Just Culture and MedWatch: Safety, Quality, and Transparency

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Mary Jo Assi, DNP, RN, NEA-BC,
FNP- BC, AHN-BC
Director, Nursing Practice &
Work Environment
November 20, 2014

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Disclosures to Participants

Please view the attachment labeled “Disclosures to Participants” for full disclosures.

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American Nurses Association



nursingworld.org

Nursing Practice & Work Environment

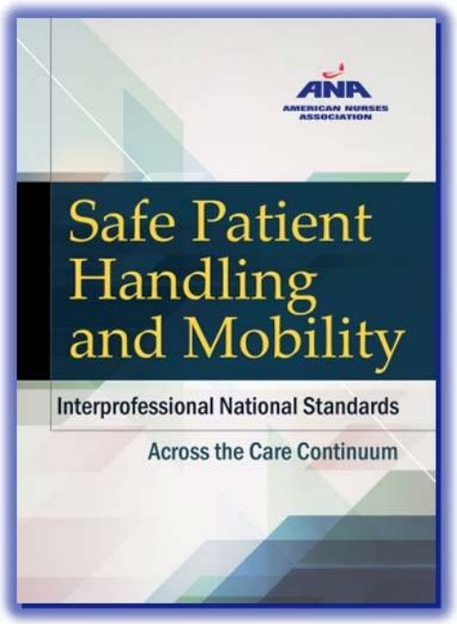
AMERICAN NURSES ASSOCIATION

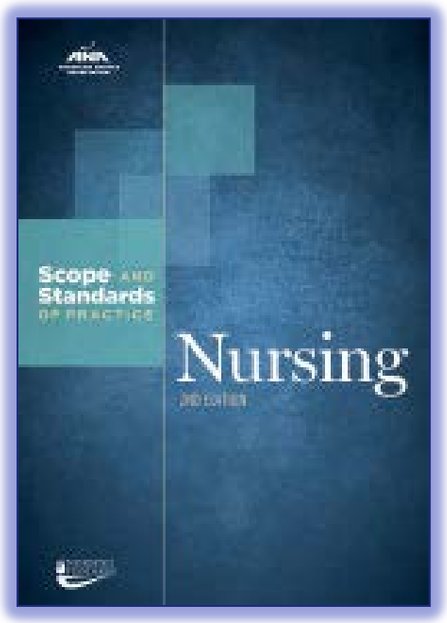
Programs and Services

- HealthyNurse ™
  - Health Risk Appraisal /Assessment
  - Promotion of Self-care
  - Nurse Wellness Resources

- Work Environment
  - Optimal staffing for safe patient care
  - Safe Patient Handling & Mobility
  - Workplace Violence
  - Fatigue

- Practice
  - Scope & Standards
  - Innovation & Health Care Transformation
  - Quality Care & Measurable Outcomes





Objective

- Describe Just Culture practices and how these practices positively impact the patient and the health care provider in regard to adverse event reporting.



1995 Case Study: A Culture of Blame

An RN was caring for a patient in the ICU with a primary diagnosis of AIDS and a secondary diagnosis of hepatitis B.



During the shift, she received a needlestick injury while administering intravenous medications to the patient.

She was reprimanded by the shift supervisor and the unit manager for carelessness and directed to attend a remediation class in medication administration.

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Establishing a Culture of Safety

- Organizational leader and employee partnership
- Core values and behaviors
- Collective and sustained commitment
- Emphasizes safety over competing goals



Maintaining a Culture of Safety

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Employee Responsibilities

- Participate in creating and maintaining a culture of safety
- Report hazards, incidents, near misses, and accidents
- Use the system to communicate and collaborate

Employer Responsibilities

- Establish a culture of safety as an organizational priority
- Create and sustain a positive, non-punitive, work environment



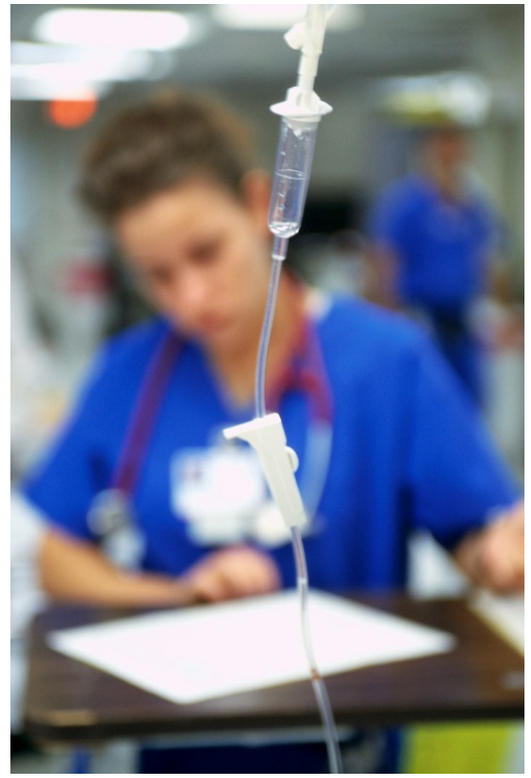
What is Just Culture?

- Create a learning culture
- Create an open and fair culture
- Designs safe systems
- Manages behavioral choices



Core Beliefs of Just Culture

- People make mistakes
- People drift
- Risk is everywhere
- Management supports appropriate values
- People are accountable



(Source: Just Culture, Training for Healthcare Managers, 2008)

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Just Culture Thought Leaders

"…shift of focus: from errors and outcomes to system design and behavioral choices."

David Marx, JD

"In a punitive system, no one learns from their mistakes"

Lucian Leape, MD



LUCIAN LEAPE AT ANA'S 2014 QUALITY CONFERENCE

Error Responsibility



Blame-Free	Just Culture	Punitive

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Human Behavior Errors

- Inadvertent mistake
- Risky behavior
- Recklessness



(Source: Marx, 2001)

Just Culture Leadership Response

- **Human error**
  - console
  - change process, procedure, training, and/or design
- **Risky behavior**
  - coach
  - Increase awareness
  - incentivize good behavior, remove incentive for risky behavior
- **Reckless behavior**
  - remedial action
  - possible punitive action



(Source: Marx, 2001)

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Summary: Just Culture Responsibilities

- **Clinical nurses**
  - advocate for Just Culture use
  - report errors appropriately

- **Educators**
  - incorporate Just Culture concepts into curriculum

- **Leaders**
  - promote Just Culture
    - healthy work environment
    - enhance patient safety



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2010: ANA Position Statement

- 2010 Position statement
- National standards for patient and RN safety
- Related topical issues
- Focus on RN health, wellness and safety



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Benefits of Just Culture



- Fear-free error reporting system
- Employee investment in safety improvements
- Improved care and safety for patients
- Improved work environment for employees
- Zero tolerance for disruptive behaviors and intimidation
- Coaching, counseling, and education for employees
- Decreased chance of repeat errors
- Sense of ownership for employees in the error process

(Source: ANA Position Statement: Just Culture, 2010)

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2005 Case Study: Just Culture in Action

An RN was caring for a patient and performed a blood glucose by fingerstick.

