Introduction to FDA's MedWatch Adverse Event Reporting Program

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Webinar Hosted by CDER's Office of Communication, Division of Drug Information (DDI)
Learning Objectives

• Describe the FDA MedWatch Program.
• Identify the types of adverse events and product problems that should be reported to FDA.
• Explain how to submit a report to the FDA MedWatch Program.
• Summarize how to obtain safety information from FDA MedWatch.
Office of the Commissioner

Office of Medical Products & Tobacco

Office of Global Reg. Ops & Policy

Office of Foods

Center for Food Safety & Applied Nutrition

Center for Veterinary Medicine

Center for Devices & Radiological Health

Center for Biologics Evaluation & Research

Center for Drug Evaluation & Research

Center for Tobacco Products

Office of Regulatory Affairs
FDA Regulates $1 Trillion Worth of Products a Year

Every morning when you wake up and
brush your teeth
put in your contact lenses
microwave your breakfast
take your medicine
feed your pet
select a lipstick
go grocery shopping
get a flu shot or a mammogram….

You have been touched by the U. S. Food and Drug Administration.
Assessment Question 1

Which is *Not* Regulated by the FDA?

A) Aspirin  
B) Anti-lice shampoo  
C) Insect repellent  
D) Lipstick
FDA MedWatch and Patient Safety

• Reports **IN**
  – Reports about problems with medical products come **IN** to MedWatch.

• Safety **OUT**
  – Safety information about medical products goes **OUT** to health professionals, patients, and consumers.

Your gateway for learning about important safety information and reporting serious problems with medical products.
MedWatch Milestones

- **1993**: MedWatch Voluntary Reporting Form Launched
- **1996**: MedWatch on the World Wide Web
- **2000**: E-List Subscribers
- **2010**: Consumer Form 3500B available
- **2013**: Mobile Technology
Why Report?

• Not all products have clinical data/trials before clearance to market

• Limitations of clinical trials to identify safety signals before marketing

• Number of patients tested may be too small to detect serious but rare problems

• Trials are brief
MedWatch Reporting IN

• Anyone can report a serious problem.

Walla Walla, WA – Pharmacist
Sacramento, CA – Nurse
Houston, TX – Dentist
Tallahassee, FL – Consumer
Portland, ME – Physician Assistant
MedWatch Reporting IN

• One person can make a difference.
MedWatch - What to Report

• Any event that:
  – Is fatal.
  – Is life-threatening.
  – Is permanently disabling.
  – Requires/prolongs hospitalization.
  – Causes a birth defect.
  – Requires intervention to prevent permanent impairment or damage.
  – Potential for harm/close calls (drugs or devices).
MedWatch - What to Report
Labels- Expression of Strength

**Before**

```
CAMPTOSAR®
Injection
irinotecan hydrochloride injection
20 mg/mL
(on basis of trihydrate)
Caution: Federal law prohibits dispensing without prescription.
Warning: For intravenous use only—must be diluted before use.
Pharmacia & Upjohn
```

**After**

```
CAMPTOSAR™
Injection
irinotecan hydrochloride injection
100 mg/5 mL
(20 mg/mL)
(on basis of trihydrate)
Caution: Federal law prohibits dispensing without prescription.
Warning: For intravenous use only—must be diluted before use.
Pharmacia & Upjohn
```
FDA is also interested in cases where the potential for harm exists. Such reports help FDA identify and better understand the risks associated with medical products.

CASE STUDY

- A child had both a gastric feeding tube for nutrition and an IV for medicine and hydration.
- When the child’s gown was changed, a family member inadvertently attached the IV tubing to the gastric feeding tube.
- The medicine was delivered through the feeding tube into the stomach.
- There was no patient harm since the event was noted in a timely manner.

POTENTIAL FOR HARM: Moderate

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/ucm313275.htm
Assessment Question 2

True or False. You must be a healthcare professional in order to submit a report to MedWatch.

False
MedWatch- Reporting IN

• How to Report:
  – Online
    (www.fda.gov/medwatch/report.htm)
  – Download the form
    • Mail
    • Fax 1–800–332–0178

• For questions about the form:
MedWatch Reporting - VOLUNTARY

Clinician Form 3500

Consumer/Patient Form 3500B
MANDATORY Form 3500A

- User Facilities (medical devices)
- Manufacturers
  - Drugs
  - Biologics
  - Human Cell and Tissue Products
  - OTC Products
  - Medical Devices
Responsive Design

- First for FDA website
- Screen will adjust to device used to access web page: i.e. tablets, smart phone
How do I report?

Report A Problem

www.fda.gov/medwatch
MedWatch Online Voluntary Reporting Form

Welcome

What to Report to FDA MedWatch:

Use the MedWatch form to report adverse events that you observe or suspect for human medical products, including serious drug side effects, product use errors, product quality problems, and therapeutic failures for:

- Prescription or over-the-counter medicines, as well as medicines administered to hospital patients or at outpatient infusion centers
- Biologics (including blood components, blood and plasma derivatives, allergenic, human cells, tissues, and cellular and tissue-based products (HCT/Ps))
- Medical devices (including in vitro diagnostic products)
- Combination products
- Special nutritional products (dietary supplements, infant formulas, and medical foods)
- Cosmetics
- Foods/beverages (including reports of serious allergic reactions)

www.fda.gov/medwatch/report
Assessment Question 3

The FDA will accept your adverse event report by which of the following methods?

