Managing Effective US Medical Device Recalls

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Discussion Points

- Definitions
- Responsibilities of Regulated Firms
  - To Recall or Not (Evaluating Risk)
  - Recall Strategy
  - Effective Communication with FDA
- Recall Classification Method
- FDA Oversight
- Risk Considerations
- Follow-up Responsibilities
- Silent Recalls
  - Enhancement vs. Product Recalls
- Summary & Useful Websites

What is a Recall?

- A company's voluntary removal or correction of a US marketed product that is:
  - Intended to reduce a health risk
  - In violation of the Federal Food Drug & Cosmetic Act FFDCA and where FDA would initiate legal action
    - e.g., Seizure
- A violative product under FFDCA or its associated regulations is defined as a product that is determined to be:
  - Misbranded (Section 502) – associated with labeling problems
  - Adulterated (Section 501) – associated with problems with the product itself

What is a Recall?

- A useful method to remove or correct FDA-regulated products from the market place

- An alternative to FDA initiated court action for removing violative products from the market
  - e.g., seizure or import detention

How to Determine if your Firm has a Medical Device Recall (1 of 2)

- Does it meet the following criteria?
  - A Removal: The physical confiscation (by recalling firm not government) from where it is used or sold, to some other location for:
    - Repair
    - Modification
    - Adjustment
    - Relabeling
    - Destruction
    - Inspection
  - A removal that is not part of regularly scheduled maintenance

How to Determine if your Firm has a Medical Device Recall (2 of 2)

- Does it meet the following criteria?
  - A Correction: On site
    - Repair
    - Modification
    - Adjustment
    - Relabeling
    - Destruction
    - Inspection
    - Including patient monitoring

How to Determine if your Firm's action is ***Not*** a Medical Device Recall

- A Correction or Removal action is ***NOT*** a recall, if it is a:
  - **Market Withdrawal** - Firm's removal or correction of a distributed product which does ***not violate or is minor violation that would not be subject to legal action by the FDA.***
    - e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.
  - **Stock Recovery** - Firm's removal or correction of a product that has ***not been marketed or that has not left the direct control of the firm*.**
  - **Safety Alert** – Firm's Notification to device users that the use of a device may, **in certain circumstances, pose a risk of substantial harm.**

Ways FDA Becomes Aware of a Recall Situation

- FDA inspections
- Consumer Complaints
- Adverse Event Reports
  - Medwatch/USP/21
  - 21 CFR 803 Medical Device Reports
- 21 CFR 806 - Correction and Removal Reports
- Information from a firm, repackager or distributor
- Competition
- Device Evaluation Reviews
- MedSun Reports
- Memos of Understanding and other country agreements
- Other methods

Initiating a Medical Device Recall?

Who can initiate a Medical Device Recall?

- A manufacturer, distributor, or other company in the supply chain
- FDA, in limited circumstances

Most medical device recalls are voluntary and company initiated.

FDA considerations when a Firm is Reluctant to Conduct a Recall?

- Evaluates firm's Health Risk Assessment
- If discrepancies between FDA and firm remain unresolved:
  - Public Notification – Public outreach
  - FDA Requested Recall
  - FDA Ordered/Mandatory Recall [518(e) under the Act/21 CFR 810 Regulation]
  - Seize product
  - Injunction – Recall clause in consent agreement
  - Import Alert
  - Foreign Country Notification

Reporting, Strategy and Communication

Regulatory Requirements for Recalls

21 CFR Part 7

- Product identity
- Reason and date discovered
- Risk evaluation
- Quantity manufactured
- Quantity distributed
- Distribution information
- Recall letter or script
- Recall strategy
- Firm official's contact information

21 CFR Part 806

- Correction &Removal number
- Recalling firm's contact information
- Brand name, intended use
- 510(k), PMA, exempt
- Model number, Lot number
- Manufacturer contact info
- Reason and actions taken
- Injuries, MDR numbers
- Quantity
- Mfr dates, expected life
- Consignee information
- Recall letter or script
- Reason(s) for data missing
- Root Cause

Correction or Removal Reporting 21 806.10(c)

- Firms regularly identify the need for a recall by demonstrating evidence of corrective action, design changes, product replacement and other corrections going back months or even years before providing DRC Correction or Removal Reports within “10-day report timeframe.”