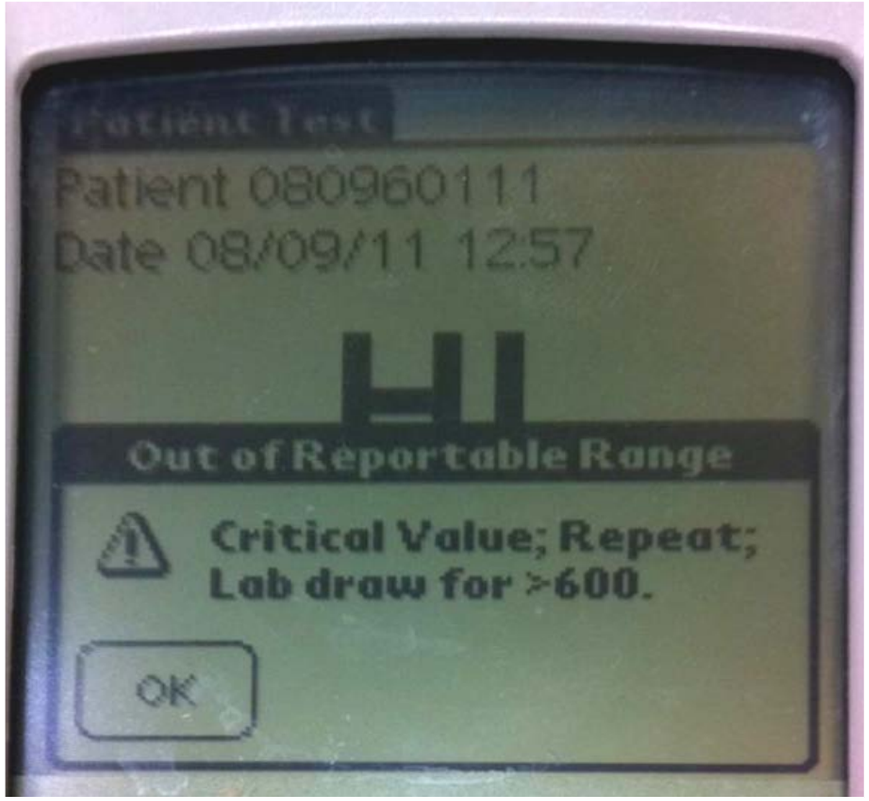
A pop-up immediately showed on the glucometer screen that read “Critical value, repeat Lab draw for >600.” The underlying reading was obscured.



2005 Case Study: Just Culture in Action

The patient received insulin, and developed severe hypoglycemia necessitating a transfer to the ICU. A similar incident occurred several days later and a root cause analysis revealed a design flaw in the device.





The devices were removed from clinical areas to correct the flaw.

References

- **ANA.** *Just Culture Position Statement*. 2010.

- **ANA.** *Safe Patient Handling and Mobility: Interprofessional National Standards.* Silver Spring, MD. 2012.

- **Marx, D.** *Patient Safety and the "Just Culture": A Primer for Health Care Executives.* New York, NY: Columbia University; 2001. http://psnet.ahrq.gov/resource.aspx?resourceID=1582

- **Outcome Engineering, LLC**. *Just Culture: Training for Healthcare Managers.* Plano, TX. 2008.

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Questions?

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ANA

AMERICAN NURSES ASSOCIATION

FDAs MedWatch Program

Cristina Whalen Klafehn, PharmD, BCPS

Office of Health and Constituent Affairs

Office of External Affairs

November 2014

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U.S. Food and Drug Administration
Protecting and Promoting Public Health

Food and Drug Administration
MedWatch
www.fda.gov

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.





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



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Office of External Affairs

Office of Health and Constituent Affairs

Food and Drug Administration
MEDWATCH

Office of Foods



Center for Food Safety & Applied Nutrition



Center for Veterinary Medicine

Office of Medical Products & Tobacco



Center for Devices & Radiological Health



Center for Biologics Evaluation & Research



Center for Drug Evaluation & Research



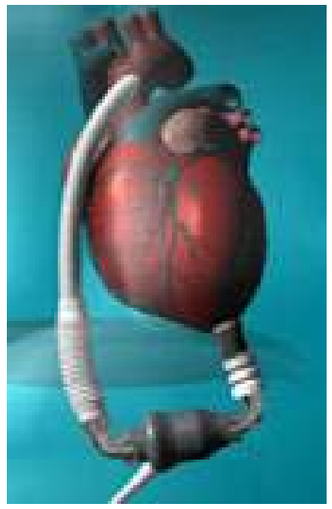
Center for Tobacco Products

Office of Global Regulatory Operations & Policy



Office of Regulatory Affairs

Medical Devices Regulated by FDA































Learning Objectives

- Describe the FDA MedWatch program
  - Highlight items nurses can report to the FDA MedWatch Program
- List the benefits of MedWatch to registered nurses
- Formulate how registered nurses can best leverage the MedWatch resources

What is MedWatch?

