

FDA's MedWatch Adverse Event Reporting Program - Opportunities to Collaborate -



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Today's Presentation

- ➔ About FDA Public Health Mission
- ➔ About the MedWatch Program
- ➔ Ways to Engage with FDA
- ➔ Challenges to Meaningful Engagement



FDA's Public Health Mission

- ➔ Ensure the safety, effectiveness, and security of human and animal drugs, biological products and medical devices
- ➔ Ensure the safety of foods, cosmetics, and radiation-emitting products
- ➔ Regulate tobacco products



FDA Regulates \$2.4 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 sunscreen
 go grocery shopping
 get a flu shot or a mammogram....

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



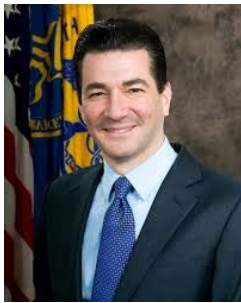
Approximately 20 cents on every dollar spent in the U.S.

FDA's Oversight Responsibilities

- ➔ 75 % of U.S. food supply
- ➔ 300,000 registered facilities, more than 80% of them abroad
- ➔ Over 17,000 prescription drug products
- ➔ Over 6,000 categories of medical devices



- ➔ Over 320 FDA-licensed biologic products
- ➔ Over 4,500 currently regulated tobacco products



**Office of the
Commissioner**

**Office of
Foods**

**Office of Medical Products
& Tobacco**

**Office of Global
Regulatory
Operations &
Policy**



**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**



What is MedWatch?

1. A way to send information you observe or experience from regulated medical products to FDA
2. A way to stay up-to-date on recently reported safety information from FDA

www.fda.gov/medwatch

Who Can Report to MedWatch?



Healthcare Professionals



Consumers and Patients



Why Report to MedWatch?

“Every product that FDA approves carries some risk...Sometimes there are risks that only come to light after a medical product gets on the market and is used in a larger number of patients, for a longer period of time, and in patients whose health characteristics are different from those of the patients studied before approval.”

- Norman Marks, M.D., retired MedWatch Medical Officer

Why Report to MedWatch?

- ➔ 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: Safety Information *IN*

*One person can
make a difference*



MedWatch *Safety Alerts*

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Total	128	139	169	138	140	203	181	149	164	159

Safety Alerts will update you on new information about:

- ➔ *Drugs and Therapeutic Biologics*
- ➔ *Medical devices*
- ➔ *Nutritional products*
- ➔ *Cosmetics*
- ➔ *Products with undeclared drugs*
- ➔ *Tobacco*

MedWatch - What to Report

➔ Serious events such as:

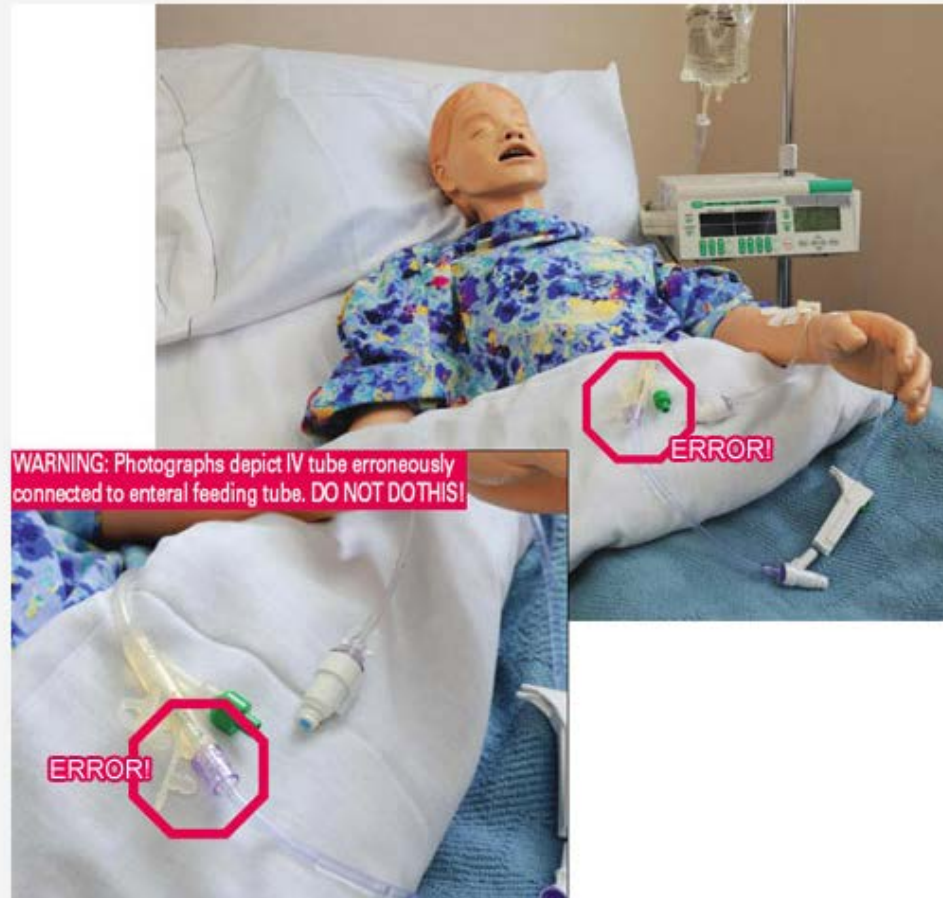
- ➔ death
- ➔ life-threatening
- ➔ permanently disabling
- ➔ prolongs hospitalization
- ➔ birth defect
- ➔ Requires intervention to prevent permanent impairment or damage

- ➔ Medication errors
- ➔ Product quality problems
- ➔ Potential for error
- ➔ Non-serious events



Potential Harm

IV tubing erroneously connected to enteral feeding tube



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

Potential Errors

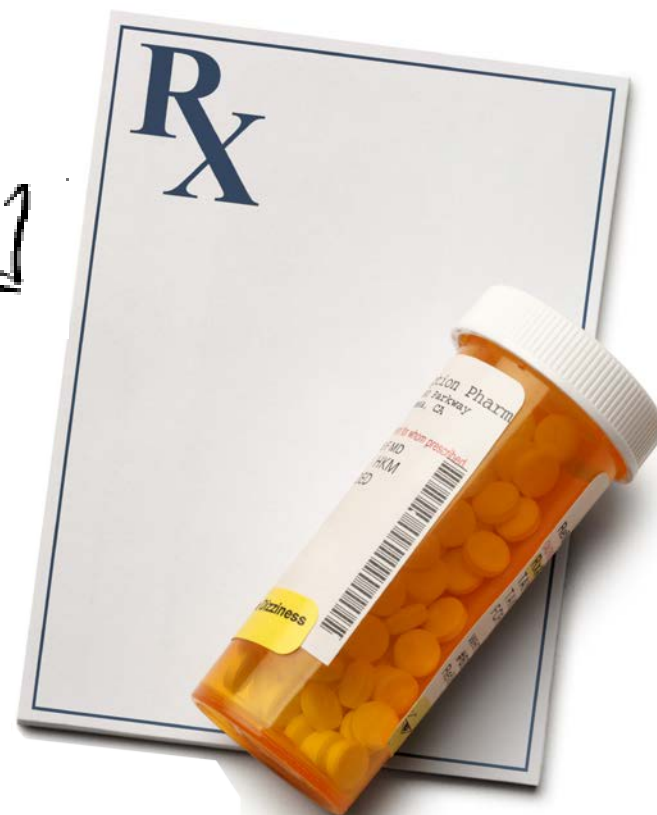
➔ Prescribing

➔ handwriting, abbreviations

Zydrin 10, 190 1/2 qd

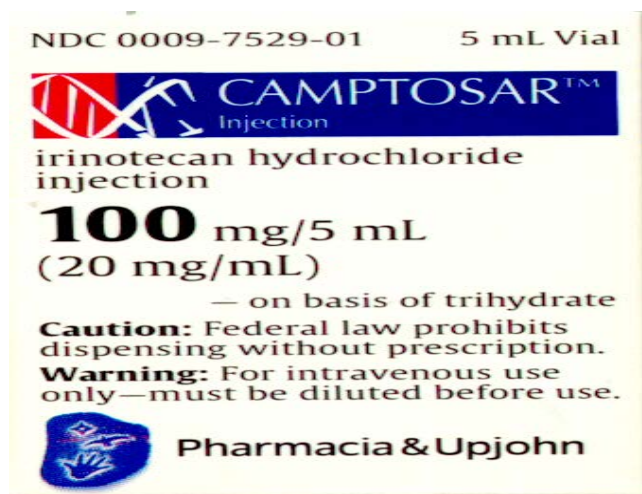
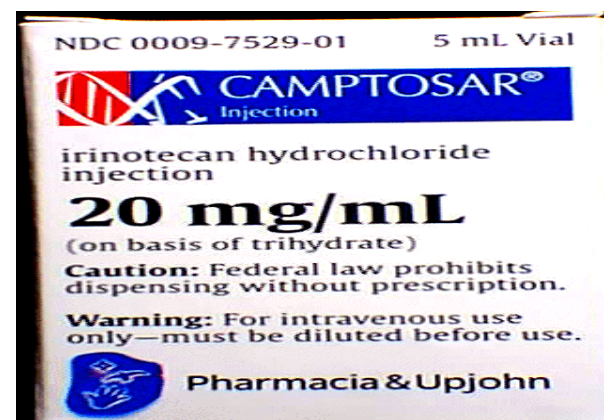
➔ Miscommunication of Orders/ Nomenclature

➔ sound alike, look alike



Potential Errors

- Label/Packaging
 - placement of information
 - expression of strength/dose
 - readability of label
 - inappropriate labeling during repackaging



MedWatch - What *Not* to Report

- ➔ Tobacco Products
- ➔ Vaccines
- ➔ Investigational Drugs
- ➔ Dietary Supplements
- ➔ Veterinary Medicine





How to Report to MedWatch?

