Medical Device Recall 2013 Update

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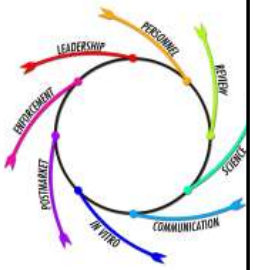
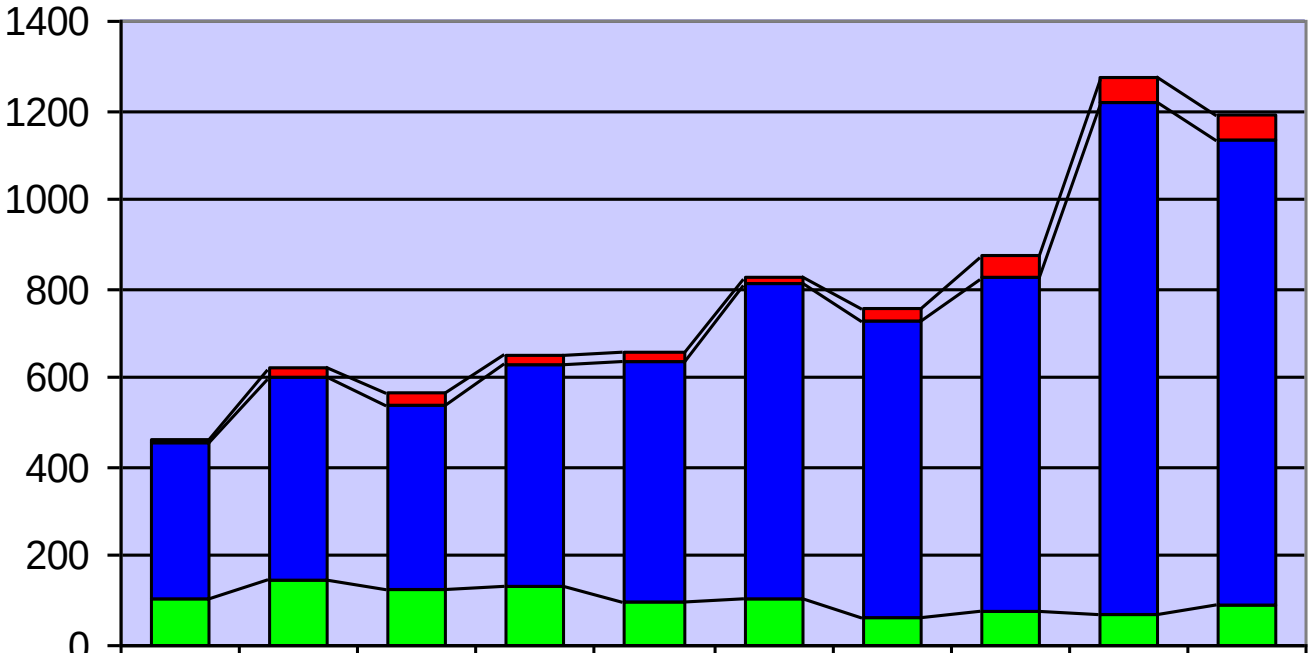