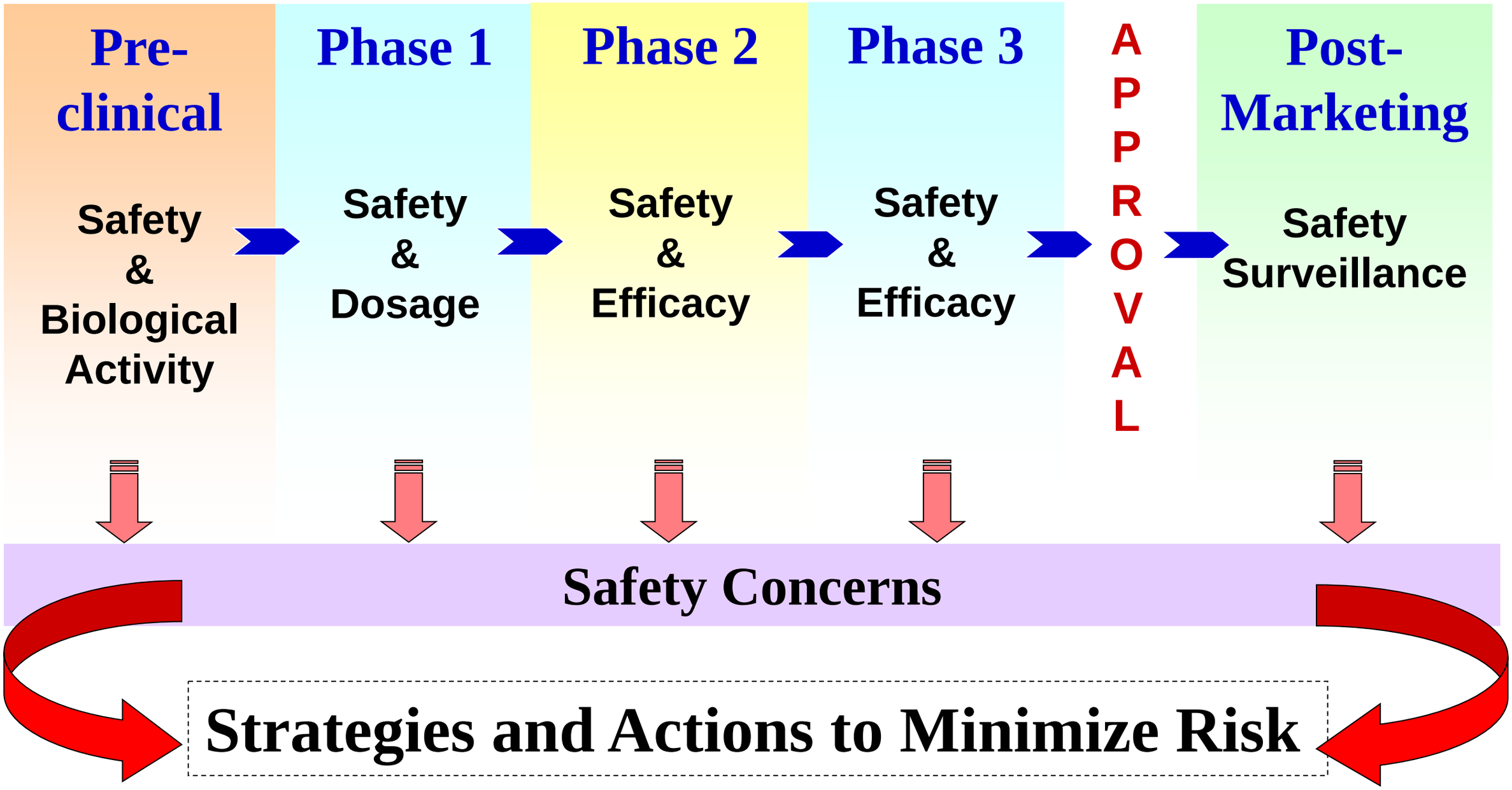
1. A way to send information to FDA

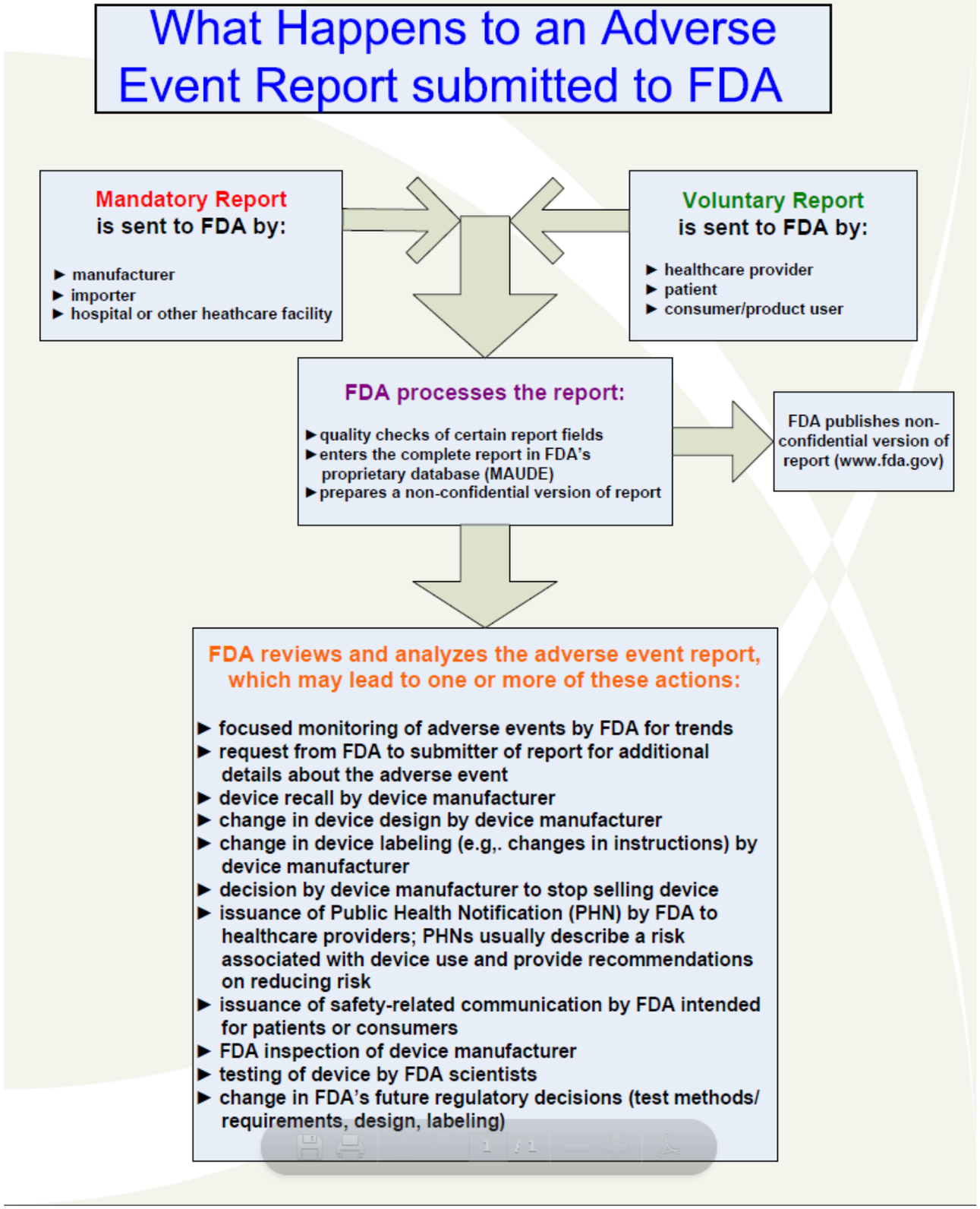
Food and Drug Administration
MedWatch

2. A way to get safety information from FDA

www.fda.gov/medwatch

Lifecycle of FDA-regulated Drugs





Lifecycle of FDA-regulated Devices

Who should report?



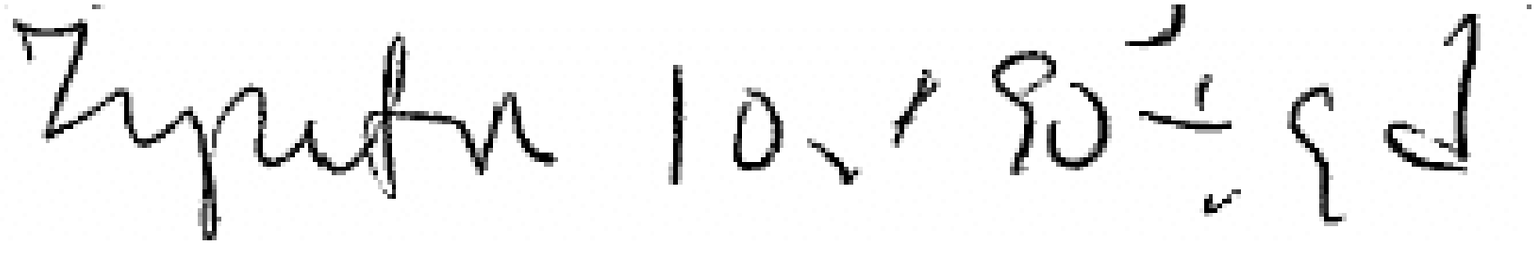
You report IN

One person can
make a difference



Potential Sources of Errors

- Prescribing (handwriting, abbreviations)





- Label /Packaging (placement of information, expression of strength/dose, readability of label, lack of appropriate labeling during repackaging)



- Miscommunication of orders/Nomenclature (sound alike, look alike)



What should I report?