Clinician Form 3500

U.S. Department of Health and Human Services
MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 (See PRA Statement on reverse)

For VOLUNTARY reporting of adverse events, product problems and product use errors

FDA USE ONLY
Triage Unit/Enclosure #

Page 1 of 3

A. PATIENT INFORMATION

1. Patient Identifier # 2. Age at Time of Event or Date of Birth: 3. Sex: 4. Weight: 5. Height:

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
(Check all that apply)

1. Adverse Event Product Problem (e.g., defects/malfunctions) Product Use Error Problem with Different Manufacturer of Same Medicine

2. Outcome Attributed to Adverse Event (Check all that apply):
 a. Death: Disability or Permanent Damage
 b. Life-threatening Congenital Anomaly/Birth Defect
 c. Hospitalization - initial or prolonged Other Serious (Important Medical Events)
 d. Required Intention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy)

C. SUSPECT MEDICAL DEVICE

1. Brand Name 2. Common Device Name 2b. Procedure 3. Manufacturer Name, City and State 4. Model # 5. Operator of Device Health Professional Lay User/Patient 6. Lot # 7. Expiration Date (mm/dd/yyyy) 8. Catalog # 9. Serial # 10. Unique Identifier (UDI) # 11. If Implanted, Give Date (mm/dd/yyyy) 12. If Explanted, Give Date (mm/dd/yyyy) 13. Is this a Single-Use Device that was Reprocessed and Reused on a Patient? Yes No 14. If Yes to Item No. 8, Enter Name and Address of Reprocessor

D. OTHER (CONCOMITANT) MEDICAL PRODUCTS
Product names and therapy dates (exclude treatment of event)

E. REPORTER (See confidentiality section on back)

1. Name and Address: Name: Address: City: State: ZIP: Phone #: E-mail:

2. Health Professional? Yes No 3. Occupation: 4. Also Reported to: Manufacturer User Facility Distributor/Importer

5. If you do NOT want your identity associated to the manufacturer, place an "X" in this box: Yes No

FORM FDA 3500 (2/13) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Consumer/Patient Form 3500B

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 (See PRA Statement on preceding general information page)

MEDWATCH Consumer Voluntary Reporting (FORM FDA 3500B)

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year, for example, 01-Jul-2015.

Section A - About the Problem

What kind of problem was it? (Check all that apply)

- Were hurt or had a bad side effect (including new or worsening symptoms)
- Used a product incorrectly which could have led to a problem
- Noticed a problem with the quality of the product
- Had problems after switching from one product maker to another maker

Did any of the following happen? (Check all that apply)

- Hospitalization - admitted or stayed longer
- Required help to prevent permanent harm (for medical devices only)
- Disability or health problem
- Birth defect
- Life-threatening
- Death (include date)(dd-mmm-yyyy): . . . - . . . - . . .
- Other serious/important medical incident (Please describe below)

Date the problem occurred (dd-mmm-yyyy)

Tell us what happened and how it happened. (Include as many details as possible)

List any relevant tests or laboratory data if you know them. (Include dates)

When do I use this form?

- You were hurt or had a bad side effect (including new or worsening symptoms) after taking a drug or using a medical device or product.
- You used a drug, product, or medical device incorrectly which could have or led to unsafe use.
- You noticed a problem with the quality of the drug, product or medical device.
- You had problems with how a drug worked after switching from one maker to another maker.

Don't use this form to report:

- Vaccines - report problems to the Vaccine Adverse Event Reporting System (VAERS).
- Investigational drugs or medical devices (those being studied) - report problems to your doctor or to the contact person listed in the clinical trial.

Will the information I report be kept private?

The FDA recognizes that privacy is an important concern with the company that makes the product. We ask only for the name and contact information that will help us understand the problem you are reporting, unless you request otherwise (see Section B).

What types of products should I report?

- Drugs, including prescription or over-the-counter medicines and biologics, but not sterile ophthalmics, and bone and joint implants.
- Medical devices, and tools or pieces of equipment, pacemakers, defibrillators, breast pumps, hearing aids, dental or orthodontic appliances, and hearing aids.
- Contraceptives and fertility products.
- Medical devices, and tools or pieces of equipment, pacemakers, defibrillators, breast pumps, hearing aids, dental or orthodontic appliances, and hearing aids.
- Contraceptives and fertility products.

For a problem with a product, including

- prescription or over-the-counter medicine
- biologics, such as human cells and tissues used for transplantation (for example, tendons, ligaments, and bone) and gene therapies
- nutrition products, such as vitamins and minerals, herbal remedies, infant formulas, and medical foods
- cosmetics or make-up products
- foods (including beverages and ingredients added to foods)

Go to Section B

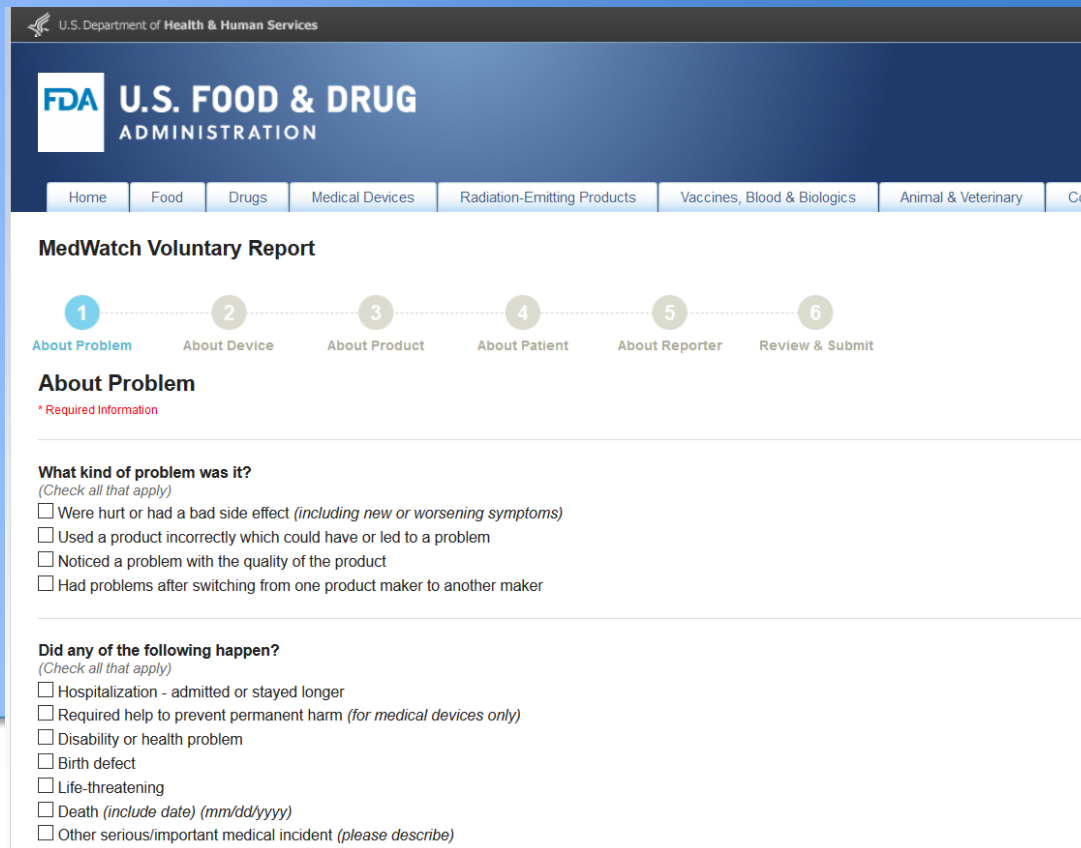
For a problem with a medical device, including

- any health-related test, tool, or piece of equipment
- health-related kits, such as glucose monitoring kits or blood pressure cuffs
- implants, such as breast implants, pacemakers, or catheters
- other consumer health products, such as contact lenses, hearing aids, and breast pumps

Go to Section C (Skip Section B)

How to Report to MedWatch?

Online Voluntary Report



U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics

MedWatch Voluntary Report

1 About Problem 2 About Device 3 About Product 4 About Patient 5 About Reporter 6 Review & Submit

About Problem

* Required Information

What kind of problem was it?
(Check all that apply)

- Were hurt or had a bad side effect (including new or worsening symptoms)
- Used a product incorrectly which could have or led to a problem
- Noticed a problem with the quality of the product
- Had problems after switching from one product maker to another maker

Did any of the following happen?
(Check all that apply)

- Hospitalization - admitted or stayed longer
- Required help to prevent permanent harm (for medical devices only)
- Disability or health problem
- Birth defect
- Life-threatening
- Death (include date) (mm/dd/yyyy)
- Other serious/important medical incident (please describe)



MedWatch Form

U.S. Department of Health and Human Services

MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

Page 1 of _____

FDA USE ONLY
Triage unit sequence # _____

A. PATIENT INFORMATION

1. Patient Identifier # _____ at time of event (or _____ if unknown)

Sex: Male Female
Weight: _____ lb or _____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. Adverse Event Product Problem (e.g., defects/malfunctions)
 Product Use Error Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)

Death: (mm/dd/yyyy) Disability or Permanent Damage
 Life-threatening Congenital Anomaly/Birth Defect
 Hospitalization - initial or prolonged Other Serious (Important Medical Events)
 Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy)

5. Describe Event, Problem or Product Use Error

6. Relevant Tests/Laboratory Data, including Dates

7. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
 Yes No Returned to Manufacturer on: (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 Name: _____
Strength: _____
Manufacturer: _____

#2 Name: _____
Strength: _____
Manufacturer: _____

2. Health Professional's Occupation
 Yes No

4. Also Reported to:
 Manufacturer
 Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:

E. SUSPECT MEDICAL DEVICE

1. Brand Name _____

2. Common Device Name _____

3. Manufacturer Name, City and State _____

4. Model # _____ Lot # _____

5. Operator of Device
 Health Professional
 Lay User/Patient
 Other: _____

6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
 Yes No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor _____

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS
Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

1. Name and Address
Name: _____
Address: _____
City: _____ State: _____ ZIP: _____
Phone # _____ E-mail: _____

2. Health Professional's Occupation
 Yes No

3. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:

4. Also Reported to:
 Manufacturer
 Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:

FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Patient Identifier

Event or Problem

Reporter

Product

Quality is Key: Case #1

- Health care worker ST reported male patient ABC123 started Drug X at 5 mg daily for type 2 diabetes on February 11, 2015.
- The patient developed liver failure.

Question: Does Case #1 contain the four elements?

YES

NO



Quality is Key: Case #1

- Health care worker **ST** reported male patient **ABC123** started **Drug X** at 5 mg daily for type 2 diabetes on February 11, 2015.
- The patient developed **liver failure**.

