

Medical Device Reporting

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Session Overview

- **Purpose:** To provide information about the FDA's Medical Device Reporting (MDR) regulation and the Voluntary Reporting program called MedWatch
- **Goal:** To introduce you to Medical Device Reporting and to help you better understand the process and benefits of Voluntary Reporting

What Types of Reports does the FDA Receive?

- **Required reports** – mandated by the Federal Food, Drug and Cosmetic Act
 - submitted by the medical device industry and certain healthcare facilities
- **Voluntary reports** – not mandated
 - submitted by the public
- Both types of reports contain information that allows the FDA to monitor the safety of medical devices

What is a Medical Device?

An item either used for diagnosis, treatment or prevention of disease, or intended to affect the body, that does not achieve its primary purpose through chemical action or metabolism within the body

*** The FDA definition is in Code 301 Section 201 (h) of FD&C Act.**

Who Must Submit Mandatory Reports to the FDA?

Manufacturer

Importer

User Facility

- Hospital
- Ambulatory Surgical Facility
- Outpatient Diagnostic Facility
- Outpatient Treatment Facility
- Nursing Home

Mandatory Reporting Requirements

Manufacturers are required to:

- Submit reports of death, serious injury and malfunction to the FDA within 30 calendar days

Importers are required to:

- Submit, within 30 calendar days, reports of death and serious injury to the FDA and manufacturer and submit reports of malfunction to the manufacturer

User Facilities are required to:

- Submit, within 10 work days, reports of death to the FDA and manufacturer and submit reports of serious injury to the manufacturer, or to the FDA if the manufacturer is unknown

User Facility Defined

- **Hospital** - performs diagnostic, therapeutic, surgical or other patient services, etc.
- **Ambulatory Surgical Facility** - performs same day outpatient surgical procedures. Examples include surgical, endoscopy or Lasik centers
- **Outpatient Diagnostic Facility** - Conducts medical diagnostic tests, such as a mammography, MRI, or in-vitro testing
- **Outpatient Treatment Facility** - provides nonsurgical therapeutic care on an outpatient basis or in a home setting. Includes ambulance providers, rescue services and home healthcare groups
- **Nursing Home** - provides skilled nursing care, hospice care, or rehabilitative services.

What about a Physician's Office?

A physician's office, whose primary purpose is to only examine, evaluate, and treat or refer patients is not subject to the FDA's reporting requirements

Examples:

- dentist
- chiropractor
- optometrist
- nurse practitioner
- school clinics
- employee health clinics
- freestanding care units