Drugs


Medical Devices


Biologics




Combination Products

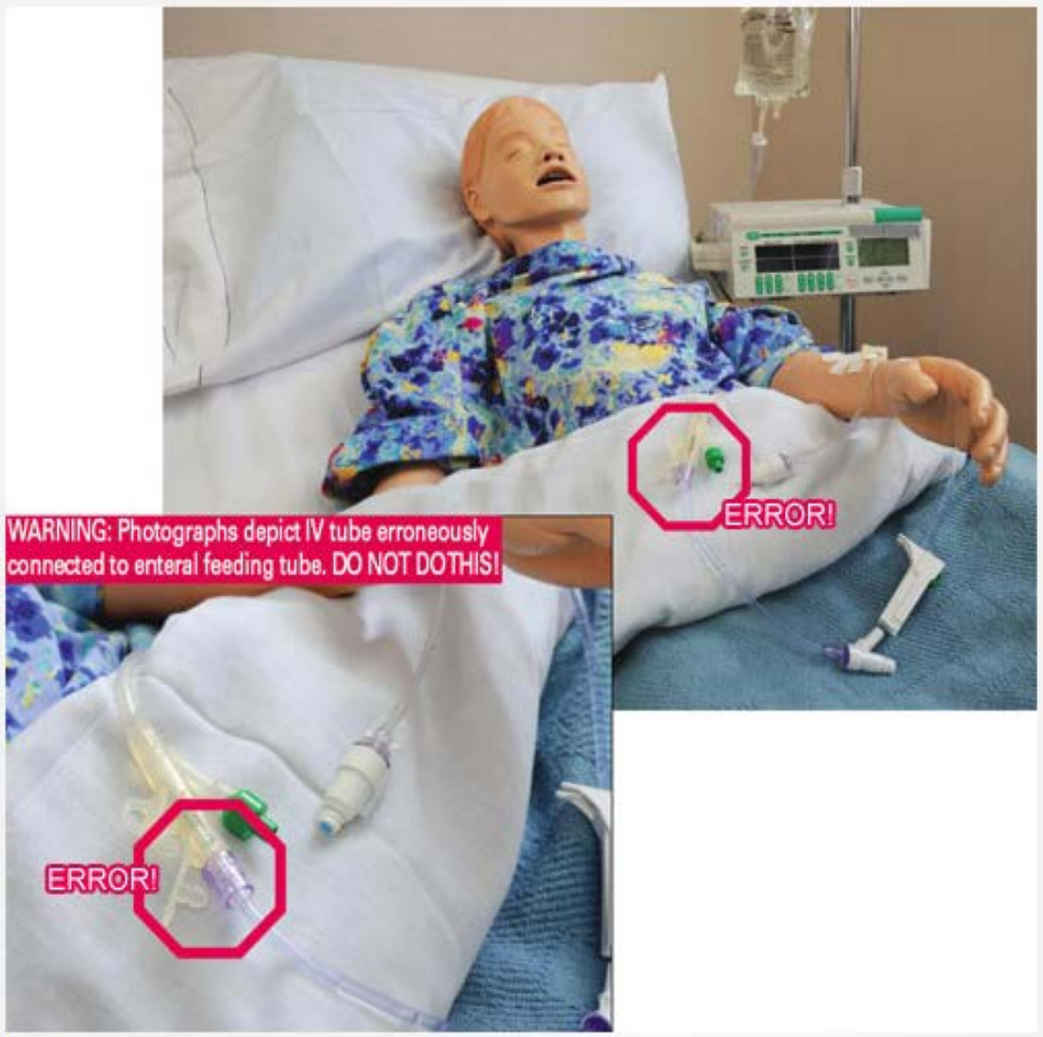

Special Nutritional Products

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

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
- 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

"Near Miss" Case Studies Available

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

What should I report?



- Generic inequivalence or failure
- Adverse event
- Medication error
- Product use error
- Product quality

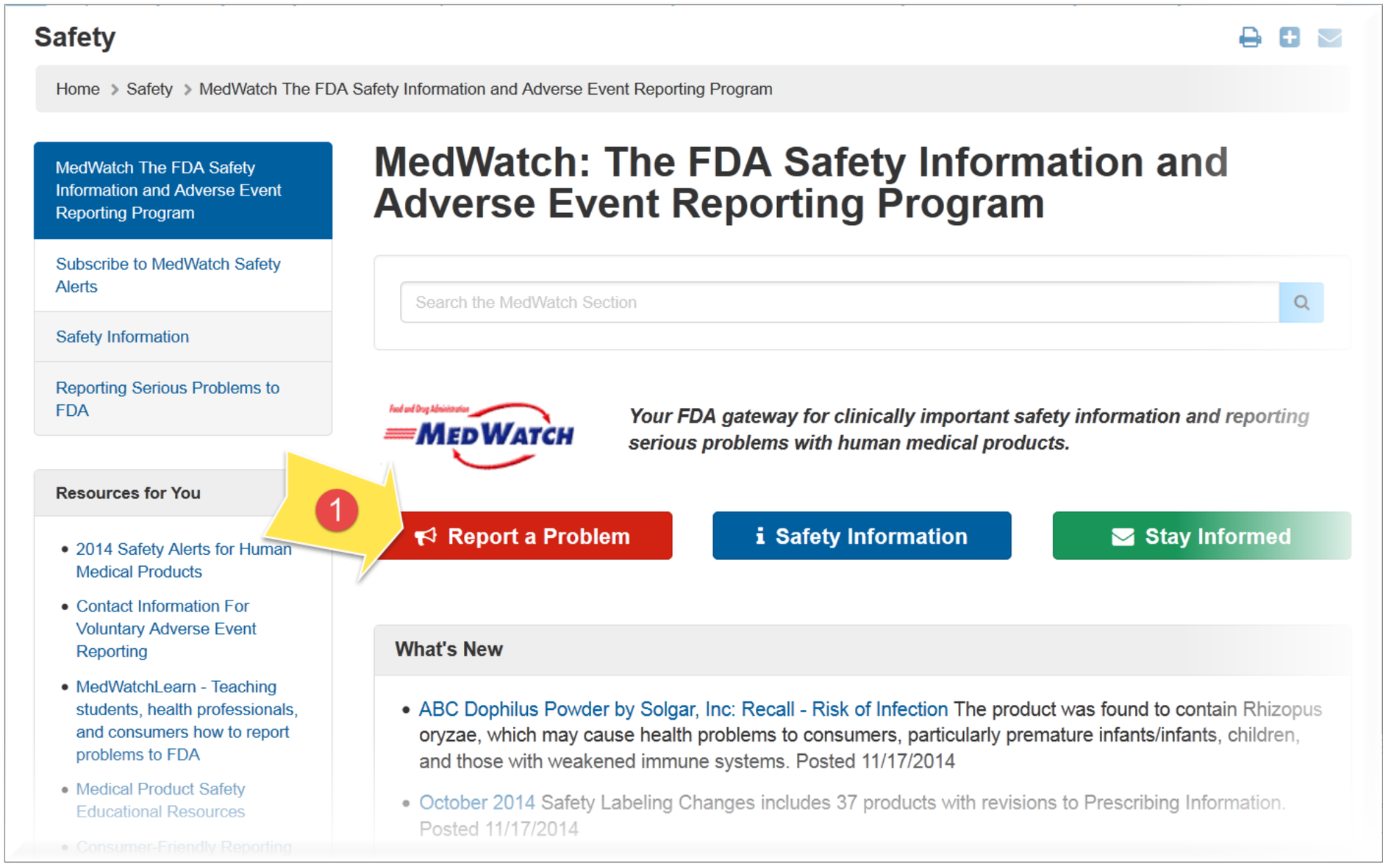
How do I report?

– Online

– Mail/Fax

– By Phone

1-800-332-1088



www.fda.gov/medwatch

The FDA Safety Information and Adverse Event Reporting Program

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)

Begin Report As a:

Health Professional

Consumer/Patient

Frequently Asked Questions

2

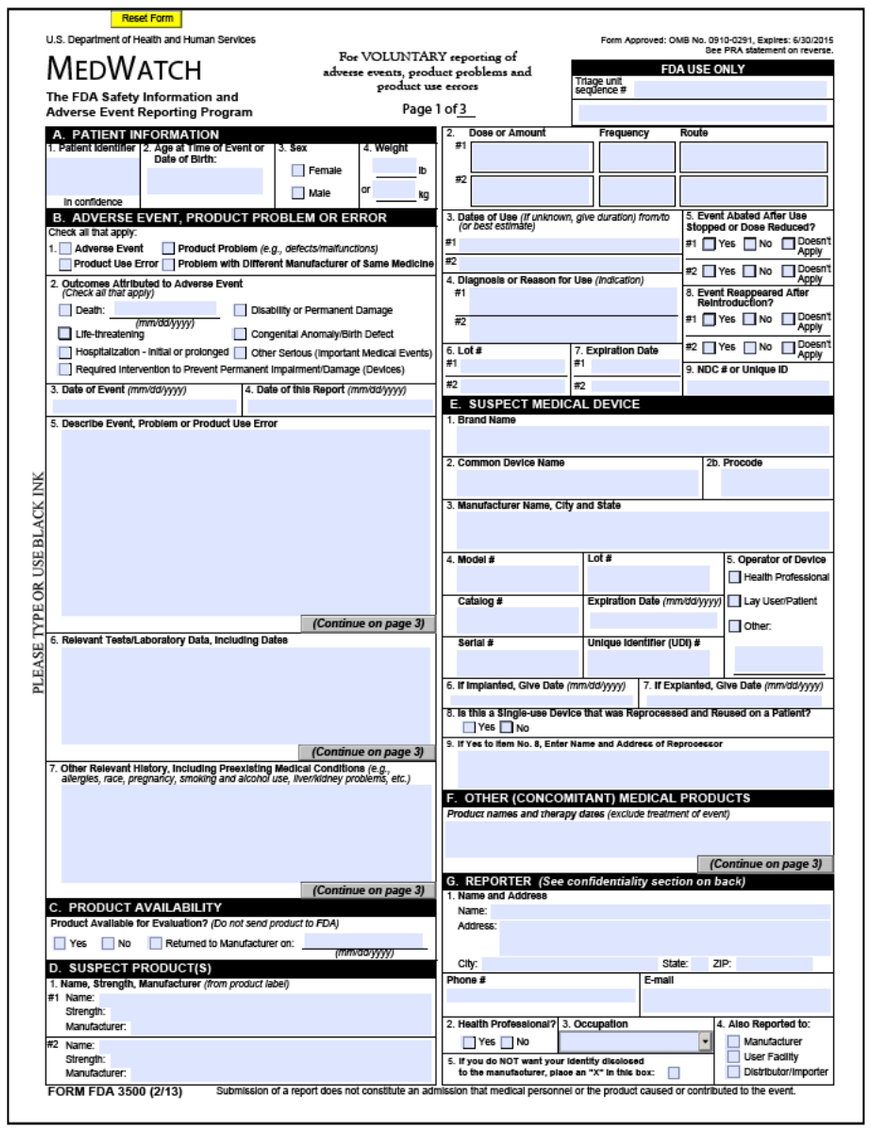
Reporting Online



www.fda.gov/medwatch/report

Reporting by Mail

Clinician Form 3500



Reset 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: 6/30/2015
See PRA statement on reverse.

