# FDA MedWatch Adverse Event Reporting Curriculum Case Study: Instructor's Guide

## DRUGS, DEVICES, & BIOLOGICS: Health professionals encounter adverse events with medical products and learn about reporting to FDA MedWatch

### LEARNING OBJECTIVES

- Identify how to receive safety information from the FDA.
- Identify how to submit a quality medical product problem report to FDA.
- Explain how reports are used by FDA to investigate medical product problems and are translated into safety actions such as recalls or safety communications.
- Review the definitions of drug, device, and biologic.

### TOPICS

Adverse event reporting; MedWatch; Forms 3500, 3500B, 3500A; Drugs; Devices; Biologics

### ASSUMPTIONS

This case study is based on the assumption that the target audience is undergraduate students or health professionals who have little experience with adverse event reporting.

### SUGGESTED APPROACH

1. Preparing Students: Students are expected to read the case study prior to the training session.

2. Engaging Students: The training session should consist of a discussion of the case study and completion of a MedWatch form.

3. Immersing Students: The training session should emphasize group discussion of the two examples in the case study. Students should be encouraged to review an additional case study on MedWatchLearn after class.

### STUDENT ACTIVITIES

**Before Class**

Review the following materials before class:

1. MedWatch Homepage
http://www.fda.gov/Safety/MedWatch/default.htm

2. Print hard copies of Form 3500B and Form 3500 and bring them to class. http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm

Answer the following questions before class:

1. How are reporting forms 3500, 3500B, and 3500A different?

Answer:

- Form FDA 3500, Voluntary Reporting: For use by health care professionals, consumers, and patients.
- Form FDA 3500B, Voluntary Reporting for Consumers: A consumer-friendly version of the 3500 reporting form.
- Form FDA 3500A Mandatory Reporting: For use by IND reporters, manufacturers, distributors, importers, and user facilities personnel.

2. True or False: Vaccine product problems should be reported to MedWatch.

Answer: **False.** Vaccine product problems should be reported to the Vaccine Adverse Event Reporting System (VAERS), not MedWatch. VAERS is a national vaccine safety surveillance program co-sponsored by FDA and the Centers for Disease Control and Prevention (CDC).

3. Good case reports include the following elements:

a. Description of the adverse events or disease experience, including time to the beginning of signs or symptoms
b. Clinical course of the event and patient outcomes (e.g., hospitalization or death)
c. Relevant therapeutic measures and laboratory data at baseline, during therapy, and subsequent to therapy, including blood levels, as appropriate
d. All of the above

Answer: **d.** All of the above

4. FDA's MedWatch program offers several ways to help you stay informed about the medical products including:

a. E-mail
b. Twitter
c. RSS feed
d. Facebook
e. a, b, and c
f. All of the above

Answer: **e.** a, b, and c

5. What gets reported to FDA MedWatch and what gets reported to the Safety Reporting Portal?

Answer:

- MedWatch supports reporting for drugs, non-vaccine biologicals, medical devices, special nutritional products, cosmetics, and over-the-counter (OTC) human drug products through the MedWatch system. The paper version of Form 3500 can be used to submit reports about tobacco products and dietary supplements to MedWatch.

- Electronic reports for tobacco products and dietary supplements should be submitted to FDA through the Safety Reporting Portal.

- Reports for vaccines should be submitted to the VAERS.

**In Class**

Suggestions for in-class group discussion:

1. Discuss what happens to a MedWatch report after it is received. What could constitute a safety signal?

Facilitate a discussion around how MedWatch reports are received and reviewed by FDA. The following could constitute a safety signal:

- a new, previously unknown, adverse event
- a new drug interaction
- an observed change in quantity, severity, or the affected populations of a known adverse event

2. How can MedWatch reports result in product changes?

Discuss how FDA can initiate actions such as product label updates; requests for changes to a product's design, manufacturing process, or packaging; product recalls; or requests for accompanying Medication Guides.

3. Break into smaller groups. Use Jim Bean or Carol Ratner's scenario from the case study to complete a MedWatch form and present to the class.

**After Class**

I. Sign up to receive MedWatch safety alerts.
http://www.fda.gov/Safety/MedWatch/ucm228488.htm

II. Practice completing a case-report on the MedWatchLearn system. Print and submit it to your instructor.
http://www.accessdata.fda.gov/scripts/MedWatchLearn/

**Additional References**

Webinar: Introduction to FDA's MedWatch Adverse Event Reporting Program

Your Guide to Reporting Problems to FDA
http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm095859.htm

FDA Basics: Drugs
http://www.fda.gov/AboutFDA/Transparency/Basics/ucm192696.htm

FDA Basics: Biological Products
http://www.fda.gov/AboutFDA/Transparency/Basics/ucm355978.htm

FDA Basics: Medical Devices
http://www.fda.gov/AboutFDA/Transparency/Basics/ucm193731.htm