)

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# 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?