Page 1 of 3

FDA USE ONLY
Triage unit seqdence #

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION
1. Patient Identifier (In confidence) | 2. Age at Time of Event or Date of Birth: | 3. Sex: Female, Male | 4. 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
(Continue on page 3)
6. Relevant Tests/Laboratory Data, Including Dates
(Continue on page 3)
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
(Continue on page 3)

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. Dose or Amount | Frequency | Route
#1
#2
3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1
#2
4. Diagnosis or Reason for Use (indication)
#1
#2
5. Event Abated After Use Stopped or Dose Reduced?
#1 Yes No Doesn't Apply
#2 Yes No Doesn't Apply
6. Lot #
#1
#2
7. Expiration Date
#1
#2
8. Event Reappeared After Reintroduction?
#1 Yes No Doesn't Apply
#2 Yes No Doesn't Apply
9. NDC # or Unique ID

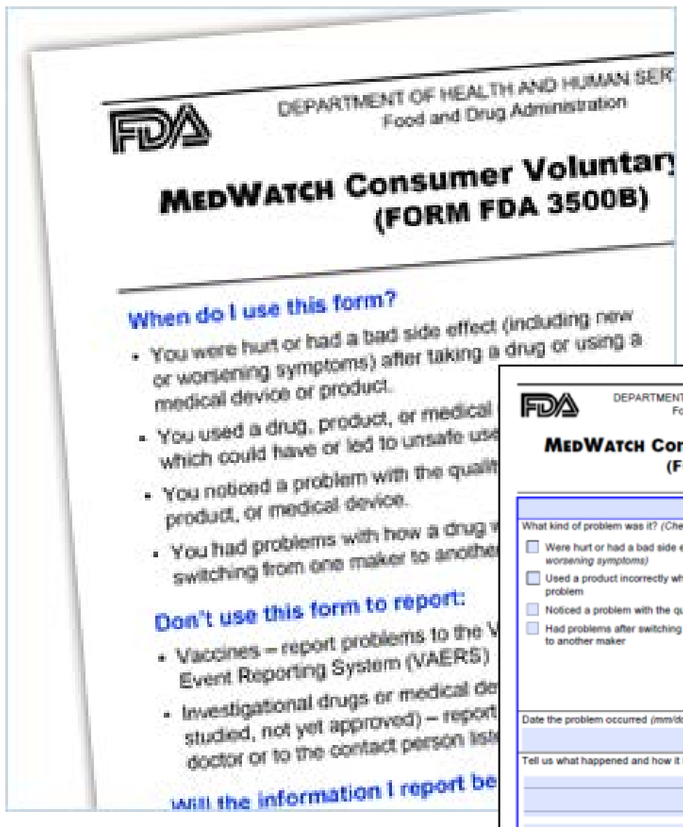
E. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name | 2b. Procode
3. Manufacturer Name, City and State
4. Model # | Lot # | 5. Operator of Device: Health Professional, Lay User/Patient, Other:
Catalog # | Expiration Date (mm/dd/yyyy)
Serial # | Unique Identifier (UDI) #
6. If Implanted, Give 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)
(Continue on page 3)

G. 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 disclosed to the manufacturer, place an "X" in this box:

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 SER
Food and Drug Administration

MedWatch Consumer Voluntary
(FORM FDA 3500B)

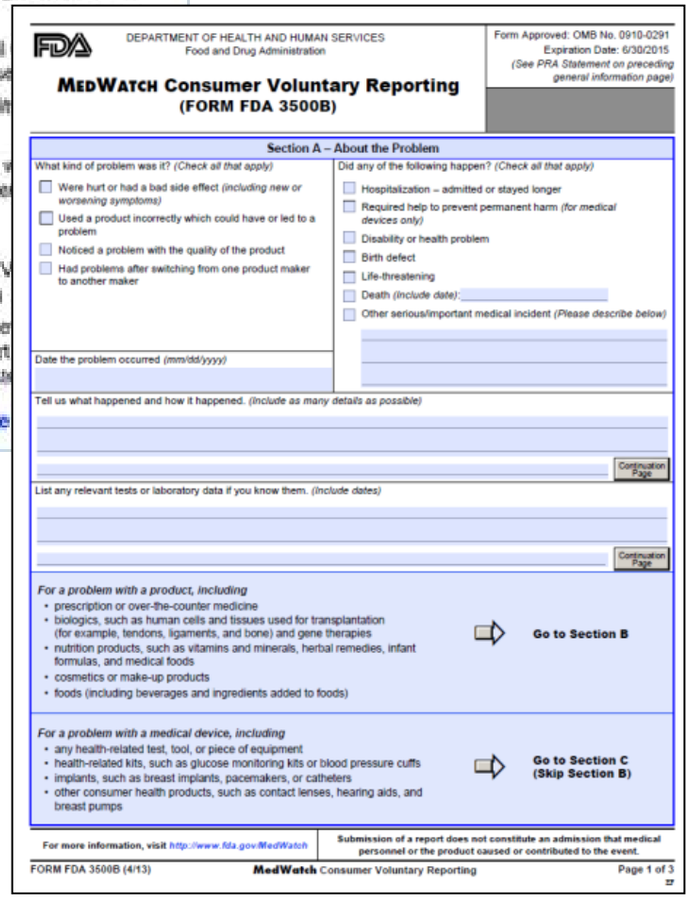
When do I use this form?

- 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
which could have or led to unsafe use
- You noticed a problem with the quali
product, or medical device.
- You had problems with how a drug
switching from one maker to another

Don't use this form to report:

- Vaccines – report problems to the V
Event Reporting System (VAERS)
- Investigational drugs or medical de
studied, not yet approved) – report
doctor or to the contact person list

With the information I report be



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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

MEDWATCH Consumer Voluntary Reporting
(FORM FDA 3500B)

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 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):
Other serious/important medical incident (Please describe below)

Date the problem occurred (mm/dd/yyyy)

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

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

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)

For more information, visit http://www.fda.gov/MedWatch

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

FORM FDA 3500B (4/13) MedWatch Consumer Voluntary Reporting Page 1 of 3

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

Page 1 of ____

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

FDA USE ONLY
Triage unit sequence #

A. PATIENT INFORMATION
1. Patient Identifier | 2. Age at Time of Event or Date of Birth: | 3. Sex: ☐ Female ☐ Male | 4. Weight: ____ lb or ____ kg
In confidence

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:

	Dose	Frequency	Route
#1			
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1
#2

4. Diagnosis or Reason for Use *(Indication)*
#1
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

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
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
Serial #	Other #	☐ 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? ☐ Yes ☐ No | 3. Occupation | 4. Also Reported to: ☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