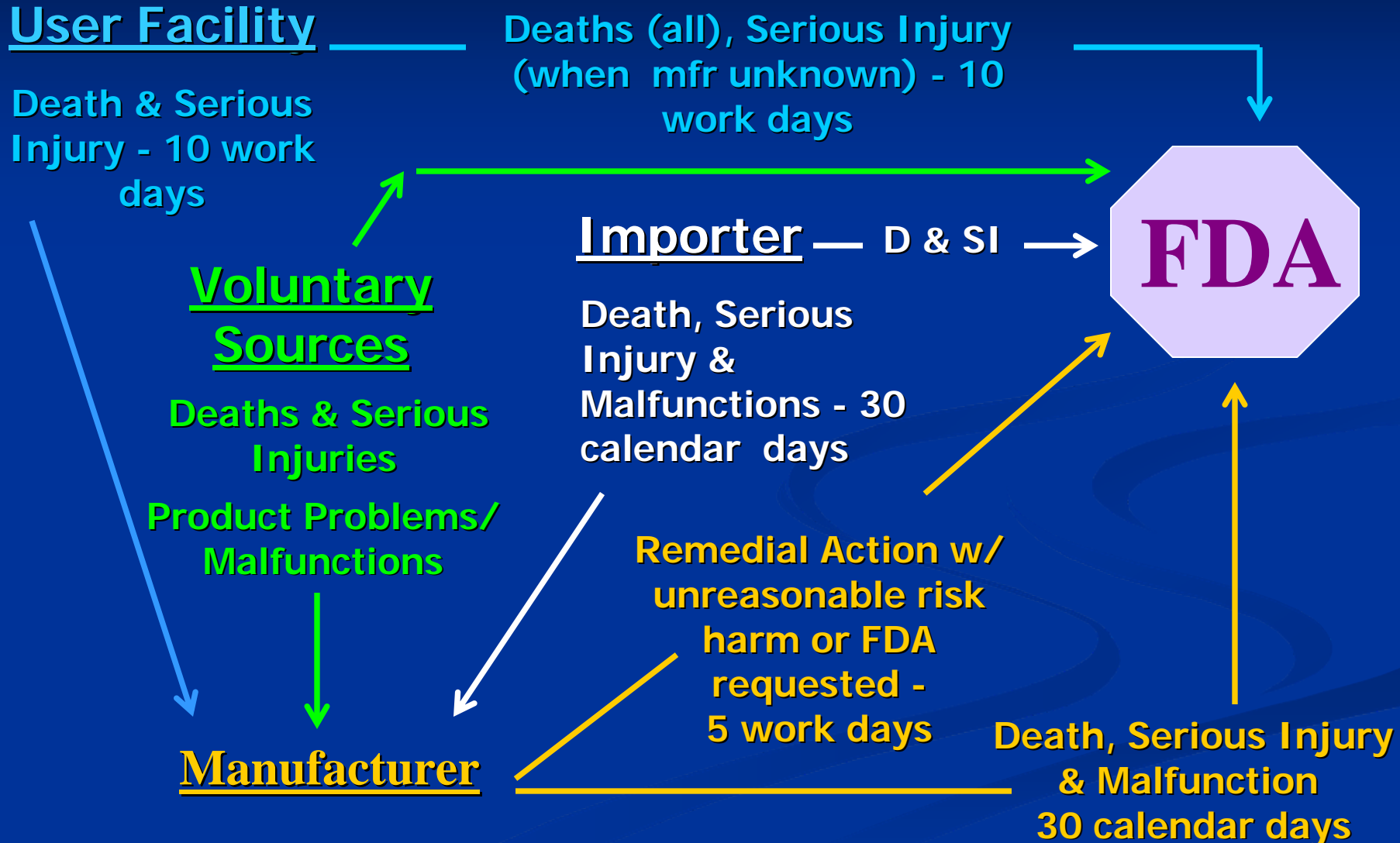
****The FDA encourages physicians to file voluntary reports**

Who can submit Voluntary Reports to the FDA?

- Patients
- Consumers
- Physicians
- Dentists
- Chiropractors
- Optometrists
- Nurse Practitioners
- School clinics
- Employee Health Clinics
- Freestanding Care Units
- ANYONE!

Voluntary Reporters are also encouraged to submit reports to the manufacturer of the device, if known

Data Flow and Reporting Timeframes



Why Does the FDA Need Medical Device Reports?

- To learn more about how marketed devices perform
- To identify devices that are not safe and effective for their intended use

How Does the FDA Use Medical Device Reports?

- Event reports are analyzed by FDA staff including health care clinicians, engineers and scientists.
- Follow-up actions that the FDA may be take:
 - Request additional information
 - Conduct an investigation of event
 - Conduct an inspection at the manufacturer, importer or user facility
 - Contact the manufacturer about a recall
 - Issue a public health advisory/safety alert

How to Submit a Voluntary Report

- Healthcare providers, consumers, and user facilities reporting malfunctions, can use the MedWatch Voluntary Reporting Program
- There are three ways to contact FDA:
 - Telephone: 1-800-FDA-1088
 - Online report form 3500 (& instructions) accessible at:
<http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM082725.pdf>
 - Download or print the form to complete and mail to the address on the form:
<http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>

What Happens to my Report?

- The FDA will send an acknowledgment letter to the reporter
- Reports are entered into the Manufacturer and User Facility Device Experience (MAUDE) database
- Reports (redacted copies) are available on the FDA's website at:
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM

Summary

- Medical Device Reporting encompasses mandatory reporting and voluntary reporting;
- Medical Device Reporting allows the FDA to monitor device performance and identify problems;
- There are three (3) reporters who must comply with the FDA's Medical Device Reporting (MDR) requirements, manufacturers, importers and user facilities;
- Voluntary reporters are encouraged to submit information to the FDA and the manufacturers;
- Learn more about mandatory reporting - See our presentations on Medical Device Reporting for Manufacturers and Importers, and Medical Device Reporting for User facilities.

Questions?

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