Effective Recall Strategy (1of 2)

- An effective recall strategy takes into account:
  - The results of the risk assessment
  - Ease of identifying the affected product(s)
  - Degree to which the product's deficiency is obvious to the consumer or user
  - Amount of product remains unused in the marketplace
  - Continued availability of essential products

Effective Recall Strategy (2 of 2)

- The recall strategy also includes the following elements:
  - Depth: lowest level in the distribution chain
  - Public Warning (if necessary): to alert the public that the product being recalled presents a serious hazard to health.
  - Effectiveness Checks: verifies all consignees, at the recall depth specified, have received notification and have taken appropriate action

Considerations During Recalling a Medical Device (1 of 3)

- Device Shortage and Recalls
  - Marketplace shortages may require recall strategy modification based on the risk
  - Will the of benefit continued use outweigh risk of removal?
  - Verification
    - 1 - Change Recall Depth or Delay
    - 2 - Detailed Instructions and monitoring
  - On-going re-evaluation by FDA
  - Final assessment from FDA

Considerations During the Recall Process (2 of 3)

Consider: Does your firm have an effective recall process in place?

Questions:

- Does your firm have an effective recall or crisis management team?
- Do you have the proper support to conduct an effective recall (crisis management operation)?
- Does your firm have the ability to recognize a crisis and to know when to be in crisis mode?

Considerations During the Recall Process (3 of 3)

Additional Questions:

- Does your firm have sufficient policies, procedures, personnel and skill to bring the risk down to an acceptable level?
  - Has the firm opened a CAPA and developed a corrective action plan?
  - Does the plan properly identify the problem and cause(s) of the problem?
  - Can your firm properly identify the products affected?
  - Can the firm properly handle results?

Firm's Responsibilities

- Assesses problem and develops recall strategy
  - Contacts customers that may have received the device under recall
  - If necessary, may issue press release
  - Supplies information to help users minimize health consequences
  - Works with FDA to identify the scope of problem and the recall strategy
  - Sends recall status reports to FDA
  - Takes action to prevent the problem from recurring

Be Prepared ***Before*** Communicating with FDA

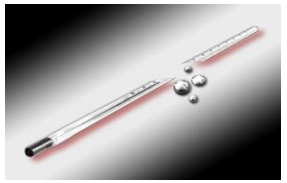
- Discuss the status of your investigation
- Discuss your intended actions
- Email or fax the DRC a draft of recall communications for discussion within 24 hours of your initial contact
- ***Negotiate*** the type and content of your recall communication with FDA prior to issuance
- Provide product labeling
- Submit recall strategy/plan for action as soon as possible
- Discuss findings of investigation and how you have determined the final nature and scope of the problem
- Submit customer list

A Firm's Recall Communication (Notification Letter)

- **Should supply information to help users identify the product and take steps to minimize health consequences**
  - Identify product subject to recall
  - Explain reason for the recall and hazard involved
  - Further distribution or use should cease immediately
  - Direct accounts should notify its customers who received the product, where appropriate
  - Instructions should be included regarding what to do with the product
- Verbal communication or other personal contacts should be confirmed by written communication and or documented in an appropriate manner.

Recalling Firm's Process During a Recall

Assesses Problem
&
Develops Recall Strategy



1. **CAPA**
2. **Determine Root Cause**

Supply Recall Notification Letter to Users (Consignees)

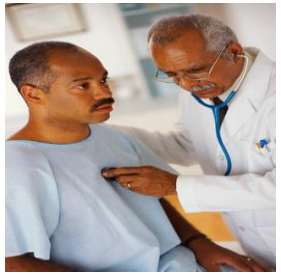
Developed In order to

Ensure Public Safety

Recalling Firm

Sends
Recall Status Report to: (Initial Contact with District Office. Submits 806 Report)

FDA



But…What may FDA be doing?