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

Required Sections

Event or Problem

Reporter

Product

Confidentiality

The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

G. 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**

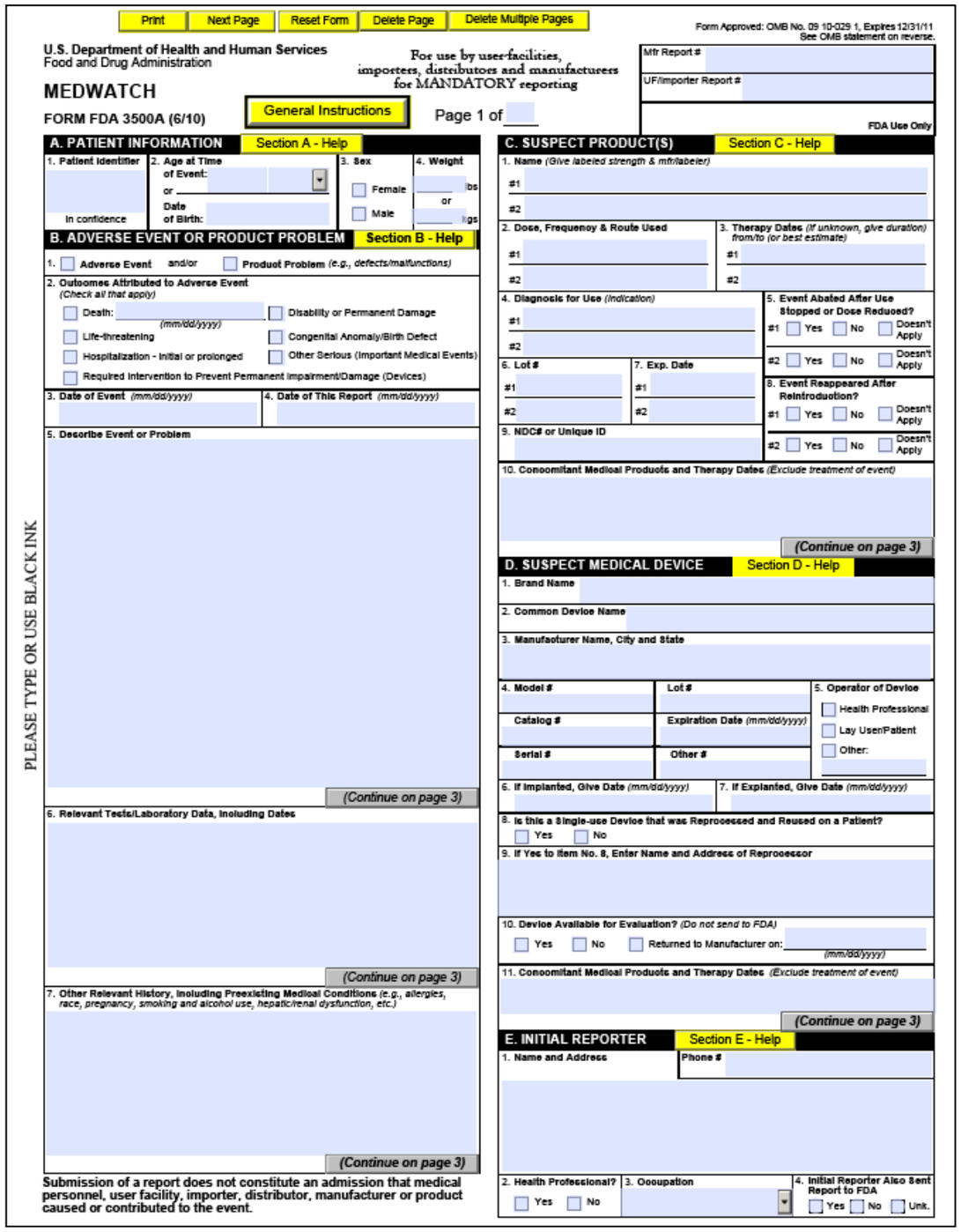
4. **Also Reported to:**
☐ Manufacturer
☐ User Facility
☐ Distributor/Importer

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

MedWatch Reporting - MANDATORY

MANDATORY Form 3500A

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


Print | Next Page | Reset Form | Delete Page | Delete Multiple Pages

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

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

MEDWATCH

FORM FDA 3500A (6/10)

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

General Instructions

Page 1 of

Mfr Report #

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION Section A - Help

1. Patient Identifier — In confidence
2. Age at Time of Event: or Date of Birth:
3. Sex — Female, Male
4. Weight — lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM Section B - Help

1. Adverse Event and/or Product Problem (e.g., defects/malfunctions)
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 or Problem

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

(Continue on page 3)

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.

C. SUSPECT PRODUCT(S) Section C - Help

1. Name (Give labeled strength & mfr/labeler) #1 #2
2. Dose, Frequency & Route Used #1 #2
3. Therapy Dates (If unknown, give duration) from/to (or best estimate) #1 #2
4. Diagnosis for Use (Indication) #1 #2
5. Event Abated After Use Stopped or Dose Reduced? #1 Yes No Doesn't Apply; #2 Yes No Doesn't Apply
6. Lot # #1 #2
7. Exp. Date #1 #2
8. Event Reappeared After Reintroduction? #1 Yes No Doesn't Apply; #2 Yes No Doesn't Apply
9. NDC# or Unique ID
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE Section D - Help

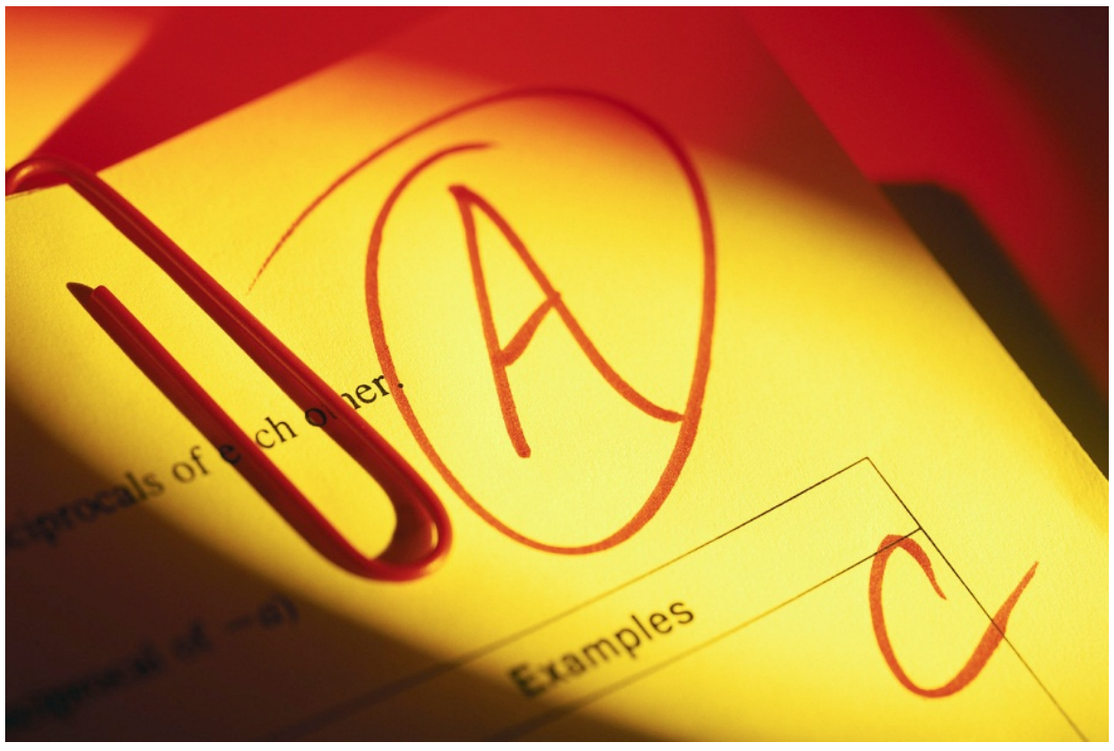
1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date (mm/dd/yyyy) / Serial # / Other #
5. Operator of Device — Health Professional, Lay User/Patient, Other:
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
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
10. Device Available for Evaluation? (Do not send to FDA) Yes No Returned to Manufacturer on: (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

