



Managing Medical Device Recalls

– Including Conduct of Health Hazard Evaluations

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Today's Discussion

- Brief overview: What is a recall?
- Recall classification
- Part 806: When to report?
- Risk to health: Conduct of a Health Hazard Evaluation
- Common challenges, conundrums, and considerations
- Roundtable and Q/A


Thought Process

- Is there a systemic issue?
 - Does the product in distribution fail to meet company specifications in compliance with FDA Quality System regulation?
 - Is product associated with a risk to health?
- Is a field action needed? If so, what type of field action?
- Is the field action reportable?



Watch out: Growing Concern Over Recalls

- There is a growing concern within CDRH and ORA regarding the increasing number of device recalls
- FDA is trying to establish the root cause of this increase.
 - Are they design issues?
 - Manufacturing issues?
 - Advertising/promotion issues?
 - Supplier Issues?
 - Complaints?
- Are these recalls an indicator of an underlying issue regarding the design of your devices?
 - Be sure to read your signal systems - complaints, MDRs, CA/PAs, NCs
 - Compare the information with your risk files to see if an adjustment may be needed
 - Some firms use heat maps to track complaints; others have established thresholds
 - Conduct Health Risk assessments to assess patient risk
- A total of 3,348 medical device recalls classified by FDA during FY 2020.
 - Of these 348 were classified as Class I, 2, 924 as Class II, and 76 as Class III



Be aware that this may be a focus of future FDA concerns at your site



Recall Regulatory Framework

- 21 C.F.R. Part 7 Subpart C is **guidance**, not law. Recalls conducted pursuant to Part 7 are “voluntary.”
 - Defines key terms and provides guidance on recall conduct
- 21 C.F.R. Part 806—Reports of Corrections and Removals
 - Has the **force of law**
 - Sets out circumstances under which “voluntary” recalls must be reported to FDA

What is a Recall?



Key Definitions



“Recall”

- “Recall means a firm’s **removal** or **correction** of a marketed product that FDA considers to be in **violation** of the laws it administers and against which the agency would initiate legal action, e.g., seizure.”
- “Recall” does not include a “market withdrawal” or “stock recovery.” 21 C.F.R. 7.3(g)



“Correction”

- The repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location. 21 C.F.R. 7.3(h)



“Removal”

- The physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction or inspection. 21 C.F.R. 7.3(i)

What is Not a Recall?

■ “Market Withdrawal”

- A firm’s removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by FDA or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc. 21 C.F.R. 7.3(j)

■ “Stock Recovery”

- A firm’s removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on the premises owned by, or under the control of, the firm, and no portion of the lot has been released for sale or use. 21 C.F.R. 7.3(k)

“Class I Recall”

- A situation in which there is a reasonable probability that use of, or exposure to, a violative product will cause serious adverse health consequences or death. 21 C.F.R. 7.3(m)(1) (emphasis added)
 - “Reasonable probability” means “that it is more likely than not that an event will occur.”
21 C.F.R. 810.2(h)
 - However, FDA does not rely on this definition – i.e., a likelihood of greater than 50% – in its conduct of HHE and recall classifications.



“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 C.F.R. 7.3(m)(2)



“Class III Recall”

- A situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences. 21 C.F.R. 7.3(m)(2)



Part 806 Reporting Requirements

- Required for any **correction** or **removal** of a medical device if the correction or removal was initiated
 - To reduce a risk to health posed by the device or
 - To remedy a violation of the FDCA caused by the device which may present a risk to health

- Report must be submitted with 10 working days of initiating the correction or removal. 21 C.F.R. Part 806



“Risk to Health” and Part 806

- Part 806 definition of “**risk to health**” tracks the **definitions for Class I and Class II recalls**.
 - “A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death”; or
 - “That use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote.”

21 C.F.R. 806.2(j)



Is a Change to a Device a Recall or a “Product Enhancement”?