A) Mail
B) Online submission
C) Fax
D) All of the Above
What makes a good report a Great report?
Reporting Tutorial – MedWatchLearn

- Online practice portal
  - Students/Health Professionals
  - Consumers Section
  - Learn how to fill out a MedWatch Report

www.fda.gov/medwatchlearn
FDA MedWatchLearn teaches students, health professionals, and consumers how to complete the forms necessary to report a problem to FDA. You may choose to practice completing the FDA Form 3500 for health professionals or the FDA Form 3500B for consumers.

Learn more about MedWatch medical product safety or submit an actual report.

To start, select either “Students and Health Professionals” or “Consumers.”

This site performs best with Internet Explorer 9 or higher, or recent versions of Firefox, Safari, and Chrome web browsers. If you have difficulty viewing or printing pages, try updating your browser to the latest available version.
What Happens to Your MedWatch Report?

- Report is captured in a database.
- FDA safety evaluator reviews the report.
- FDA safety evaluator looks for similar reports.
- FDA review division may consult with manufacturer.
- FDA /manufacturer conducts further epidemiological studies or post-market clinical trials as needed.
How can MedWatch Reports Result in Product Changes?

– Update the product label.
– Include a Medication Guide.
– Request a change in the product’s design, process, packaging, or distribution.
– Request a product recall.
MedWatch-Safety OUT

- Subscribe to MedWatch
  - E-list
  - Twitter
  - RSS feeds
Example of Individual MedWatch Safety Alert

Eszopiclone Containing Sleep Aids: Drug Safety Communication - Can Cause Next-Day Impairment

Including Lunesta and generics

[Posted 05/15/2014]

AUDIENCE: Pharmacy, Primary Care Medicine

ISSUE: FDA has notified health professionals and their medical care organizations of a new warning that the insomnia drug Lunesta (eszopiclone) can cause next-day impairment of driving and other activities that require alertness. FDA recommends a decreased starting dose of Lunesta to 1 mg at bedtime. Women and men are equally susceptible to impairment from Lunesta, so the recommended starting dose of 1 mg is the same for both. FDA approved changes to the Lunesta prescribing information and the patient Medication Guide to include these new recommendations. The drug labels for generic eszopiclone products will also be updated to include these changes.

BACKGROUND: A study of Lunesta found that the previously recommended dose of 3 mg can cause impairment to driving skills, memory, and coordination that can last more than 11 hours after receiving an evening dose (see Data Summary). Despite these driving and other problems, patients were often unaware they were impaired. The new lower recommended starting dose of 1 mg at bedtime will result in less drug in the blood the next day.

RECOMMENDATION: Health care professionals should follow the new dosing recommendations when starting patients on Lunesta. Patients should continue taking their prescribed dose of Lunesta and contact their health care professionals to ask about the most appropriate dose for them. FDA is continuing to evaluate the risk of impaired mental alertness with the entire class of sleep aid drugs, including over-the-counter drugs available without a prescription, and will update the public as new information becomes available.

[06/15/2014 - Drug Safety Communication - FDA]
Related MedWatch Alert:
[06/14/2013 - Zolpidem Containing Products]
## June 2015

### Drug Safety Labeling Changes

The summary view includes drug products with safety labeling changes to the BOXED WARNING, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, or PATIENT PACKAGE INSERT/MEDICATION GUIDE sections. The "quick view" table below provides the drug name and sections modified. Click on the drug name to go to the detailed view. The detailed view includes sections and subsections modified, a description of new or modified safety information in the BOXED WARNING, CONTRAINDICATIONS, or WARNINGS sections, and a link to the revised prescribing information.

**Key to Label Section Acronyms:**
- BW = BOXED WARNING
- C = CONTRAINDICATIONS
- W = WARNINGS
- P = PRECAUTIONS
- AR = ADVERSE REACTIONS
- PPI/MG = PATIENT PACKAGE INSERT/MEDICATION GUIDE

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<th>DRUG NAME</th>
<th>BW</th>
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<td>Enjuvia (synthetic conjugated estrogens, B) Tablets</td>
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<td>Capoten (captopril) Tablets</td>
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<td>Rocephin (ceftiraxone sodium) for injection</td>
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<td>Angeliq (drospirenone and estradiol) Tablets</td>
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**Monthly Safety Labeling Changes**
MedWatch Communication OUT

- Distributes important and timely information about safety issues involving medical products via MedWatch safety alerts:
  - 149 MedWatch Alerts in 2015
    - 76 drugs and therapeutic biologics
    - 65 medical devices
    - 7 products with undeclared ingredients
    - 1 special nutritional
  - 484 safety labeling changes posted for medical products in 2015
    - Update to the prescribing information, package insert, medication guide, and/or product label
Conclusion/Review

• MedWatch is the FDA's safety information and adverse event reporting program.
• Through FDA MedWatch, healthcare professionals should report serious events adverse events.
• Healthcare professionals can submit the completed Form 3500 to the FDA MedWatch system online, by fax, or mail.
Thank You
Questions?

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