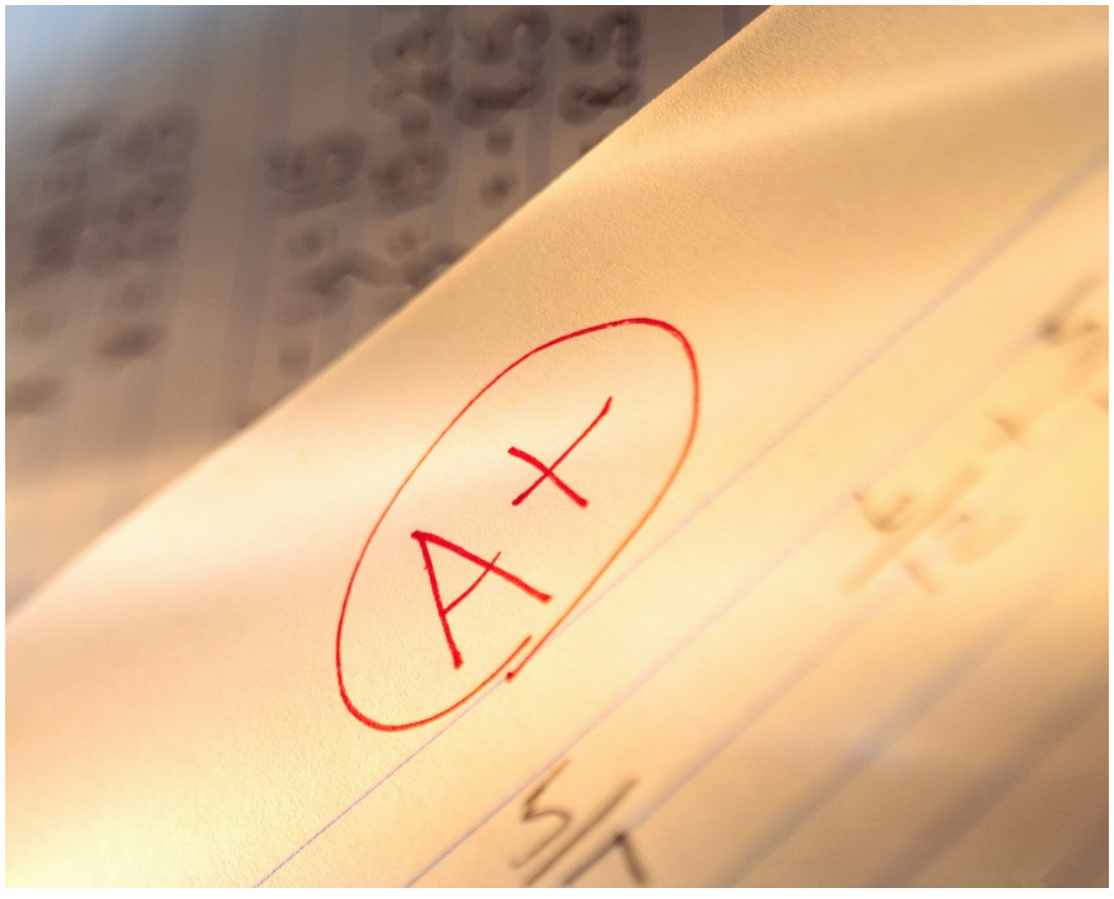
(Continue on page 3)

E. INITIAL REPORTER Section E - Help

1. Name and Address
Phone #
2. Health Professional? Yes No
3. Occupation
4. Initial Reporter Also Sent Report to FDA Yes No Unk.

What makes a good report a





Great report ?

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MedWatch*Learn*

FDA **MedWatch*Learn*** teaches students, health professionals, and consumers how to complete the forms necessary to report problems to 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)

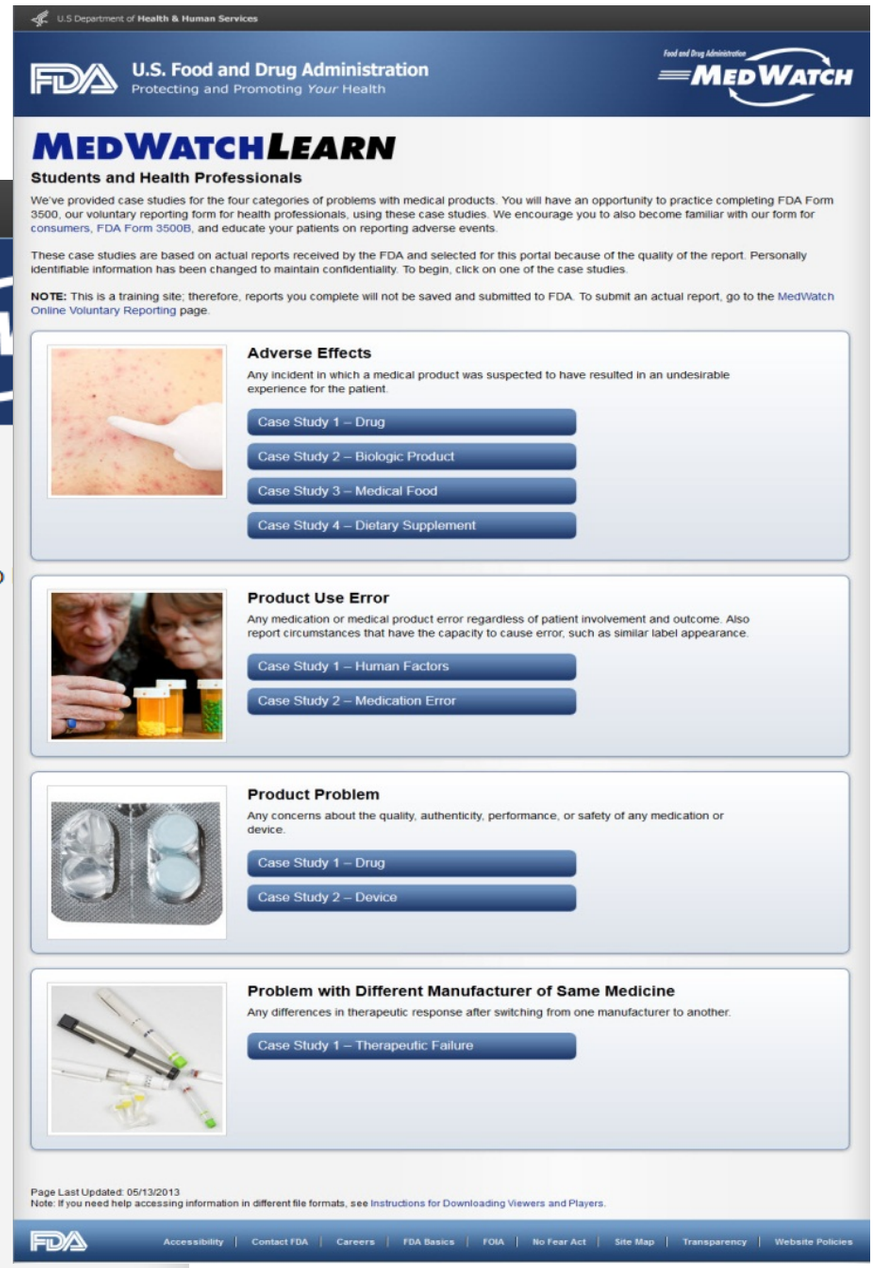


Consumers
(FDA Form 3500B)