Recall Counts FY2003 - FY2012

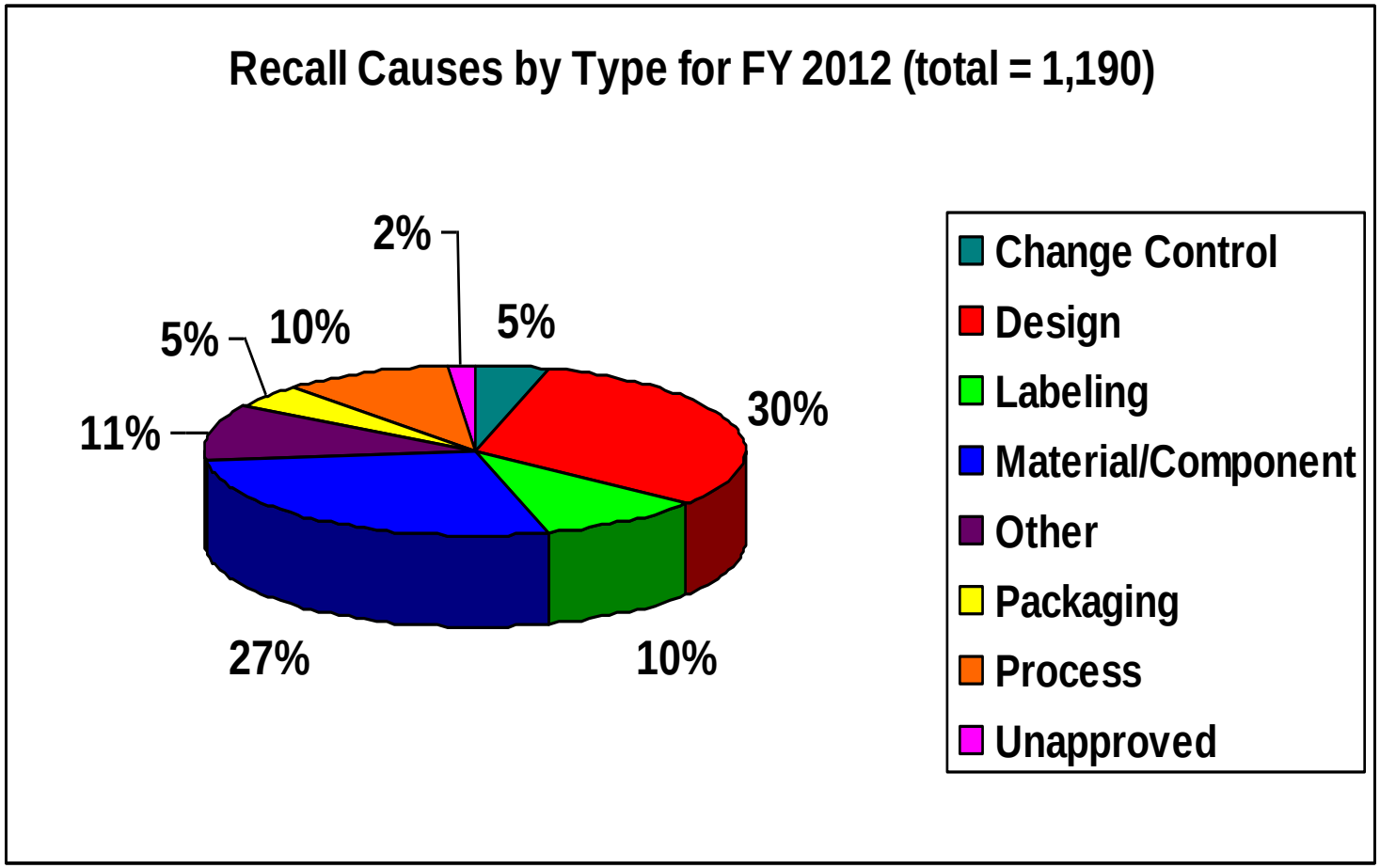


	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Class I	5	25	25	22	26	14	32	49	50	57
Class II	350	456	414	498	538	707	661	754	1152	1043
Class III	106	145	128	134	96	108	65	74	69	91

Probable Causes of Recent Increases

- Elimination of backlog within FDA
- Increased vigilance of device manufacturers
- Increased reporting by Industry
- Increased number of devices and manufacturers

Recall Causes in FY 2012



Recall Challenges

- Understanding the Risk
- Adequate Notification
- Recall Cause Analysis
- Corrective and Preventive Actions
- Closing a Recall
- Terminating a Recall

What is a recall?

- Firm's removal or correction of a marketed product in violation of the F, D, & C Act and against which FDA would initiate legal action
  - Voluntary action taken by a firm when they determine a device is misbranded § 502 or adulterated § 501 of the Act
  - Effective method to remove or correct consumer products from the market place
  - Alternative to FDA initiated court action for removing violative products from the market (seizure) or import detention

Classes of Recalls

- Class I- *Situation in which there is a* **reasonable probability** *that the use of, or exposure to, a violative product* **will cause serious adverse health consequences or death**
- Class II- *Situation in which use of, or exposure to, a violative product* **may cause temporary or medically reversible adverse health consequences** *or where the probability of* **serious adverse health consequences is remote**
- Class III- *Situation in which use of, or exposure to, a violative product is* **not likely to cause adverse health consequences**.