MedWatch Reporting- MANDATORY

MANDATORY Form 3500A

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

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH
FORM FDA 3500A (10/15)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Page 1 of 3

Form Approved OMB No. 0910-0291, Expires: 9/30/2016
See PRA statement on reverse

MR Report # _____
UF/Importer Report # _____
FDA Use Only

Note: For date prompts of "dd-mm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. Patient Identifier # _____
2. Age: Year(s) Month(s) Day(s) Week(s) Days(s)
or Date of Birth (e.g., 08 Feb 1925) _____
3. Sex: Male Female
4. Weight: lb kg
5.a. Ethnicity (Check single best answer) Asian American Indian or Alaskan Native Hispanic/Latino Black or African American White Not Hispanic/Latino Native Hawaiian or Other Pacific Islander
5.b. Race (Check all that apply)

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event and/or Product Problem (e.g., defects/malfunctions)
2. Outcome Attributed to Adverse Event (Check all that apply)
 Death (include date (dd-mm-yyyy)) _____ Disability or Permanent Damage
 Life-threatening Hospitalization - initial or prolonged Congenital Anomaly/Birth Defects
 Other Serious (Important Medical Events)
 Required Intervention to Prevent Permanent Impairment/Damage (Devices)
3. Date of Event (dd-mm-yyyy) _____ 4. Date of this Report (dd-mm-yyyy) _____
5. Describe Event or Problem
(Continue on page 3)
6. Relevant Test/Laboratory Data, Including Dates
(Continue on page 3)
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
(Continue on page 3)

C. SUSPECT PRODUCT(S)

1. Name, Manufacturer/Compounder, Strength
#1 - Name and Strength _____ #1 - NDC # or Unique ID _____
#1 - Manufacturer/Compounder _____ #1 - Lot # _____
#2 - Name and Strength _____ #2 - NDC # or Unique ID _____
#2 - Manufacturer/Compounder _____ #2 - Lot # _____
2. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name _____
2. Common Device Name _____ 2b. Procode _____
3. Manufacturer Name, City and State _____
4. Model # _____ Lot # _____
Catalog # _____ Expiration Date (dd-mm-yyyy) _____
Serial # _____ Unique Identifier (UDI) # _____
5. Operator of Device
 Health Professional Lay User/Patient Other
6. If Implanted, Give Date (dd-mm-yyyy) _____ 7. If Explanted, Give Date (dd-mm-yyyy) _____
8. Is this a single-use device that was reprocessed and reused on a patient? Yes No
9. If Yes to Item 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA)
 Yes No Returned to Manufacturer on: _____
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
Last Name: _____ First Name: _____
Address: _____
City: _____ State/Province/Region: _____
Country: _____ ZIP/Postal Code: _____
Phone #: _____ Email: _____

2. Health Professional? Yes No
3. Occupation (Select from list) _____
4. Initial Reporter Also Sent Report to FDA Yes No Unk

PLEASE TYPE OR USE BLACK INK

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

Reporting Tutorial – MedWatchLearn

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



The screenshot shows the MedWatchLearn website interface. At the top, it features the U.S. Department of Health & Human Services logo and the FDA logo with the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". The MedWatch logo is also present. The main heading is "MEDWATCHLEARN". Below this, a paragraph states: "FDA MedWatchLearn teaches students, health professionals, and consumers how to complete the forms necessary to report problems to FDA. Here, you have the opportunity to practice filling out FDA Form 3500 (for health professionals) or FDA Form 3500B (for consumers)." There are two links: "Learn more about MedWatch medical product safety or submit an actual report." and "To start, select either 'Students and Health Professionals' or 'Consumers.'" Below these links are two buttons: a blue button for "Students and Health Professionals (FDA Form 3500)" and a green button for "Consumers (FDA Form 3500B)". At the bottom, there is a note about browser compatibility and a page update date of 05/29/2013.

Reporting Tutorial - MedWatch Learn

Food and Drug Administration
MEDWATCH

MEDWATCHLEARN

FDA **MedWatchLearn** teaches students, health professionals, and consumers how to complete the forms necessary to report an adverse event. You have the opportunity to practice filling out **FDA Form 3500** (for health professionals) or **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."



Students and Health Professionals
(FDA Form 3500)



Consumers
(FDA Form 3500B)

This site performs best with Internet Explorer 9 or higher, or recent versions of Firefox, Safari, and Chrome web browsers. If you are having trouble viewing or printing pages, try updating your browser to the latest available version.

Page Last Updated: 05/29/2013
Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).
MedWatchLearn v1.0

FDA U.S. Food and Drug Administration
Protecting and Promoting Your Health
MEDWATCHLEARN
Students and Health Professionals

We've provided case studies for the four categories of problems with medical products. You will have an opportunity to practice completing FDA Form 3500, our voluntary reporting form for health professionals, using these case studies. We encourage you to also become familiar with our form for consumers, FDA Form 3500B, and educate your patients on reporting adverse events.

These case studies are based on actual reports received by the FDA and selected for this portal because of the quality of the report. Personally identifiable information has been changed to maintain confidentiality. To begin, click on one of the case studies.

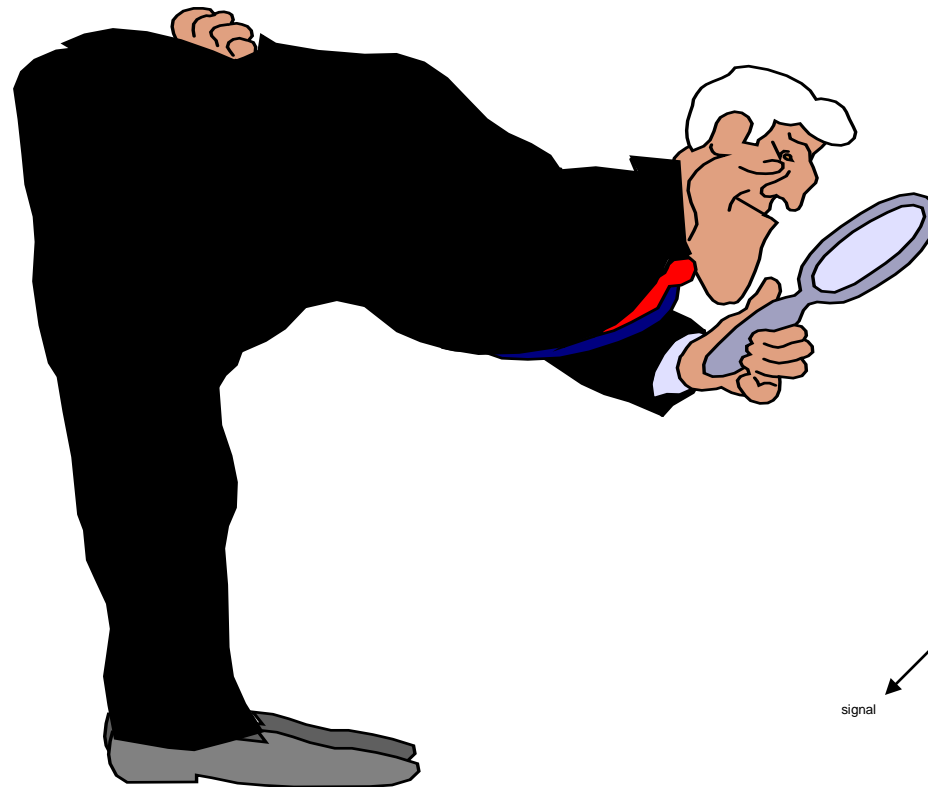
NOTE: This is a training site; therefore, reports you complete will not be saved and submitted to FDA. To submit an actual report, go to the MedWatch Online Voluntary Reporting page.

- Adverse Effects**
Any incident in which a medical product was suspected to have resulted in an undesirable experience for the patient.
 - Case Study 1 – Drug
 - Case Study 2 – Biologic Product
 - Case Study 3 – Medical Food
 - Case Study 4 – Dietary Supplement
- Product Use Error**
Any medication or medical product error regardless of patient involvement and outside report circumstances that have the capacity to cause error, such as similar labels.
 - Case Study 1 – Human Factors
 - Case Study 2 – Medication Error
- Product Problem**
Any concerns about the quality, authenticity, performance, or safety of any medication or device.
 - Case Study 1 – Drug
 - Case Study 2 – Device
- Problem with Different Manufacturer of Same Medicine**
Any differences in therapeutic response after switching from one manufacturer to another.
 - Case Study 1 – Therapeutic Failure

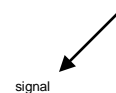
Page Last Updated: 05/13/2013
Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

FDA Accessibility | Contact FDA | Careers | FDA Basics | FOIA | No Fear Act | Site Map | Transparency | Website Policies

What happens to my report?



Did you
see it??



signal

MedWatch: Safety Information *IN*

L-citrulline investigation 2014

- ➔ Late January
 - ➔ Puzzling case at medical center
- ➔ February 7
 - ➔ Pharmacist submits report
 - ➔ Mother submits report
- ➔ February 7-13
 - ➔ FDA investigation
- ➔ February 14
 - ➔ Manufacturer recall
 - ➔ MedWatch Safety Alert communication



*FDA Healthcare Professionals
in Action*

Safety Info *Out*

Safety Information

Possible FDA Actions

Request Labeling Changes

Enhance Education

Send Safety Alert

Request Removal from Market

**Pharmacovigilance
More Studies or New Trials**

Request Change to Design, Packaging, Manufacturing

Request Medication Guide

Lidocaine Viscous: Drug Safety Communication - Boxed Warning Required - Should Not Be Used to Treat Teething Pain

MedWatch Safety Alert

Example

ISSUE: FDA notified health professionals, their provider organizations and caregivers for infants, that prescription oral viscous lidocaine 2% solution should not be used to treat infants and children with teething pain. FDA is requiring a Boxed Warning to be added to the prescribing information (label) to highlight this information. Oral viscous lidocaine solution is not approved to treat teething pain, and use in infants and young children can cause serious harm, including death.

Topical pain relievers and medications that are rubbed on the gums are not necessary or even useful because they wash out of the baby's mouth within minutes. When too much viscous lidocaine is given to infants and young children or they accidentally swallow it, they can result in seizures, severe brain injury, and problems with the heart. Cases of overdose due to wrong use or accidental ingestion have resulted in infants and children being hospitalized or dying.

22 case reports

BACKGROUND: In 2014, FDA reviewed 22 case reports of serious adverse reactions, including deaths, in infants and young children 5 months to 3.5 years of age who were given oral viscous lidocaine 2 percent solution for the treatment of mouth pain, including teething and stomatitis, or who had accidental ingestions. See further details in the FDA Drug Safety Communication.

RECOMMENDATION: Health care professionals should not prescribe or recommend this product for teething pain. Parents and caregivers should follow the American Academy of Pediatrics' recommendations for treating teething pain.

- Use a teething ring chilled in the refrigerator (not frozen).
- Gently rub or massage the child's gums with your finger to relieve the symptoms.

FDA is also encouraging parents and caregivers not to use topical medications for teething pain that are available over the counter (OTC) because some of them can be harmful. FDA recommends following the American Academy of Pediatrics' recommendations to help lessen teething pain.

