

# Post-market Pharmacovigilance Data Analysis and Decision Making

**Edward Kim, MPA, MPH**

Data Team Epidemiologist

Clinical Safety Surveillance Staff (CSSS)

Office of Generic Drugs

CDER | US FDA

Generic Drugs Forum 2020– April 16, 2020

## Poll Question

Have you or someone you have known experienced a side-effect or adverse event while taking any medications in the past 2 years?

- No
- Yes
- Yes and completed a MedWatch form
- No Vote

## Objectives & Talk Highlights

### Generic Drug Post-market Pharmacovigilance:

- What we consider when doing it
- When do we look at it
- Where can we expect challenges with it
- How do we move it forward

# MedWatch

## ➤ Online Voluntary Reporting

- <https://www.accessdata.fda.gov/scripts/medwatch/>

## ➤ Mandatory Reporting\*

- Investigational New Drug reporters, manufacturers, distributors, importers, user facilities personnel

## ➤ FDA Safety Information and Adverse Event Reporting Program

- <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>



\*The Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b, 355, 360i, 360 l, and 393); and the Public Health Service Act (42 U.S.C. 262)



# Safety Information

- Information about adverse events, medication errors, and product problems
- Post-market: Occurring after the administration of approved drug and therapeutic biologic products
- Timely information about the products used, prescribed, or dispensed every day

Can lead to clinically important medical product safety alerts

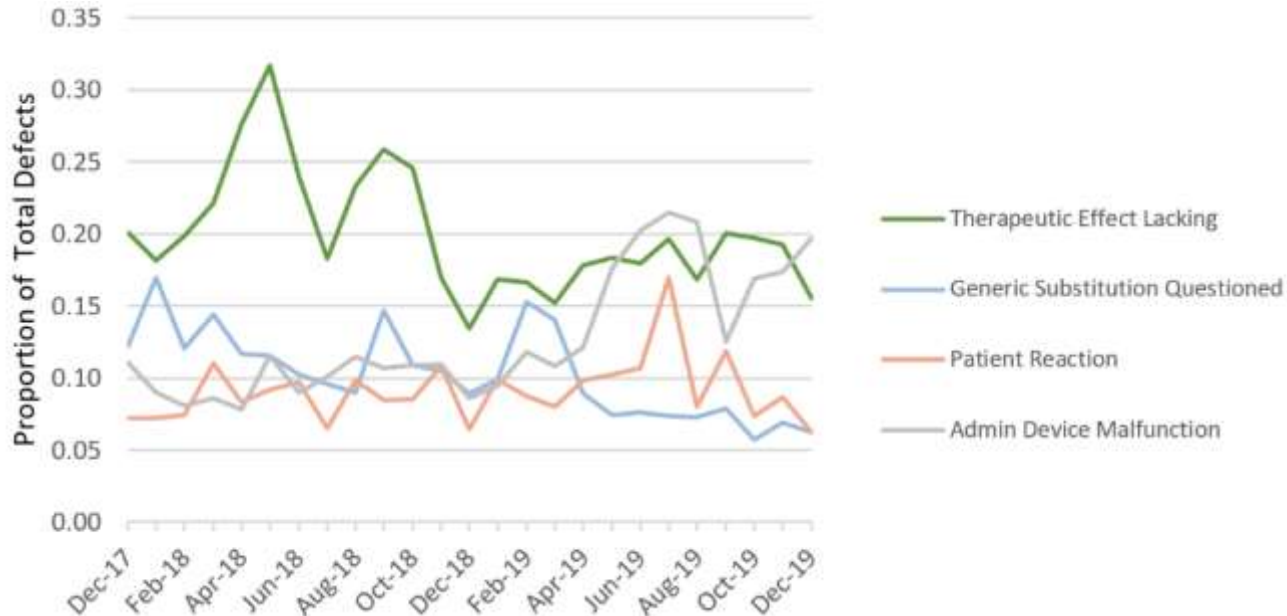
# Potential Signal Identification

- Contacts from the public directly to FDA (email, phone)
- Collaboration with other CDER Offices
- **Clinical Safety Surveillance Staff (CSSS) current use of Drug Quality Reporting System (DQRS) - Subset of MedWatch**