(A Look Behind the Scenes)

- May be developing contingency plans to respond to the recall
- Notifying other governments (international harmonizations) and governmental agencies
  - U.S. Military
  - CDC
  - State & Local Agencies
- Responding to press, consumer, professionals & trade inquires
- Deciding or preparing to initiate inspect the firm during the recall
- Inspecting other firms who manufacture the same type of product and collect samples
- Conducting research (scientific literature review, expert consultation or laboratory research)

Recall Classification Determination

Recall Classification

- The numeric designation assigned by the FDA to indicate the relative degree of risk to public health and;

•Attributed to the product being recalled

•Designated as:

- Class I

- Class II

- Class III

Recall Classification – Class I

- **Class I Recall -** A 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
  (21 CDR 7.3(m)(1))
  - The recalling firm notifies its customers and directs them to notify the intended recipients of the device.
  - The notification usually contains the name of the device being recalled; identifying lot or serial numbers; the reason for the recall; explains concisely the risk involved; and gives instructions describing how to correct, avoid, or minimize the problem. It should also provide a contact information for questions
  - The recalling firm issues a press release to notify the public, if appropriate to minimize health consequences.

Class I Recall Example

A situation in which a catheter may kink or rupture during use, leaving remnants in the patient with reasonable probability of serious patient injuries or death.

Example - Class I Recall

- **Implantable Cardioverter Defibrillators (ICDs)**
  - **Problem:** During an attempted shock delivery, arcing diverts the shock current away from the heart and into the backfill tube or into the can.
  - **Root Cause:** Deterioration in a wire insulator within the lead connector block, in conjunction with other factors, resulted in an electrical short. The short caused diversion of shock therapy energy away from the heart and into device circuitry.
  - **Risk to Health:** Permanent loss of shock therapy and pacing.
  - **Number of Devices:** 26,000

Recall Classification - Class II

- **Class II Recall -** A 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.** **(21 CFR 7.3(m)(2))**
- The recalling firm notifies its customers & sometimes asks them to notify the intended recipients of the device.
  - A press release would be issued ***if*** there is a specific need
    - e.g., If the device could affect the health of a large number of people, if patients need more information, or if the recalling firm could not reach every intended recipient

Class II Recall Example

- A package defect in which sterility has been compromised and could lead to contamination of the medical device with remote risk of serious patient complications.

- Potential for **remote risk of** failure of a capacitor during use which would prevent the AED from delivering effective defibrillation therapy when indicated.

Recall Classification – Class III

- **Class III Recall -** A situation in which use of, or exposure to, a violative product **is not likely to cause adverse health consequences.** **(21CFR 7.3(m)(3))**

  – The recalling firm notifies its customers

  – Press release is not usually expected

Class III Recall Example

- A labeling defect where the expiration date does not appear on the product label.
- A mislabeled package that contains one size of a particular medical device but is labeled as another size and patient injury is unlikely.
- The product is mislabeled, in that, zero/low controls were mislabeled as medium/high, and the medium/high controls were labeled zero/low.

Classification Determination

- A firm will provide FDA with their classification for the recall

BUT

- Final classification for all recalls are determined by FDA and posted on FDA's Weekly Enforcement Report.

Health Hazard Evaluation

Defining the Risk

- Technical assessment of the defect defines likelihood of device failure
- Clinical understanding of product defect and real life situations clarifies risk
- Lack of reported injuries does not mean lower risk or recall classification

Containing & Controlling Risk

- Does your firm have in place a process for containing and controlling risk to health?
- Questions:
  - Is your firm capable of conducting a risk assessment [meaningful health hazard assessment]?
  - Is you firm capable of identifying population(s) at risk/or higher risk?
  - Is your firm capable of identifying the **Worst Case Scenario**?
  - Can your firm develop adequate risk control measures with respect to:
    - Marketed products?
    - At risk populations who have or are using product?

Firm's Risk Control Communication Plan

- Questions:
- Does your firm have policies and procedures in place to
  - Develop adequate press releases and/or media responses?
  - Respond to health professionals?
  - Provide patient/user/customer support?

Firm's Adequate Risk Control Measures

- Questions:
  - How is stock being held that has not yet been distributed?
  - What measures are in place for "returned" recalled stock?
  - What about future production?
  - Who is responsible for adequately coordinating firm's activities?
  - Is that same person responsible for supervising the firm's risk control activities until an acceptable level of risk is obtained?

Follow-up Responsibilities

Monitoring Recalls

- Firm reports to the District Recall Coordinator (DRC) on effectiveness and disposition
- DRC conducts audits of consignees
- Class 1 recalls have mandatory status reports to DRC
  - Firm reports every 2 weeks
  - Mandatory inspection
- CDRH/Office of Compliance can request updates on Class 2 device notification and disposition.