MedWatch: Safety Info *Out*

Safety

Home > Safety > MedWatch The FDA Safety Information and Adverse Event Reporting Program > Safety Information > Safety Alerts for Human Medical Products

Safety Alerts for Human Medical Products

[2018 Safety Alerts for Human Medical Products](#)

[2017 Safety Alerts for Human Medical Products](#)

Hydromorphone HCL Injection USP by Hospira: Recall - Potential For Empty Or Cracked Glass Vials

[f SHARE](#) [t TWEET](#) [in LINKEDIN](#) [p PIN IT](#) [e EMAIL](#) [p PRINT](#)

[Posted 03/05/2018]

AUDIENCE: Pharmacy, Risk Manager

ISSUE: Hospira is voluntarily recalling three lots of Hydromorphone HCl Injection, USP CII 10 mg/mL, 1 mL in 2 mL Single Dose Vials lot numbers 71330DD (NDC 0409-2634-01), and 691853F and 700753F (NDC 0703-0110-01 – Teva lots) to the hospital/institution level. Hospira initiated this recall on February 07, 2018 due to the potential that units from these lots may be empty or cracked at the bottom of the glass vial.

Cracked vials may compromise the sterility of the product. Use of or exposure to cracked units may be associated with adverse events such as sharps injury to healthcare professionals. Intravenous infusion of a non-sterile solution can lead to bloodstream infections, which may potentially lead to bacteremia or sepsis. These infections are of concern especially to immunocompromised patients.

BACKGROUND: Hydromorphone HCl is an opioid agonist indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. It is also indicated for use in opioid-tolerant patients who require higher doses of opioids for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Hydromorphone HCl Injection, USP CII 10 mg/mL, 1 mL in 2 mL Single Dose Vials, is packaged in a carton of 10 x 1 mL Single-dose vials. The affected lots include the following NDC, lot numbers and expiry dates. Product was distributed nationwide to wholesalers/distributors/retailers/hospitals in the United States and Puerto Rico from October 2016 to July 2017.

RECOMMENDATION: Hospira, Inc. has notified wholesalers/ distributors/retailers/hospitals by recall letter to arrange for return of any recalled product. Wholesalers/distributors/retailers/hospitals with an existing inventory of the lots subject to this recall should stop use and distribution of the remaining units and quarantine immediately. Healthcare Professionals in your organization should be informed of this recall. If you have further

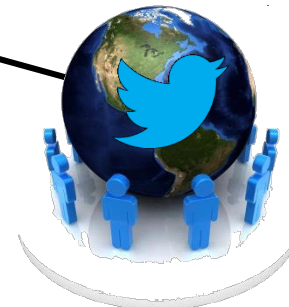
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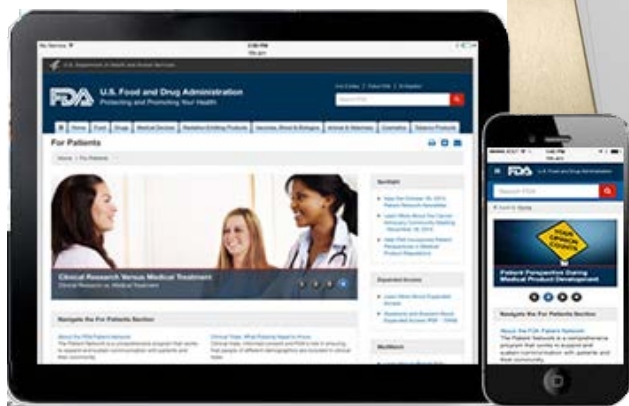


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drugsafety

High doses of loperamide can cause serious cardiac events

BRUNDA J. ROSE

FDA is warning that taking higher-than-recommended doses of the common OTC and prescription anti-diarrheal medicine loperamide, including through abuse or misuse of the product, can cause serious cardiac events, including Torsades de pointes, cardiac arrest, ventricular tachycardia, syncope, and death. The risk of these serious cardiac events may also be increased when high doses of loperamide are taken with several kinds of medicines that interact with loperamide.

The majority of reported serious heart problems occurred in individuals who were intentionally missing and abusing high doses of loperamide in attempts to self-treat opioid withdrawal symptoms or to achieve a feeling of euphoria.

Background
Loperamide is approved to help control symptoms of diarrhea, including traveler's diarrhea. It is sold under the OTC brand name Imodium A-D, as store brands, and as generics.

It is important not to exceed the total

In the majority of severe cases, individuals intentionally abused loperamide.
daily dose that is recommended on the drug label. Loperamide is approved for use in single doses of 4 mg for the first dose, followed by 2 mg after each loose stool for adults. The maximum approved total daily dose is 8 mg per day for OTC use and 16 mg per day for prescription use. Dosing for children depends on the age of the child and is not recommended for use in children younger than 2 years.

Loperamide can interact with drugs that are cytochrome CYP3A4 inhibitors (e.g., itraconazole, clarithromycin, omeprazole), CYP2C8 inhibitors (e.g., gemfibrozil), and P-glycoprotein inhibitors (e.g., quinidine).

Safety data
In the 29 years between when loperamide was first approved in 1976 and 2015, FDA received reports of 48 cases of serious heart problems associated

with use of loperamide. Thirty-one of these cases resulted in hospitalizations, and 10 patients died.

More than one-half of the 48 cases were reported after 2010.

In the majority of severe cases, individuals intentionally abused loperamide. Some patients also missed loperamide by taking higher-than-recommended doses to treat their diarrhea. In the most severe cases, individuals self-treated with doses ranging from 70 mg to 1,600 mg per day, which is 4 to 100 times the recommended dose. In several cases, individuals

used concomitant drugs—CYP3A4 inhibitors, CYP2C8 inhibitors, and P-glycoprotein inhibitors—to increase gastrointestinal absorption, decrease loperamide metabolism, and increase blood brain barrier penetration.

In addition to reviewing the reports described above, FDA searched the medical literature and identified other cases of serious cardiac events with loperamide. Data from U.S. poison control call centers also indicate that since 2005, and particularly since 2010, calls have increased for intentional loperamide exposures, which include cases of intentional abuse, intentional misuse, suspected suicide attempt, and unknown intentional exposures.

As the members of the health care team most often available at the

point of purchase, pharmacists have an opportunity to help patients and caregivers select an appropriate OTC product. Pharmacists should provide the following information when counseling patients and caregivers seeking loperamide-containing products:

- Direct patients to take loperamide only at the dose directed by their primary care provider or according to the OTC Drug Facts label.

- Counsel patients about the cardiac risks of loperamide, and tell them not to use more than the recommended dose.

- Instruct patients to stop taking loperamide and contact their primary care provider if their diarrhea lasts more than 2 days, their symptoms get worse, or they have abdominal swelling or bloating.

- Warn patients that drug interactions with commonly used medications also increase the risk of serious cardiac adverse events.

- Refer patients with opioid use disorders for treatment. There are FDA-approved drugs to reduce opioid withdrawal symptoms.

Pharmacists are encouraged to report adverse events related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program, as follows:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm.
- Download the form or call 800-332-1088 to request a reporting form, then complete and return to the address on the preaddressed form, or submit by fax to 800-FDA-0178.

FDA will continue to evaluate this safety issue and will determine if additional FDA actions are needed.

FDA Case Studies

FDA CASE STUDY

FDA MedWatch Adverse Event Reporting Curriculum Case Study

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

This fictionalized case study is part of an educational series published by the U.S. Food and Drug Administration.

A Patch of a Different Color

Dr. Jim Bean was excited as he reached examination room 4, where his last patient of the day was waiting for him. The family practice physician would be on a plane heading to Miami for a national medical conference later that evening. Old colleagues he hadn't seen since his residency, workshops and presentations on the latest advances in medicine and, most importantly, the remaining continuing education credits he needed for his licensure were a few short hours away. Pulling a chart out of the file holder on the wooden door, Jim knocked and let himself in after the voice on the other side said he could enter.

"Hello, Chris! How are you today?" Jim asked, shaking the young man's hand before sitting on a low stool in a corner of the room. Jim had joined the family practice of six physicians 2 years earlier. He had just finished his residency at the time, and Chris had become one of his first regular patients.

"I'm doing well. Dr. Bean," Chris smiled.

"That's what I like to hear," Jim said as he looked down at Chris' charts. The 24-year-old had been successfully treated for years with medication



for Attention Deficit Hyperactivity Disorder (ADHD). In the 2 years that Jim had been treating Chris, he had switched his patient from oral ADHD medications to a patch worn on the skin. He noted the last prescription date in charts and said, "I'll need to refill your prescription. Let's get you checked out first and then I'll have the nurses send the prescription to your pharmacy before you leave."

After a routine checkup, Jim turned his attention to Chris' patch. Peeling it off, he noticed that some of Chris' skin at the application site was discolored. "Chris," he said, eyebrows pinched with concern. "I'm noticing some depigmentation underneath your patch that wasn't here the last time I saw you. Can you tell me when this first started happening?"

"I'm not sure," Chris replied. He took a few moments to think. "I noticed my skin was getting lighter there, but didn't think anything of it since I tend to put the patch in the same place and this area isn't exposed much to light."

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**
- Preparing Students: Students are expected to read the case study prior to the training session.
 - Engaging Students: The training session should consist of a discussion of the case study and completion of a MedWatch form.
 - 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:
- MedWatch Homepage
<http://www.fda.gov/Safety/MedWatch/default.htm>

STUDENT ACTIVITIES

Before Class

Review the following materials before class:

- MedWatch Homepage
<http://www.fda.gov/Safety/MedWatch/default.htm>

- Print hard copies of Form 3500B and Form 3500 and bring them to class. <http://www.fda.gov/Safety/MedWatch/lowToReport/DownloadForms/default.htm>
- Answer the following questions before class:
- 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.
- 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).

- Good case reports include the following elements:

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

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

FDA CASE STUDY

FDA Drug Information Curriculum Case Study

Useful FDA Drug Information for Clinicians: Practicing clinicians seek available information on a new drug before making a treatment decision

"Okay, everyone," Dr. Carosel began, "our patient of the day is named Simone, a 52-year-old female who was admitted two days ago after experiencing severe chest pain. This is not her first myocardial infarction (heart attack)," he continued. "She was

This fictionalized case study is part of an educational series published by the U.S. Food and Drug Administration.

A Rounding Team and One Patient

If they listened closely, the patients in the cardiology wing of Sun Valley hospital could hear them. Several pairs of rubber-soled shoes slapped the ground in quick patterns as they tried to keep up with the long stride of Dr. Michael Carosel, attending physician and director of the cardiology department. In his walk, the steady and practiced steps of his chief resident, Dr. Andrea Nash, barely made a sound as she followed with ease. Behind her, the newest crop of residents and interns beginning their four-week rotation program worked hard to keep pace in what many nurses at the community hospital jokingly called "Carosel's Running of the Interns."