# CSSS Data Team: Innovations Example 1

## ➤ Temporal Patterns in DQRS Data

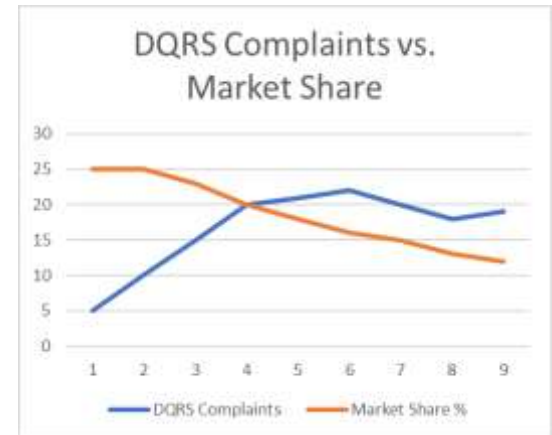
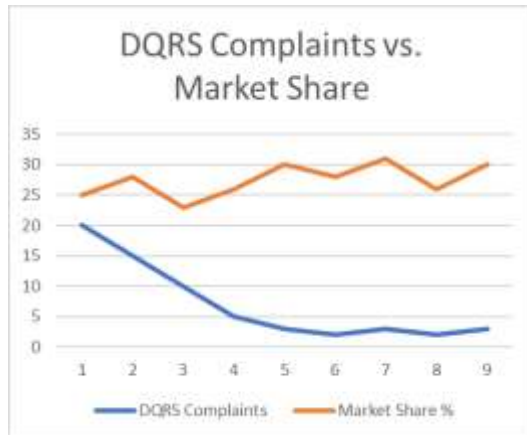
- Long-term (yearly) and short-term (monthly) visualization of complaint types; inform regulatory decision-making



# CSSS Data Team: Innovations Example 2

## ➤ Real World Data: Patient Experience & Utilization Data

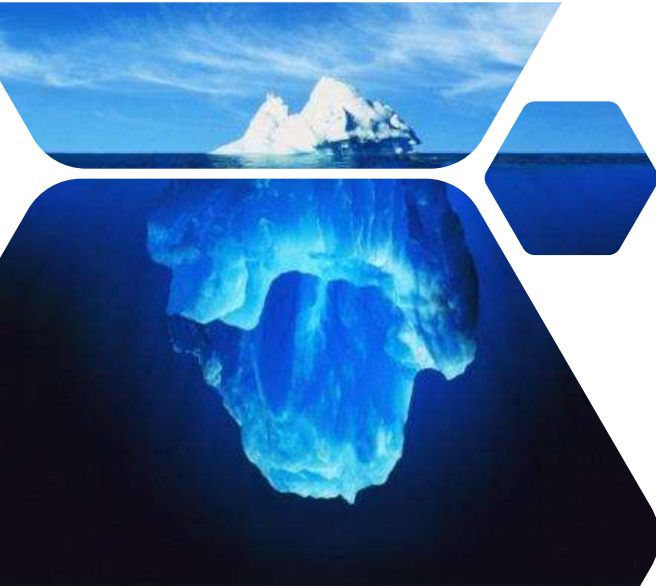
- Trends in DQRS complaints over time compared with IQVIA® market share data
- Informs regulatory decision-making: level of concern is based on factors such as frequency of complaints, severity of complaints as well as market share





# Potential Signal Interpretation

“Tip of the Iceberg”



## ➤ Potential Limitations of Patient Reported Data

- Some reports do not identify a specific generic product
- Some complaints for generic products are misattributed to the brand
- Stimulated Reporting

# FDA Adverse Event Reporting System

Difficulty identifying brand versus generic; many  
 patient reports  
 misadventures

**Provides details in patient narratives  
 that help us to understand the nature  
 of the problem at the patient use level**

- Patient
- Safety is a key component of the overall product quality
- Safety signals are difficult to identify and verify due to concurrent medications or illnesses

# Generic Drug Surveillance Enhancements

## FDA Adverse Event Reporting System (FAERS II) Enhancing Every Aspect of Generic Pharmacovigilance

- CSSS engaged in the development of new systems
- Improved generic drug signal detection
- Improved generic drug data management
- Enhanced generic drug analytics

### **FAERS data is available to the public**

[FAERS dashboard](#): interactive web-based tool

[FAERS data files](#): raw data

# Generic Drug Surveillance Enhancements

## MedWatch Form Updates

- Increased prominence and clarity of manufacturer information
- Improvements:
  - Form revisions
  - Electronic reporting