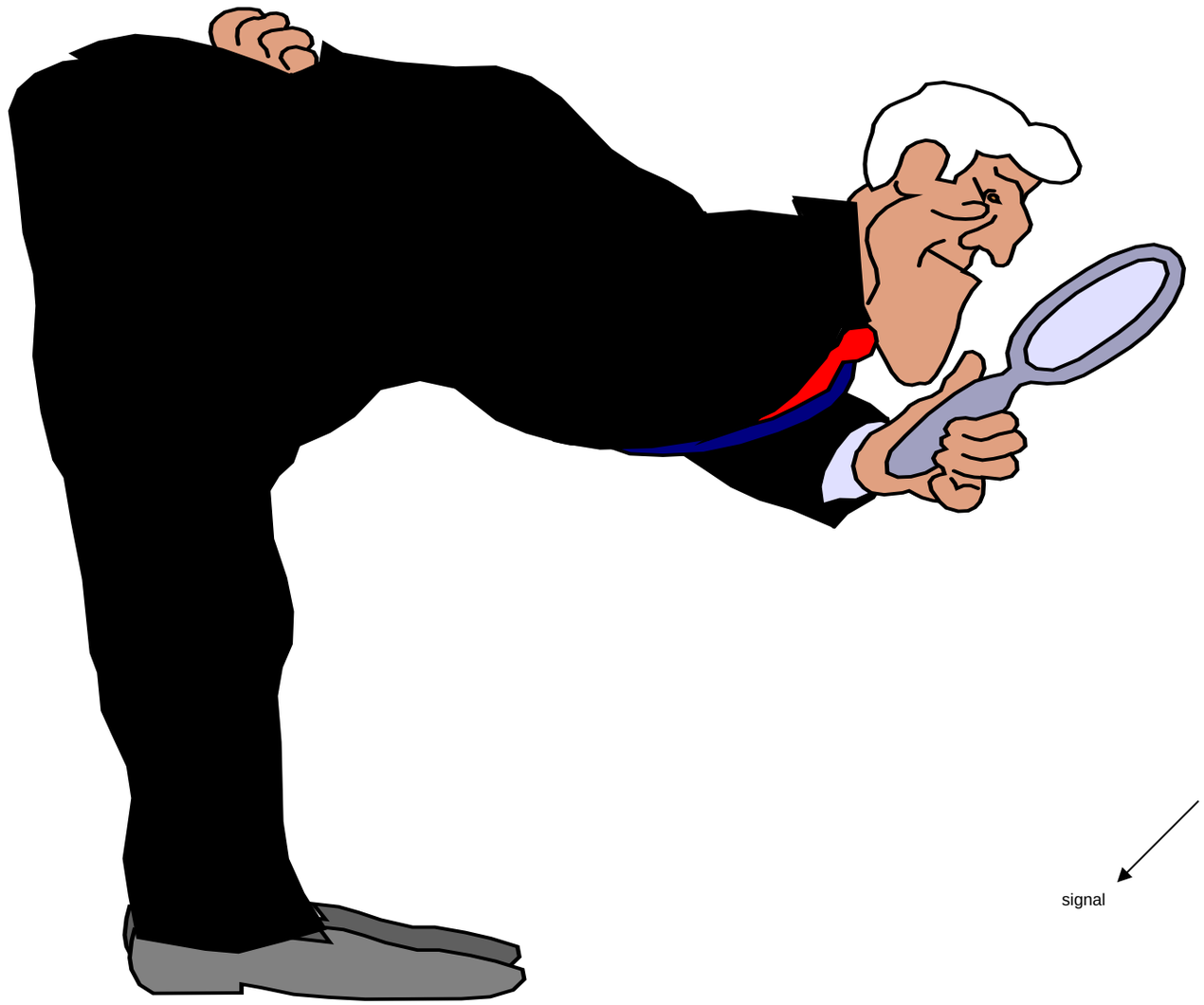
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MedWatchLearn v1.0

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What happens to my report?



Did you see it??

signal

FDA Action Example

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

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 w[illegible]hen too much viscous lidocaine is given to infants and young children or they accidentally swallow[illegible]esult in seizures, severe brain injury, and problems with the heart. Cases of overdose due to wr[illegible]dental 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.

Other FDA Actions

- Update to the product label
- Addition of a medication guide
- Request a change in the product's design, process, packaging, or distribution
- Request a product recall
- Issue a safety communication
- Hold a public workshop
- Inform pre-market reviews



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FDA reports OUT

Drug Safety Labeling Changes

June 2014

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, PCI= PATIENT COUNSELING INFORMATION

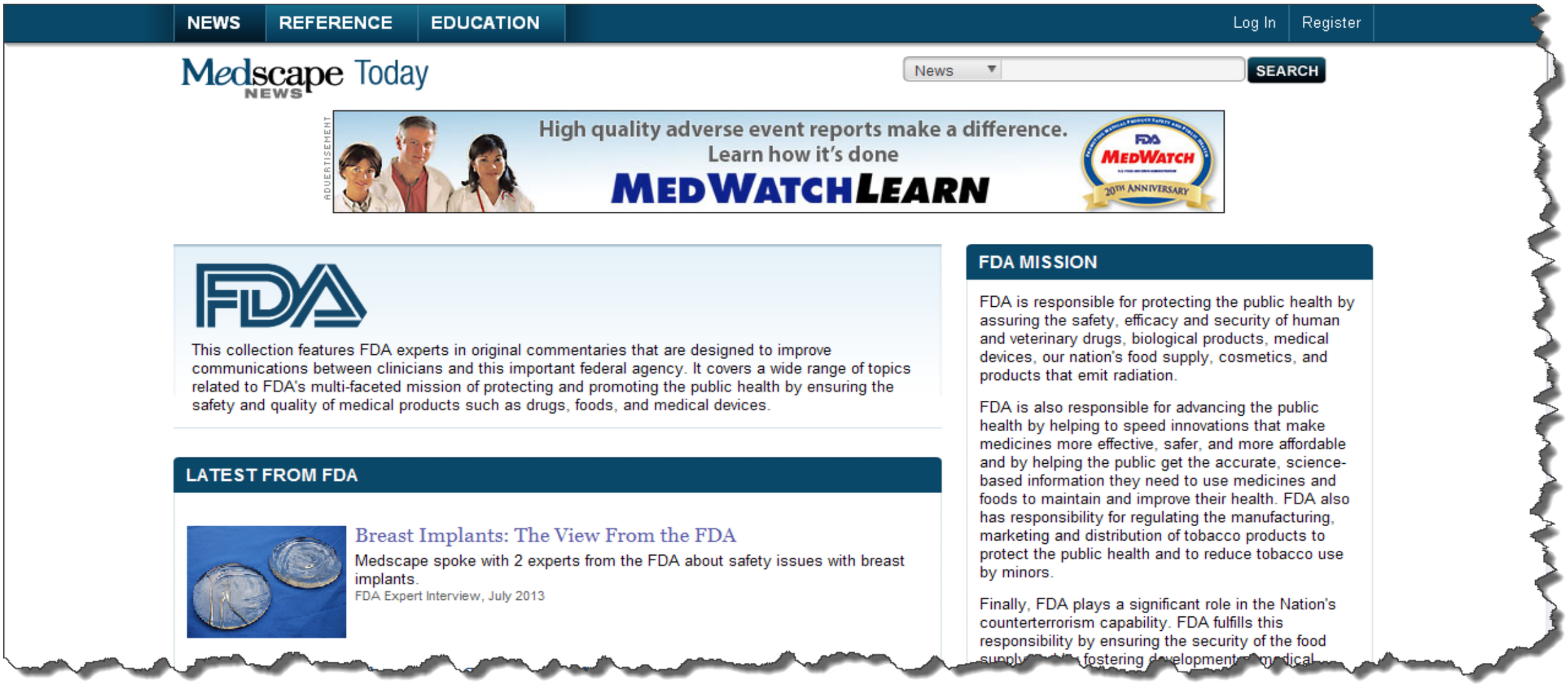
DRUG NAME	SECTIONS MODIFIED					
(Click on drug name to go to detailed view)	BW	C	W	P	AR	PPI/MG
Sporanox (itraconazole) Capsules	X	X	X	X	X	X
Sporanox (itraconazole) Oral Solution	X	X	X	X	X	X

Monthly Safety Labeling Changes

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Collaboration: Medscape



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1. A way to send information to FDA

Food and Drug Administration
MedWatch

2. A way to get safety information from FDA

www.fda.gov/medwatch

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