However, no one complained. Dr. Carosel was well-respected in the California medical community. A practitioner of medicine for over 20 years, he had served as the Director of Cardiology at Sun Valley for the past 11 years. In that time, he had managed to employ Andrea, one fellow, and two residents. The four were among the brightest talents in cardiology in the country.

Quick signs of relief once the march

FDA Drug Information Curriculum Case Study: Instructor's Guide

FDA Useful Drug Information for Clinicians: Practicing clinicians seek available information on a new drug before making a treatment decision

LEARNING OBJECTIVES

- Identify an online resource for FDA's drug review materials found at: www.fda.gov.
- Determine if a drug or biologic marketed in the U.S. has been discussed at an FDA advisory committee meeting.
- Gain an understanding of the FDA advisory committee's evaluation of a product's benefits and risks.
- Explain the characteristics of a new molecular entity (NME).
- Gain an understanding of risk evaluation and mitigation strategies (REMS) and their role.

TOPICS

FDA Drug Information Resources; Drugs@FDA; Risk Evaluation and Mitigation Strategy (REMS); FDA CardioBeat; FDA Drug Shortages Program

ASSUMPTIONS

This case study is based on the assumption that the target audience is undergraduate students or health professionals who are unfamiliar with FDA drug information resources.

SUGGESTED APPROACH

- Preparing Students: Students are expected to read the case study prior to the training session.
- Engaging Students: The training session should consist of a discussion of the case study.
- Immersing Students: The training session should emphasize group discussion of the case study. Students should be encouraged to use their mobile devices to access the drug resources apps mentioned in the case study and navigate to the FDA websites referenced in class.

STUDENT ACTIVITIES

Before Class

Review the following websites:

- Drugs@FDA
<http://www.accessdata.fda.gov/scripts/cder/drugsattda/index.cfm>
- FDA Advisory Committee <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/default.htm>
- REMS@FDA
<http://www.accessdata.fda.gov/scripts/cder/rem/index.cfm>
- Drug Shortages Program
<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/>

Answer the following questions before class:

- What is Drugs@FDA?

Answer: Drugs@FDA is a searchable database of drug product labels and approval-related documents, including reviews, approval letters, and current and archived labels.

- True or False: Advisory Committee members are FDA employees.

Answer: **False.** Advisory committees are made up of outside experts that provide FDA with independent opinions and recommendations on applications to market new drugs and on FDA policies. The marketing applications they review include data about the safety and effectiveness of human drugs. The committees receive summary information about the drug applications and copies of FDA's review of the application documents. Based on this information, advisory

<http://www.fda.gov/ForHealthProfessionals/LearningActivities/default.htm>

Information for Health Professionals

- ➔ Healthcare Professional Network
- ➔ Bi-weekly Email Newsletter
- ➔ MedWatch
- ➔ Webinars and Education
- ➔ Disease Specific Email Updates



Information for Patients

- ➔ FDA Patient Network
- ➔ Bi-weekly Email Newsletter
- ➔ Website
- ➔ Webinars & In-person Meeting's
- ➔ Disease Specific Email Updates
- ➔ Twitter



FDA Health Professional and FDA Patient Network Newsletter



FDA U.S. FOOD & DRUG
ADMINISTRATION



Updates for Health Professionals from the FDA Office of Health and Consumer Affairs

February 21, 2018

ANNOUNCEMENTS

[FDA issued a final rule titled "Human Subject Protection: Acceptance of Data from Clinical Investigations"](#)

The rule updates the FDA's standards for accepting clinical data from medical device studies in the U.S. to support a device research or marketing application or submission, including 510(k), premarket approval, and the exacerbation of chronic conditions such as asthma and congestive heart failure.

[FDA Commissioner Scott Gottlieb, M.D. statement on the efficacy of the 2017-2018 influenza season](#)

Seasonal flu has been widespread this year, impacting millions of people across the country during a challenging season, with high rates of hospitalization for both influenza and its complications and the exacerbation of chronic conditions such as asthma and congestive heart failure.

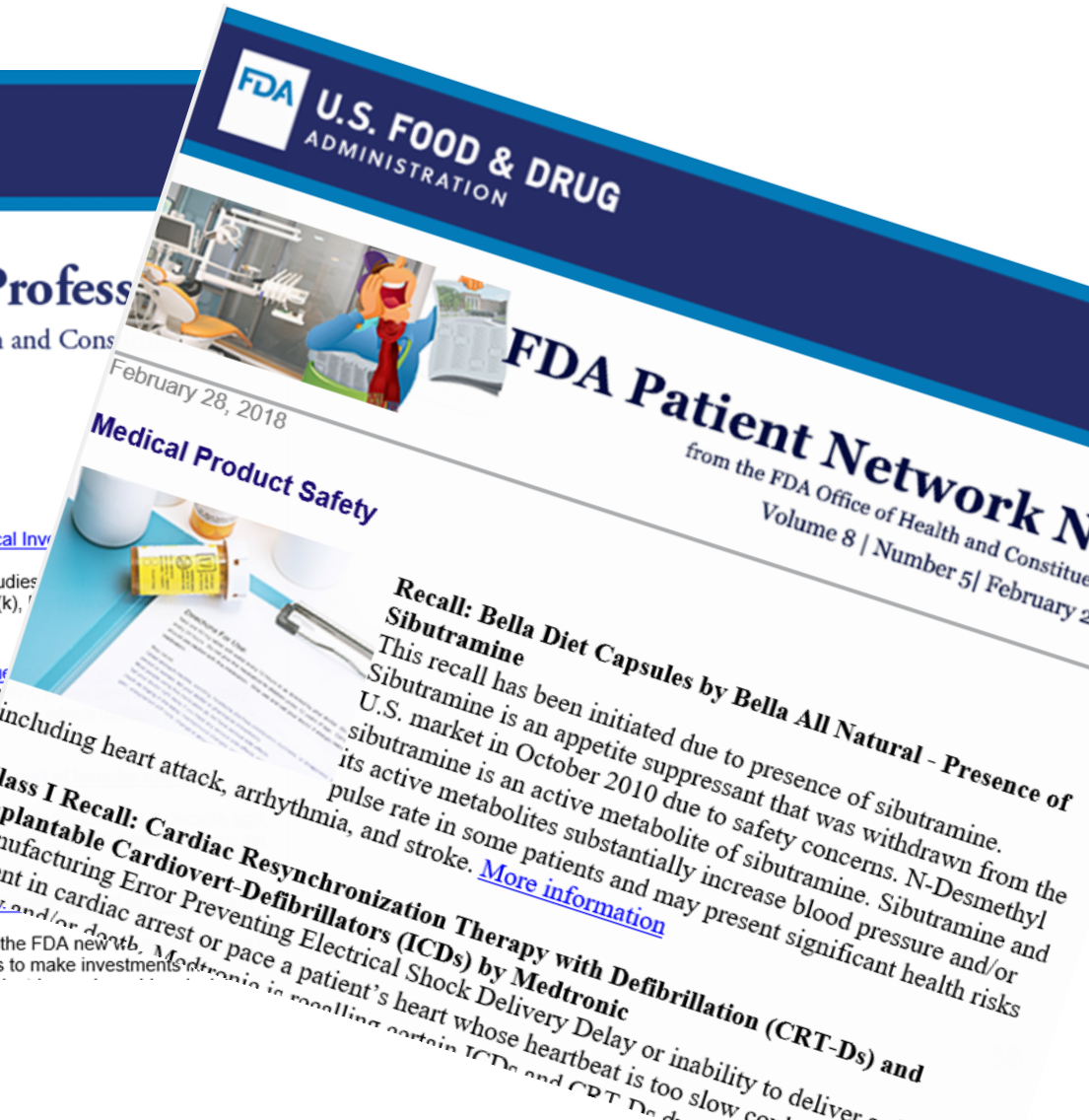
[Statement on advancing the development of novel treatments for neurological conditions and modernizing FDA's new drug review programs](#)

New medical breakthroughs are altering how diseases are treated in ways that seem unprecedented. Perhaps one of the most significant developments is the advent of new gene therapy systems that target tumor cells.

[Statement on Administration's request for new FDA funding to promote innovation and competition](#)

New scientific opportunities, as well as advances in manufacturing and commerce, give the FDA new opportunities to protect and promote public health. Leveraging these opportunities requires us to make investments in research and development, and to make investments in research and development.