# Generic Drug Surveillance Enhancements

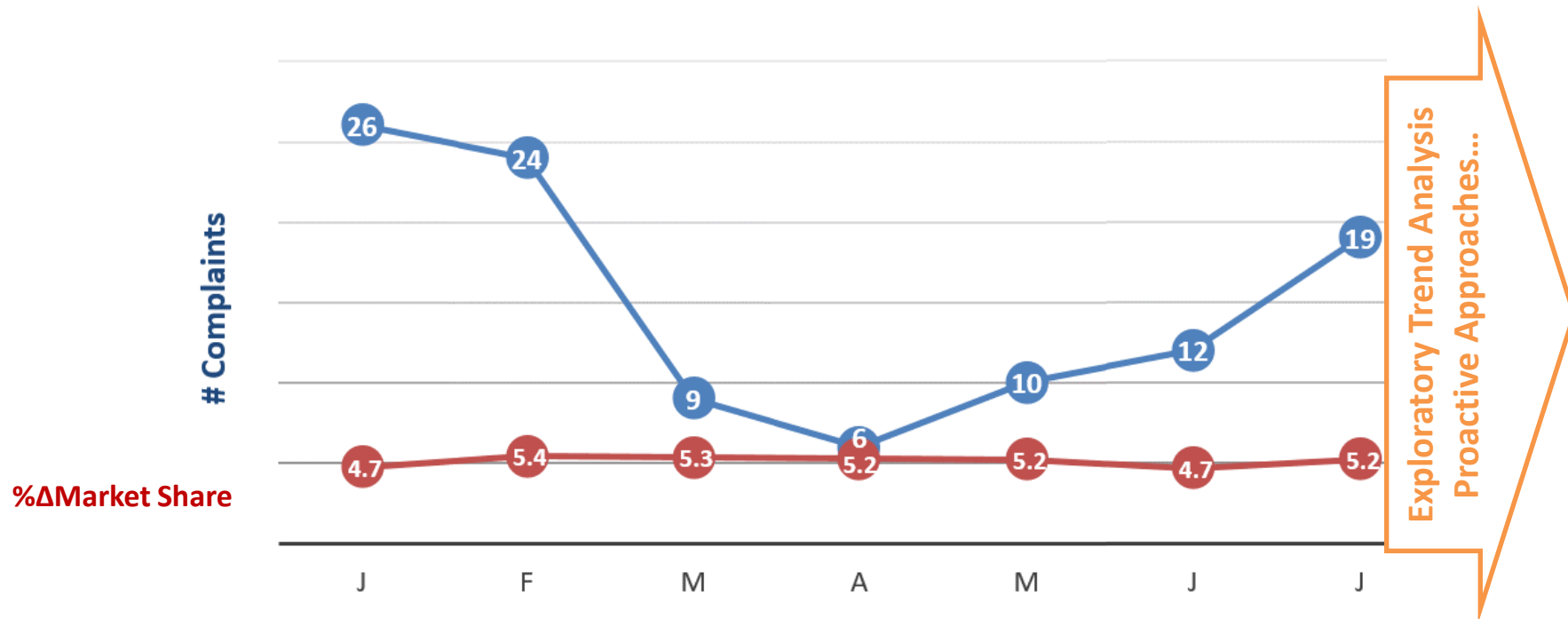
## Cross-Office Data Collaboration

- Sentinel (Office of Surveillance and Epidemiology):
  - Assess safety of approved medical products
  - Identify research questions to answer generic drug safety questions
- RAPID (Office of Translational Sciences)
  - Real-time Application for Portable Interactive Devices (RAPID) for Data Safety and Patient Outcomes  
<https://vimeo.com/279739622/b986eb8329>
- Office of Generic Drugs (OGD) regulatory science projects
  - <https://www.fda.gov/drugs/generic-drugs/2019-office-generic-drugs-annual-report#OGD>
- Geographical Information System (GIS)

# Proactive Approaches to Safety Surveillance

- Exploratory data analysis may help us “early detect” generic drug complaints or medication use errors at the patient user interface

# IQVIA Drug Utilization Data Example





# Summary

- OGD continues to enhance every aspect of generic pharmacovigilance as a high-level priority
- Data can demonstrate that generic drugs have the same safety profile as brand drugs



# Challenge Questions

- Who can submit adverse events or medication errors to FDA MedWatch?
  - a) Health Professionals
  - b) Patients and Consumers
  - c) Industry
  - d) All of the Above
  
- What FAERS data available to the public?
  - a) FAERS dashboard
  - b) FAERS dashboard and data files
  - c) Formally requested only
  - d) Data is not publicly available

# Acknowledgements

## ➤ **Howard Chazin, MD**

Director, Clinical Safety Surveillance Staff (CSSS)

### CSSS Data Team

- **James Osterhout, PhD**
  - Data Team Leader
- **Jung Lee, RPh**
  - Data Analyst

### CSSS Clinical Team

- **Karen Feibus, MD**
  - Clinical Team Leader
- **Linda Forsyth, MD**
- **Glenn Mannheim, MD**
  - Medical Officers

## ➤ **Debra Catterson, RPh**

CSSS Drug Safety Coordinator