Recall Regulations

- **21 CFR 7** (7.40-7.59 Recalls)
  - How to conduct a recall
  - Guidance for firms (voluntary)
  - Requirements for FDA

- **21 CFR 806** (Medical Device Reports of Removals and Corrections)
  - Reporting requirement for medical device manufacturers & importers
    - for situations with a risk to health (class 1 & 2 recalls)

- **21 CFR 810** (Mandatory Medical Device Recalls)
    - Rarely used

Related Regulations

- 21 CFR 820 Quality System Regulation
  - GMPs
    - Design control
    - Product & Process changes
    - Validation of device and process changes
    - Acceptance activities
    - CAPA
    - Complaint files
    - etc
- 21 CFR 803 Medical Device Reporting
- 21 CFR 807.81(a)(3) Pre-Market Notification when changes are introduced

Ways CDRH May Become Aware of a Recall Situation

- 806 - Correction and Removal Reports
- FDA Inspections
  - Directed
  - Routine
- Consumer Complaints
- Adverse Event Reports
  - Medwatch Report
  - MDRs (Medical Device Report), OSB
- List is not all inclusive
  - Information received by a firm, repackager or distributor
  - Competitors
  - Internal Device Reviews
  - MedSun Reports
  - MRA and other Country Agreements
  - Radiation Product Reports

Triggering Events

- 21 CFR 806.10(a)
  - Each device manufacturer or importer shall submit a written report to your FDA district office of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated:
    1. To reduce a risk to health posed by the device; or
    2. To remedy a violation of the act caused by the device which may present a risk to health
- 21 CFR 806.10(b)
  - The manufacturer or importer shall submit any required report within 10-working (business) days of initiating such correction or removal.

21 CFR Part 7.42: A Firm's Recall Strategy

- The recall strategy will include the following elements:
  - Depth – level in the distribution chain
  - Public Warning – purpose is to alert the public that the product being recalled presents a serious hazard to health
  - Effectiveness Checks – verifies that all consignees at the recall depth specified have received notification and have taken appropriate action
- The recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted

A Risk Assessment Should Be Conducted:

- Prior to
  - Stock Recoveries
  - Safety Alerts
  - Market Withdrawals
  - Recalls

Other FDA/CDRH information

- **Part 806 – Reports of Corrections and Removals**
- **http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=806**

- **Customer Notification Letter & Press Release template and other important links**
- **http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm**

- **CDRHLearn modules**
- **http://www.fda.gov/Training/CDRHLearn/ucm162015.htm**

Other FDA/CDRH information

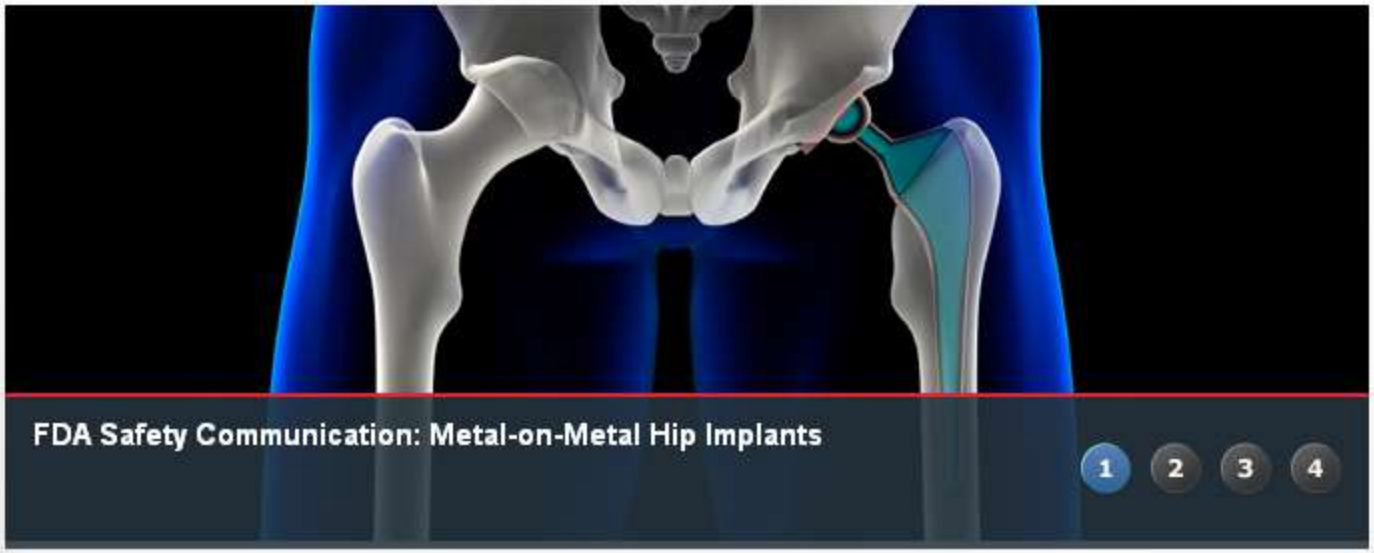
- **Distinguishing Medical Device Recalls from Product Enhancements – Draft Guidance**
- **http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm340518.htm**