www.FDA.gov/ForPatients

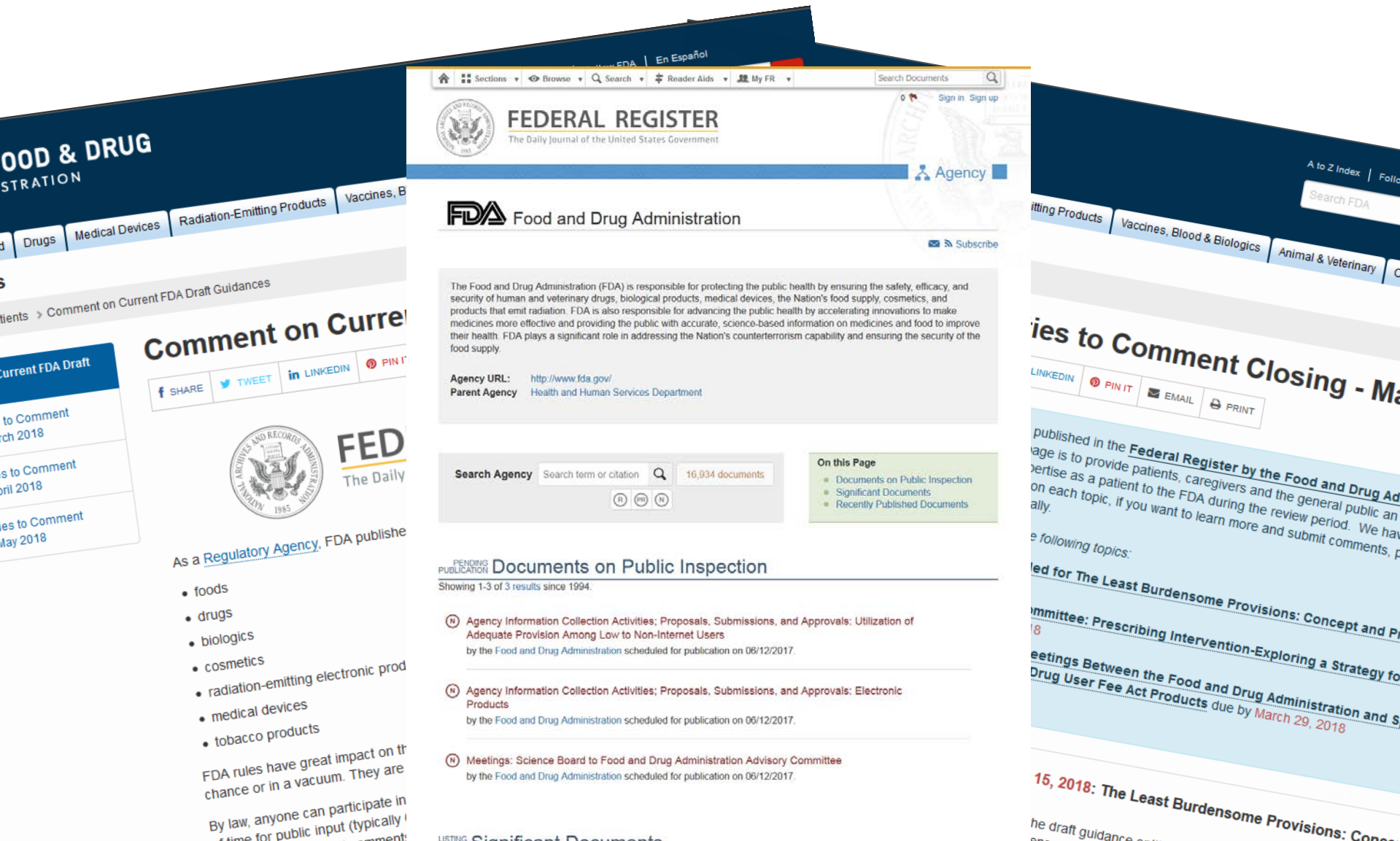


FDA Patient Representative Program

- ➔ Began in 1990s
- ➔ Patients having an active role on FDA Advisory Committees and consultations with review divisions
- ➔ Patient voice represented in important discussions about regulatory decision-making
- ➔ Presence at the table
- ➔ 200 Patient Representatives, over 300 diseases/conditions



Submit Comments Through the Federal Register



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The Daily Journal of the United States Government

FDA Food and Drug Administration

The Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the Nation's food supply, cosmetics, and products that emit radiation. FDA is also responsible for advancing the public health by accelerating innovations to make medicines more effective and providing the public with accurate, science-based information on medicines and food to improve their health. FDA plays a significant role in addressing the Nation's counterterrorism capability and ensuring the security of the food supply.

Agency URL: <http://www.fda.gov/>
Parent Agency: Health and Human Services Department

Search Agency: Search term or citation 16,034 documents

On this Page

- Documents on Public Inspection
- Significant Documents
- Recently Published Documents

Documents on Public Inspection

Showing 1-3 of 3 results since 1994.

- Agency Information Collection Activities; Proposals, Submissions, and Approvals: Utilization of Adequate Provision Among Low to Non-Internet Users by the Food and Drug Administration scheduled for publication on 06/12/2017.
- Agency Information Collection Activities; Proposals, Submissions, and Approvals: Electronic Products by the Food and Drug Administration scheduled for publication on 06/12/2017.
- Meetings: Science Board to Food and Drug Administration Advisory Committee by the Food and Drug Administration scheduled for publication on 06/12/2017.

Comment on Current FDA Draft

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The Daily

As a **Regulatory Agency**, FDA publishes

- foods
- drugs
- biologics
- cosmetics
- radiation-emitting electronic products
- medical devices
- tobacco products

FDA rules have great impact on the chance or in a vacuum. They are

By law, anyone can participate in the time for public input (typically 30 days).

Committee: Prescribing Intervention-Exploring a Strategy for

Meetings Between the Food and Drug Administration and Drug User Fee Act Products due by **March 29, 2018**

15, 2018: The Least Burdensome Provisions: Concept and



Participate in an FDA Sponsored Public Meeting

Home > For Patients > Calendar of Public Meetings

Calendar of Public Meetings

Calendar of FDA Sponsored Public Meetings - March 2018

Calendar of FDA Sponsored Public Meetings - April 2018

Calendar of FDA Sponsored Public Meetings - May 2018

Calendar of FDA Sponsored Public Meetings

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Public Meetings

- advisory committee meetings
- public workshops
- public conferences
- other FDA sponsored meetings



In this section you will find a comprehensive list of all the meetings that the FDA sponsors. The meetings may include advisory committee meetings, public workshops and public conferences that are seeking to hear from patients and caregivers.

Most FDA meetings are free to the public and do not require registration. The meetings may include advisory committee meetings, public workshops and public conferences that are seeking to hear from patients and caregivers. Other types of meetings listed may require prior registration.

Home > For Patients > Calendar of Public Meetings

Calendar of Public Meetings

Calendar of FDA Sponsored Public Meetings - March 2018

Calendar of FDA Sponsored Public Meetings - April 2018

Calendar of FDA Sponsored Public Meetings - May 2018

Calendar of FDA Sponsored Public Meetings - March 2018

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In this section you will find a comprehensive list of all the meetings that the FDA sponsors. The meetings may include advisory committee meetings, public workshops and public conferences that are seeking to hear from patients and caregivers. Most FDA meetings are free to the public and do not require the public to register. The meetings may include advisory committee meetings, public workshops and public conferences that are seeking to hear from patients and caregivers. Other types of meetings listed may require prior registration and fees.

Advisory Committee Meeting: Risk Communication
Date: March 5, 2018, 8:00 am to 5:00 pm
Location: FDA White Oak Campus, Great Room, 10903 New Hampshire Avenue, Silver Spring, MD 20910

Agenda: On March 5 and 6, 2018, the committee will discuss the impact of pregnancy and lactation information in prescription drug and biological products as modified under the Pregnancy and Lactation Labeling Rule (PLLR) was implemented in 2015. The Agency seeks input and recommendations on: (1) How information on pregnancy and lactation is being perceived and used by health care providers and other stakeholders, (2) how to convey risk information to health care providers and other stakeholders, and (3) how to convey risk information to health care providers and other stakeholders. Other types of meetings listed may require prior registration and fees.

Advisory Committee Meeting: Risk Communication
Date: March 6, 2018, 9:00 am to 12:30 pm
Location: FDA White Oak Campus, Great Room, 10903 New Hampshire Avenue, Silver Spring, MD 20910

Agenda: On March 5 and 6, 2018, the committee will discuss the impact of pregnancy and lactation information in prescription drug and biological products as modified under the Pregnancy and Lactation Labeling Rule (PLLR) was implemented in 2015. The Agency seeks input and recommendations on: (1) How information on pregnancy and lactation is being perceived and used by health care providers and other stakeholders, (2) how to convey risk information to health care providers and other stakeholders, and (3) how to convey risk information to health care providers and other stakeholders. Other types of meetings listed may require prior registration and fees.

Information for Health Professionals and Patients

Home > For Patients > Clinical Trials: What Patients Need to Know

Clinical Trials: What Patients Need to Know

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Learn more about clinical trials and find a trial that might be right for you. Clinical trials are voluntary research studies conducted in people and designed to answer specific questions about the safety or effectiveness of drugs, vaccines, other therapies, or new ways of using existing treatments. It is important to remember that the FDA does not conduct Clinical Trials.

Search for a Clinical Trial

Enter a word or phrase, such as the name of a medical condition or intervention.
 Example: Cancer AND Los Angeles or expanded access AND compassionate use

- Resources for You**
- NIH Clinical Research Trials and You
 - Good Clinical Practice
 - Interactive Patient Education Tutorial On Clinical Trials
 - Protecting America's Health Through Human Drugs
 - Protection of Human Subjects of Research
 - Get to Know ClinicalTrials.GOV (webinar)

Learn More About Clinical Trials

- [Clinical Research Versus Medical Treatment](#)
Understand the differences between clinical research and medical treatment and what those difference for you. Find answers to your questions about clinical trials, such as why they are done, who should or participating, and issues to consider before joining a trial.
- [What are the Different Types of Clinical Research](#)
Understand the different types of research and the four clinical trial phases, such as their purpose and how many people participate in each of the phases.
- [Informed Consent for Clinical Trials](#)
Understand what informed consent is and the questions you need to know before signing informed consent.
- [Diversity in Clinical Trial Participation](#)
It is important to test drugs and medical products in the people they are meant to help. Learn about FDASIA 907 and how FDA works to make sure that people of different ages, races, ethnic groups, and genders are included in clinical trials.
- [What is an Institutional Review Board](#)
Understand what Institutional Review Boards are, who is on them and who they protect.



Home > For Patients > Clinical Trials: What Patients Need to Know > Informed Consent for Clinical Trials

Informed Consent for Clinical Trials

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On this page you will find information on:

- [What is Informed Consent](#)
- [Before enrolling in a clinical trial, the following information must be given to each potential research subject](#)
- [When Appropriate, one or more of the following elements of information must also be provided in the informed consent document](#)
- [A potential research subject must have an opportunity to](#)
- [Informed consent may not include language that](#)

To many, the term *informed consent* is mistakenly viewed as the same as getting a research participant's signature on the consent form. FDA believes that obtaining research participant's verbal or written informed consent is only part of the process. Informed consent involves providing a potential participant with:

- adequate information to allow for an informed decision about participation in the clinical investigation.
- facilitating the potential participant's understanding of the information.
- an appropriate amount of time to ask questions and to discuss with family and friends the research protocol and whether you should participate.
- obtaining the potential participant's voluntary agreement to participate.
- continuing to provide information as the clinical investigation progresses or as the subject or situation requires.

To be effective, the process must provide sufficient opportunity for the participant to consider whether to participate. (21 CFR 50.20.) FDA considers this to include allowing sufficient time for participants to consider the information and providing time and opportunity for the participant to ask questions and have those questions answered. The investigator (or other study staff who are conducting the informed consent interview) and the participant should exchange information and discuss the contents of the informed consent document. This process must occur under circumstances that minimize the possibility of coercion or undue influence. (21 CFR 50.20.)

What is Informed Consent?

As new medical products are being developed, no one knows for sure whether the products will find. Clinical trials are used to answer questions about whether a new product is safe and effective.

- Are new



Information for Health Professionals and Patients

Home > For Patients > Learn About Other Treatment Options

Learn About Other Treatment Options

Understanding Investigational Drugs

Expanded Access: Information for Patients

Understanding Unapproved Use of Approved Drugs "Off Label"

Learn About Expanded Access and Other Treatment Options

When a patient does not respond to current approved treatments for a variety of reasons, other options still may be available. For serious and life-threatening illnesses, some patients may want to talk to their healthcare provider about trying an investigational drug either through a clinical trial or expanded access, or trying an approved drug that is used for a different purpose than what is listed on the FDA-approved drug label (this use is called off-label).