Recall Status Reports

- FDA requests that recalling firms submit recall status reports to their FDA District Office.
  - Agency may assess the progress of the recall
- Frequency of these reports will be determined by the relative urgency of the recall as decided by FDA.
  - **Generally between 2 and 4 weeks**
- FDA terminates recalls

Quality System Requirements

- Firms are responsible for following the Quality System Requirements found in 21 CFR Part 820.100 through 21 CFR 820.250
  - Establishing and maintaining procedures for implementing corrective and preventative action
- This will aid in ensuring that the necessary corrective fixes are made on all units
- Additional information is available at:

  www.fda.gov/Training/CDRHLearm/ucm162015.htm

Enhancement vs. Product Recall (Silent Recall)

Product Enhancement Considerations

- Medical Devices are developed and used in an environment of constant change. These changes are part of continuous ongoing efforts by manufacturers to design and develop a device that meets the needs for the user and/or patients.

Product Enhancement Considerations

- Manufacturers bringing an improved product to market must give strong consideration to the reason for the improvement.
  - Consider if the improvement could result in a potential health hazard from any of the following:
    - Inspecting the device for any problems
    - Repair of the device
    - Adjustment to the setting
    - Re-labeling
    - Destruction
    - Notification to patient of problem
    - Monitoring patients for health issues

Product Enhancement Consideration

The manufacturer ***must*** consider whether the older product is subject to a recall, either for correction or removal from the market.

If older product meets all specification, is not defective, and presents no unusual or unexpected hazard, there may not be a legal justification for a manufacturer to remove of the product.

Product Enhancement
Proposed Definition

- Submission of a 510(k), software change or 30-day notice to enhance or improve medical device product there functioning in a manner in which they are suppose to function to make the operation better and do not pose any known risk to health are considered an enhancement and no recall is indicated.

But, if…

Silent Recall

Submission of a 30-day notice, new 510(k) or change to software design in which you have a known or reportable MDR issue, pose a risk to health, or have a pending recall at CDRH it is considered a **Silent Recall.**

FDA Recall Enforcement Tools

FDA Enforcement

FDA is looking to industry to accomplish rapid voluntary action for removal of unsafe products or FDA will use enforcement tools.

Reviewing data for repeat trends, such as “Out of Spec” issues, changes in supplier, changes in subcontractor.

Inspections of Class I recalls

- 21 CFR 7 requires an inspection of firms during a Class I recall.
- 21 CFR 7 requires recalling firm to submit status reports to the DCR on effectiveness of a Class I recall every two weeks during the audit process.
- FDA is considering, after a Class I decision is rendered, if a comprehensive follow-up inspection of the firm is warranted.

Park Doctrine (Misdemeanor Prosecution)

- FDA has developed criteria, included in the Regulatory Procedures Manual, to revitalize the "Park Doctrine."
  - Based on a 1975 U.S. Supreme Court Case that does the following:
    - Provides that a responsible corporate official can be held liable for a first time misdemeanor and possible subsequent felony under the FD&C Act.
    - There does not have to be proof that the corporate official had any actual knowledge of, or participation in, the specific offense.
    - The FD&C Act makes it a criminal misdemeanor to violate the FD&C Act even if a person is not aware of the situation.

Enforcement of 21 CFR 806

- FDA is considering:
  - Initiating the use of 21 CFR 806 to enforce firms reporting complete and timely recall documents.
  - If firm has failed to comply with regulation, and does not provide the information required by 21 CFR 806.10(c) the Agency is considering issuing a Warning Letter or Untitled Letter, depending on the circumstances.

Summary

- Once the elements of a recall are understood, FDA collaborates with the company and its consignees to determine that an effective recall is conducted.
- Different departments within FDA stay informed of current recall activities through various communication avenues; this will support an efficient and effective public notification process
- Effective recall management supports improvement of public health and potential harm to patients

References & Websites

- *Federal Register* June 16, 1978, Part 7
- FDA Regulatory Procedures Manual, Chapter 7 - Guidance for Firms (Voluntary)
- 21 CFR Part 7, 21 CFR Parts 806, 810, 820 (Requirements)
  - www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm (CDRH site)
  - www.fda.gov/opacom/Enforce.html (ORA site)
- FDA Weekly *Enforcement Report*
  - www.fda.gov/bbs/topics/ENFORCE/ENF00416.html
- Additional data:
  - www.fda.gov/downloads/ICECI/EnforcementActions/UCM247845.pdf