- Is the change being made to a “violative” device?
 - Fails to meet specifications
 - Fails to perform as intended – such devices are “of a quality below what they purport or are represented to possess”
 - Changes being made to false or misleading labeling
- FDA guidance advises that a design change to improve the safety and effectiveness of a device is not reportable under Part 806 if the design change is not done to remedy a violative device



Health Hazard Evaluations

- The **FDA's HHE** determines
 - The recall classification
 - How FDA communicates information about the recall to the public, including issuance of a press release
- A **manufacturer's HHE** guides decision-making and the conduct of a voluntary recall
 - Should a voluntary recall (i.e., a correction or removal) be conducted?
 - If so, is it reportable to FDA under Part 806?
 - Input to CAPA (Should design, including user interface, or manufacturing be modified for future products?)

Conduct of an HHE by Manufacturer

Consider aligning your approach with CDRH HHE process

I. Product Data

Name, Model, Lot/Serial Numbers, PMA or 510(k) Number, Total Number in Distribution, Number Subject to Review or Recall, Manufacturer, Product Description (including Intended Use from Labeling)

II. Problem Definition and Analysis, including

Reason for Recall or Conduct of Risk Assessment
CAPA Investigation (if available)

III. Health Risks

“TO BE COMPLETED BY MEDICAL OFFICER OR COMMITTEE”

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm217880.htm>



Please save as a different filename before filling out this form.
HHE Version 3.1 01/17/2007

Health Hazard Evaluation
or Health Risk Assessment
Center for Devices and Radiological Health

Date: _____ RES #: _____ Safety Officer: _____

I. Product Data

Panel Code: _____ Device Name: _____
Product Code: _____
Model: _____ Lot/Serial Numbers: _____
Marketing Status (Include 510(K) Or PMA Number, Specify If Class I Exempt From 510(K): _____

Total Number Of Devices In Distribution:
U.S.: _____ Foreign: _____
Number Of Devices Subject To Recall or Review:
U.S.: _____ Foreign: _____

Manufacturer / Recalling Firm, Address: _____

Product Description (Include Intended Use From Labeling): _____

ORACLE # _____
Class: _____ Recall # (s): _____

II. Problem Definition and Analysis

CDRH HHE Guidance Version 3-1

Reason for the Recall or Health Risk

- **Description** of the “Defect, Malfunction, or Error in Use”
- **Root Cause** (if known)
- **Factors That May Contribute to Risk** (“i.e., device design, manufacturing, or user error”)
- **Design Factors That Might Mitigate Risk**
- **If Device Failure Occurs, Is it Easily Recognized by User** (e.g., health care provider, caretaker, or patient)



Include user error in the analysis

II. Problem Definition and Analysis

CDRH HHE Guidance Version 3-1

Data Input from CAPA Investigation

- **Estimate of number of devices that will develop the defect and/or fail, with date of analysis**
 - Number of devices from Affected Lots that are expected to have or develop the defect
 - For implants or reusable devices, number of devices likely to exhibit the failure over lifetime of the device
 - Of those devices that fail, how many are likely to cause injury if used [i.e., upon patient exposure to the defective device]

What about devices provided as a set? For example, a cartridge of surgical staples?

Use terms public will understand, such as actual numbers or “one out of 100” rather than patient-years

III. Health Risks:

TO BE COMPLETED BY MEDICAL OFFICER OR COMMITTEE

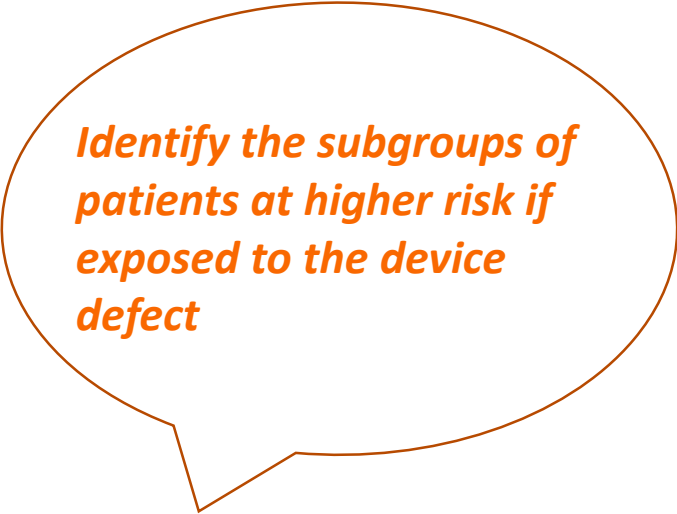
CDRH HHE Guidance Version 3-1

Immediate and Long Range Health Consequences

- Health consequences that may result from use of or exposure to the defective device
 - “Include known off label uses”
- Any clinical factors that may mitigate risk
- Segment of the population that is “Most at Risk”
 - “e.g., infants, elderly, pregnant women, critically ill patients, immunocompromised”
- Any significant public health impact beyond users