Understanding Unapproved Use of Approved Drugs "Off-Label"

Has your healthcare provider ever talked to you about a drug to treat your disease or medical condition that has not been studied on patients with your disease? It may be helpful for you to understand what "Off-Label" use means and the questions you may need to ask your healthcare provider.

[Read More](#)



Understanding Investigational Drugs

Has your healthcare provider ever talked to you about an investigational drug to treat your disease or medical condition? It may be helpful for you to understand what an investigational drug is before deciding if you want to try it. Learn the basics of what they are and the questions you may need to ask your healthcare provider.

[Read More](#)



Understanding Expanded Access (Compassionate Use)

Information about FDA's requirements for enrolling in a clinical trial and the steps you can take to get access to an investigational drug.

[Read More](#)

Home > For Patients > Learn About Other Treatment Options > Understanding Unapproved Use of Approved Drugs "Off Label"

Understanding Unapproved Use of Approved Drugs "Off Label"

Resources for You

- Medication Guides
- Drugs@FDA Database
- DailyMed

Understanding Unapproved Use of Approved Drugs "Off Label"

Has your healthcare provider ever talked to you about using an FDA-approved drug for an unapproved use (sometimes called an "off-label" use) to treat your disease or medical condition?

It is important to know that before a drug can be approved, a company must submit clinical data and other information to FDA for review. The company must show that the drug is safe and effective for its intended uses. "Safe" does not mean that the drug has no side effects. Instead, it means the FDA has determined the benefits of using the drug for a particular use outweigh the potential risks.

When you are prescribed a drug for its approved use, you can be sure:

- That FDA has conducted a careful evaluation of its benefits and risks for that use.
- The decision to use the drug is supported by strong scientific data.
- There is approved drug labeling for healthcare providers on how to use the drug safely and effectively for that use.

- The approved drug labeling for healthcare providers gives key information about the drug that includes:
 - The specific diseases and conditions that the drug is approved to treat.
 - How to use the drug to treat those specific diseases and conditions.
 - Information about the risks of the drug.
- Information that healthcare providers should discuss with patients before they take a drug.

Some drugs may also have labeling information for patients such as Medication Guides, Patient Package Inserts and Instructions for Use.

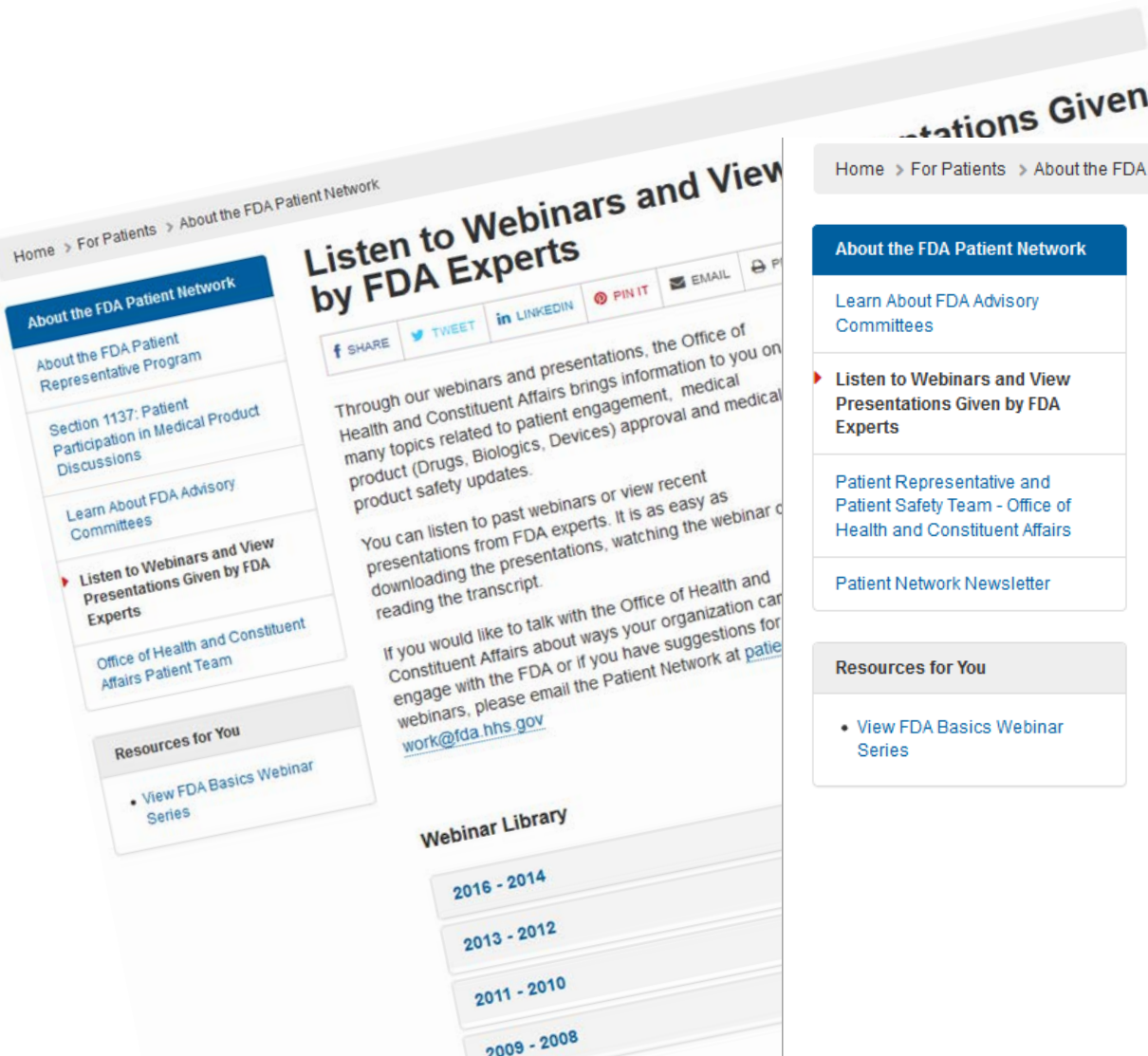
Why might an approved drug be used for an unapproved use?

From the FDA perspective, once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient. You may be asking yourself why your healthcare provider would want to prescribe a drug to treat a disease or medical condition that the drug is not approved for. One reason is that there might not be an approved drug to treat your disease or medical condition. Another is that you may have tried all approved treatments and are not seeing any benefits. In situations like these, you and your healthcare provider may decide to try a drug for an unapproved use to treat your disease or medical condition.

What are examples of unapproved use of approved drugs?



Watch Webinars Led by FDA Experts



Home > For Patients > About the FDA Patient Network

About the FDA Patient Network

- Learn About FDA Advisory Committees
- Listen to Webinars and View Presentations Given by FDA Experts**
- Patient Representative and Patient Safety Team - Office of Health and Constituent Affairs
- Patient Network Newsletter

Resources for You

- View FDA Basics Webinar Series

Listen to Webinars and View Presentations Given by FDA Experts

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Through our webinars and presentations, the Office of Health and Constituent Affairs brings information to you on many topics related to patient engagement, medical product (Drugs, Biologics, Devices) approval and medical product safety updates.

You can listen to past webinars or view recent presentations from FDA experts. It is as easy as downloading the presentations, watching the webinar or reading the transcript.

If you would like to talk with the Office of Health and Constituent Affairs about ways your organization can engage with the FDA or if you have suggestions for future webinars, please email the Patient Network at patient_network@fda.hhs.gov

Webinar Library

- 2018 - 2014
- 2016 - 2014
- 2013 - 2012
- 2011 - 2010
- 2009 - 2008

Webinar Library

2018 - 2014

2018

Sentinel Initiative and Sentinel Engagement Partners Workgroup
February 1, 2018

Presenters:



Learn How Medical Products are Developed and Approved

The image displays two overlapping screenshots of the FDA website's 'The Drug Development Process' page. The top screenshot shows the navigation path: Home > For Patients > Learn About Drug and Device Approvals > The Drug Development Process. The page title is 'The Drug Development Process'. A sidebar on the left lists the steps: Step 1: Device Discovery and Concept, Step 2: Preclinical Research-Prototype, Step 3: Pathway to Approval, Step 4: FDA Review, and Step 5: FDA Post-Market Safety Monitoring. The main content area is a vertical flowchart with five steps, each with a description and a 'More Information' button. The bottom screenshot shows a similar view but with a different sidebar menu: Drug Development Process, 1: Discovery and Development, Preclinical Research, Clinical Research, Review, and Post-Market Safety. The flowchart steps are: Step 1: Discovery and Development, Step 2: Preclinical Research, Step 3: Clinical Research, Step 4: FDA Review, and Step 5: FDA Post-Market Safety Monitoring. At the bottom of the page, there is a footer with links: FDA Basics, FOIA, No FEAR Act, Site Map, Transparency, and Website Policies.

Home > For Patients > Learn About Drug and Device Approvals > The Device Development Process

The Device Development Process

The Device Development Process

- Step 1: Device Discovery and Concept
- Step 2: Preclinical Research-Prototype
- Step 3: Pathway to Approval
- Step 4: FDA Review
- Step 5: FDA Post-Market Safety Monitoring

Step 1: Device Discovery and Concept
Research for a new drug or device begins in the laboratory.
[More Information](#)

Step 2: Preclinical Research - Prototype
Devices undergo laboratory and animal testing to answer basic questions about safety.
[More Information](#)

Step 3: Pathway to Approval
Devices are tested on people to make sure they are safe and effective.
[More Information](#)

Step 4: FDA Review
FDA review teams thoroughly examine all of the submitted data related to the drug or device and make a decision to approve or not to approve it.
[More Information](#)

Step 5: FDA Post-Market Safety Monitoring
FDA monitors all drug and device safety once products are available for use by the public.
[More Information](#)

Home > For Patients > Learn About Drug and Device Approvals > The Drug Development Process

The Drug Development Process

Drug Development Process

- 1: Discovery and Development
- Preclinical Research
- Clinical Research
- Review
- Post-Market Safety

Step 1: Discovery and Development
Research for a new drug begins in the laboratory.
[More Information](#)

Step 2: Preclinical Research
Drugs undergo laboratory and animal testing to answer basic questions about safety.
[More Information](#)

Step 3: Clinical Research
Drugs are tested on people to make sure they are safe and effective.
[More Information](#)