- **Guidance for Industry: Product Recalls, Including Removals and Corrections**
- **http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm**

Other FDA/CDRH information

- **News - http://www.fda.gov/MedicalDevices/NewsEvents/default.htm**
- **Device approvals - http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/default.htm**
- **Compliance actions http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/default.htm**

Medical Devices



Medical Devices Topics

Products and Medical Procedures
Approvals & Clearances, Home Use, Surgical, Implants & Prosthetics, In Vitro Diagnostics, more...

Medical Device Safety
Alerts & Notices, Recalls, Report a Problem, MedSun, Emergency Situations

Device Advice: Comprehensive Regulatory Assistance
How to Market a Device, Postmarket Requirements,

Science and Research (Medical Devices)
Chemistry & Materials Science, Solid & Fluid Mechanics, Imaging & Applied Mathematics, Electrical & Software Engineering, more...

News & Events (Medical Devices)
Medical Device News, Videos, Workshops & Meetings

Resources for You (Medical Devices)
Consumers, Health Care Providers, Regulated Industry

Spotlight

- FDA announces public-private partnership to develop regulatory science that will speed patient access to new medical device technologies
- Improvements in Device Review: Results of CDRH's Plan of Action for Premarket Review of Devices
- National Medical Device Postmarket Surveillance Plan
- CDRH Mission, Vision and Shared Values
- CDRH 2013 Strategic Priorities

Recalls & Alerts

- FDA warns against improper advertising, promotion of lasers intended for LASIK corrective eye surgery
- Narrowed Indications for Use for

Medical & Radiation Emitting Device Recalls

Search Medical & Radiation Emitting Device Recalls

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Product Name

Recall Class All **Recall Number**

Date Posted to

Reason for Recall

Recalling Firm

Sort by Date Record Posted (Descending)

For full-text search, select *Go to Simple Search* button.
This database contains classified medical device recalls since november 1, 2002.

Go to Simple Search | 10 **Records per Report Page** | Search | Clear

Page Last Updated: 02/12/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

MAUDE - Manufacturer and User Facility Device Experience

- MAUDE data represents reports of adverse events involving medical devices. The data consists of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. MAUDE may not include reports made according to exemptions, variances, or alternative reporting requirements granted under 21 CFR 803.19.
- The on-line search allows you to search CDRH database information on medical devices which may have malfunctioned or caused a death or serious injury. MAUDE is scheduled to be updated monthly and the search page reflects the date of the most recent update. FDA seeks to include all reports received prior to the update. However, the inclusion of some reports may be delayed by technical or clerical difficulties.
- MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices. Please be aware that reports regarding device trade names may have been submitted under different manufacturer names. Searches only retrieve records that contain the search term(s) provided by the requester.

Search MAUDE Database

Help | Download Files | More About MAUDE

Enter a search term below, choose a date range and select *Search*

Date Report Received by FDA
(press CTRL key for multiple years)

ALL YEARS
2013
2012
2011
2010

Enter a single word (e.g., electromechanical), an exact phrase (e.g., electromechanical pump) or multiple words. To Search by Brand Name, Manufacturer, Event Type, 510K Number, PMA Number, Product Code, or date, select *Go To Advanced Search* button.

Go to Advanced Search | 10 Records per Report Page | Search | Clear

- The Freedom of Information Act (FOIA) is found in Title 5 of the United States Code, Section 552. FOIA generally provides that any person has the right to request access to federal agency records or information except to the extent the records are protected from disclosure by any of nine exemptions

Thank You

Questions?