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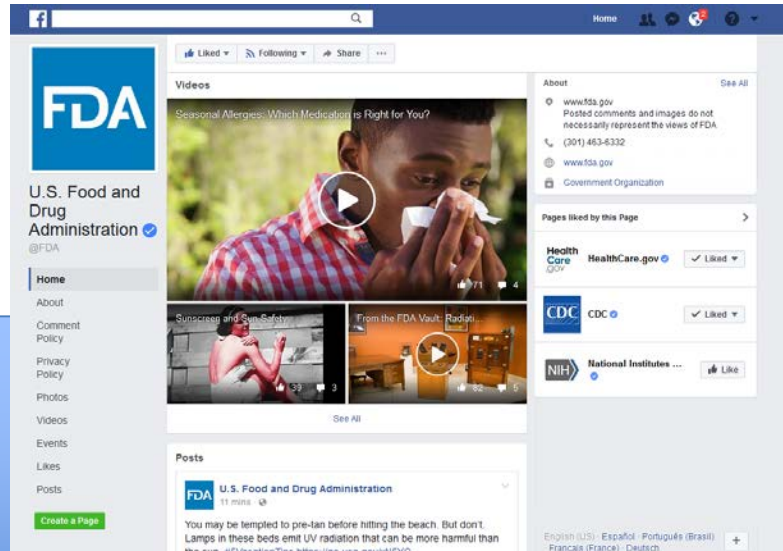
Step 5: FDA Post-Market Safety Monitoring
FDA monitors all drug and device safety once products are available for use by the public.
[More Information](#)

FDA Basics FOIA No FEAR Act Site Map Transparency Website Policies

Disease Specific Email Updates



FDA Facebook and Twitter



Center for Drug Evaluation and Research



Director's Corner with Dr. Janet Woodcock

The Director's Corner is an audio podcast series featuring the director of FDA's Center for Drug Evaluation and Research and produced by CDER's Office of Communications.

Antibiotic Misuse and Resistance. Dr. Woodcock discusses the issues surrounding the use and misuse of antibiotic medicines, as well as the emergence of antibiotic-resistant bacteria and how the issues are related.

Moving forward in 2017. Dr. Woodcock provides her perspective on the goals and priorities for CDER in 2017.

Looking back on 2016 accomplish an highly productive year in CDER with our last year's major events.

CDER Conversations

From our perspective: Interchangeable biological products

Learn Cheryl, Ph.D., Associate Director for Therapeutic Biologics and head of the Therapeutic Biologics and Generics Staff in the Office of New Drugs, discusses new guidance for developing interchangeable biological products.

Therapeutic biological products

A therapeutic biological product may be approved as an original, biosimilar or interchangeable product. In an earlier CDER perspective article, I compared the type of data and information needed to support approval of an original product with that needed to support approval of a biosimilar product. In short, an original product is approved based on a full profile of toxicology and clinical data that demonstrates its safety and effectiveness, while a biosimilar product's approval is based on an array of biologically meaningful data that demonstrate its safety and effectiveness, and a biosimilar product's approval is based on an array of biologically meaningful data that demonstrate its safety and effectiveness, and a biosimilar product's approval is based on an array of biologically meaningful data that demonstrate its safety and effectiveness.

DRUG INFORMATION SOUNDCAST in CLINICAL ONCOLOGY (DISCO)

FDA Drug Information Soundcast in Clinical Oncology (DISCO) is an FDA podcast series that provides information about new product approvals, emerging safety information for cancer treatments, and other current topics in cancer drug development.

SPOTLIGHT on CDER SCIENCE

Center for Tobacco Products

Public Health Education

Health Information

Public Education Campaigns

Youth & Tobacco

Public Health Education

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While there has been significant progress, tobacco use remains a major problem in the United States—one that FDA is working hard to help reduce. Among other efforts, we are investing in a number of public campaigns to help educate about the dangers of tobacco products.

Tobacco products are harmful, yet widely used, and are responsible for severe health problems in both users and non-users. These health problems include several kinds of cancer and lung and heart disease, all of which often lead to death.

Health Information

- Access the latest [health information](#), including resources from our federal partners.
- [Tips to Help Avoid Vape Battery Explosions](#)
- [Chemicals in Cigarettes: From Plant to Product to Puff](#).
- [Learn about tobacco-related health fraud.](#)

Public Education Campaigns

We are investing in a number of [public education campaigns](#), such as [The Real Cost](#), [Fresh Empire](#), and [This Free Life](#) to help educate the public—especially youth—about the dangers of regulated tobacco products. Rooted in science, these efforts are directly linked to our authority to regulate the marketing and sales of tobacco products.



Center for Devices and Radiological Health

Medical Devices

Home > Medical Devices > Resources for You (Medical Devices) > Consumers (Medical Devices)

Consumers (Medical Devices)

Consumers (Medical Devices)

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- [Introduction](#)
- [What is a Medical Device?](#)
- [How are Devices Classified?](#)
- [How are Medical Devices Regulated in the United States?](#)
- [What is the Difference Between Cleared and Approved?](#)
- [How do I report a problem with a Medical Device?](#)
- [Contact CDRH](#)

The Food and Drug Administration (FDA) assures that patients and health care providers have timely and continued access to safe, effective, and high-quality medical devices. In addition, it provides consumers, patients, caregivers, and healthcare providers with understandable and accessible science-based information about the products it oversees.

In order to understand medical devices, it is important to understand what a medical device is and how the FDA classifies medical devices.

What is a Medical Device?

A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

Memoranda of Understanding

About FDA

Home > About FDA > Partnerships: Enhancing Science Through Collaborations With FDA > Memoranda of Understanding (MOUs)

Memoranda of Understanding (MOUs)

Whom to Contact About MOUs

- Domestic MOUs
- Academia MOUs
- Non-Profit MOUs

Resources for You

- Agency Contacts for MOUs

FDA Memoranda of Understanding

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Overview

A memorandum of Understanding (MOU) is a formal agreement between the Food and Drug Administration (FDA) and federal, state, or local government agencies; academic institutions; and other entities. The MOU constitutes an understanding between the parties but is a non-binding agreement. It is FDA's policy to enter into MOUs with other entities whenever there is a need to define lines of authority or responsibility, or to clarify cooperative procedures. The intent of the MOU is to improve consumer protection through more effective use of collective resources and to eliminate duplication of activities.

International MOUs

- Cooperative Arrangements (FDA Cooperative Arrangements for International Memoranda of Understanding, etc.)

Page Last Updated: 06/17/2016

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Language Assistance Available: Español | 中文 | Tiếng Việt | 한국어 | Tagalog | Pycckий | हिन्दी | Kreyòl Ayisyen | Français | English

Accessibility | Careers | FDA Basics | FDA | No FEAR Act

FDA Consumer Updates

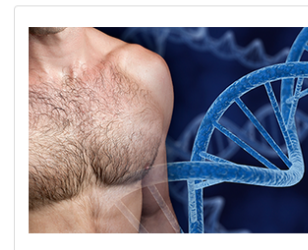
Breast Cancer in Men: Treatments and Genetic Counseling

Español

Subscribe: [FDA Consumer Health Information](#)

Can men get breast cancer? Yes. Although breast cancer is a disease usually associated with women, men get it too.

Because male breast cancer is rare, there is very limited information on how to treat men diagnosed with the disease. "In the absence of better information to guide us, we use the same way we treat breast cancer in women."



FDA and Medscape

FDA Expert Commentary and Interview Series on Medscape

As part of the continuing collaboration between FDA and [Medscape](#), a series of interviews and commentaries are available to communicate important safety information to clinicians. Featuring FDA experts, these original commentaries cover a wide range of topics related to FDA's multi-faceted mission of protecting and promoting the public health by ensuring the safety and quality of medical products such as drugs, foods, and medical devices.

Interviews



Postmarket Drug Safety: The View From the FDA

http://www.medscape.com/viewarticle/880216_1

Featuring Gerald Dal Pan, MD, MHS, Director, Office of Surveillance and Epidemiology, FDA Center for Drug Evaluation and Research, May 2017



Does Your Patient Need Both an Opioid and Benzodiazepine?

<http://www.medscape.com/viewarticle/871284>

Featuring Dr. John Whyte, Director of Professional Affairs and Stakeholder Engagement, FDA Center for Drug Evaluation and Research, November 2016



The Focus on Orphan Disease R&D at FDA

<http://www.medscape.com/viewarticle/871115>

Featuring Dr. John Whyte, Director of Professional Affairs and Stakeholder Engagement, and Dr. Gayatri Rao, Director of the Office of Orphan Products Development, FDA Center for Drug Evaluation and Research, October 2016

Why is the Patient/Health Professional Voice Important?

- ➔ Provide insight on issues, problems, and/or questions that are important to patients and health professionals
- ➔ Both patients and health professionals have a vested interest in improving health
- ➔ Varied perspectives, both in terms of associated risk tolerance and perceived potential benefit
- ➔ The human element (judgment vs. empirical data)



What Value Might Be Added by Community Engagement?

- ➔ Faster recruitment and improved retention in trials
- ➔ Reducing the time for product development
- ➔ Cutting cost of drug development
- ➔ Help develop meaningful endpoints and measurements
- ➔ Medical products that better reflect outcome and quality of life measures most important to patients



Challenges to meaningful engagement

- ➔ **Understanding of trial design** (meaningful endpoints and data, measuring outcome, control arms)
- ➔ **Understanding the regulatory framework**, standards, and requirements (level of evidence)
- ➔ **Legal and practical limitations** facing sponsors (promotion v. education and engagement)
- ➔ **Division** within patient communities and healthcare professional organizations
- ➔ **Different objectives** or agendas among organizations
- ➔ **Disagreement** on meaningful measurement

Testing Your Knowledge!



What is FDA's Public Health Mission?

Ensure the _____, _____, and _____ of human and animal drugs, biological products and medical devices

- a. Safety, effectiveness and security
- b. Accuracy, effectiveness, and purity
- c. Timelines, reliability and security



Who can report adverse events to the MedWatch Program?

- a. Healthcare professionals
- b. Patients
- c. Consumers
- d. Industry/Pharmaceutical Companies
- e. All of the above



How can MedWatch reports result in improved product safety?

- a. By updating the product label.
- b. Requiring a medication guide.
- c. Requesting a product to be removed from the market.
- d. a and b
- e. All of the above



How can you be involved in the FDA decision making process?

- a. Attend an FDA Advisory Committee meeting.
- b. Attend a protest at the FDA.
- c. Participate in webinars and workshops hosted by FDA experts.
- d. a and c
- e. All of the above



Which is Not Regulated by the FDA

- a. Tamper-resistant packaging for over-the-counter (OTC) drugs
- b. Child-proof packaging for OTC drugs
- c. Plastic containers for soft drinks
- d. Valentine heart box containing chocolates
- e. Tube containing medical ointment



Thank you



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