Consider off-label uses



Identify the subgroups of patients at higher risk if exposed to the device defect

FDA HHE Assessment of Health Risks

Relies on FDA definition of “serious injury” – 21 C.F.R. 803.3

“An injury or illness that:

- Is **life-threatening**,
- Results in **permanent impairment** of a body function or permanent damage to a body structure, or
- **Necessitates medical or surgical intervention** to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent means irreversible damage to a body structure or function, excluding trivial impairment or damage.”



Definition for identification of complaints that must be reported as serious injuries in MDRs

III. Health Risks:

TO BE COMPLETED BY MEDICAL OFFICER OR COMMITTEE

Estimate the seriousness of the potential harms

CDRH HHE Guidance Version 3-1

Assess the hazards associated with the use of the defective product

Check All that Might Occur:

Population at Greatest Risk

Overall Population Using Device

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Life-threatening (death has or could occur)

Results in permanent impairment of body function or permanent damage to a body structure.

Necessitates medical or surgical intervention.

Temporary or reversible (without medical intervention).

Limited (transient, minor impairment or complaints).

No adverse health consequences.

Hazard cannot be assessed with the data currently available.

Separately consider the highest health risk scenarios and patients, not just "average patients"

III. Health Risks:

TO BE COMPLETED BY MEDICAL OFFICER OR COMMITTEE

Estimate the probability of the potential harms

CDRH HHE Guidance Version 3-1

Assess the Probability that Use of, or Exposure to, Product under Recall will Cause Adverse Health Consequences

For HHE, FDA has not defined "reasonable probability" or "remote probability"

Serious Adverse Health Consequences

(Death, Life Threatening, Results in Permanent Impairment)

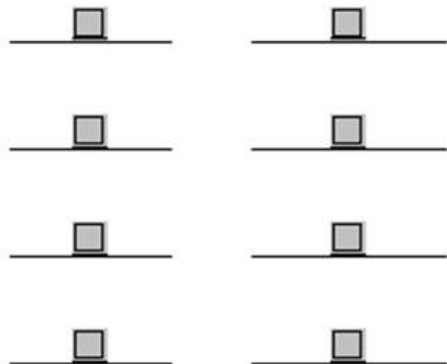
Overall Population Using Device Population at Greatest Risk

Every Time

Reasonable Probability that Use will Cause

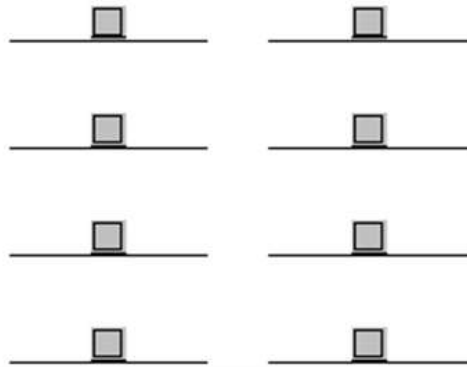
Remote Probability that Use will Cause

Not Likely that Use will Cause Any Adverse Events



Medically Reversible or Transient Adverse Health Consequences

Overall Population Using Device Population at Greatest Risk



Challenges: Sources of Information

- **Complaint file (U.S. and global) – not just MDRs**
- Repair and service history
- Publications, case reports, presentations at medical meetings
- Training/proctoring
- Internal signals: Manufacturing, vendor, supplier
- Issues that may have escaped the Quality System
- Health risk of recalls of similar products by competitors
- What else?



Conundrums: Incomplete Information

- Incomplete or unverified information
- No or few returns of product that is defective
- Uncertain extent of hazard/root cause not fully identified
- Under-reporting of injuries and near misses
- COVID-19 disruption

When FDA conducts an HHE with limited information...

“When forming conclusions, clinicians assume a reasonable worst case scenario.”

Jacqueline Ryan, MD. Medical Officer. Office of Compliance. CDRH. May 10, 2016

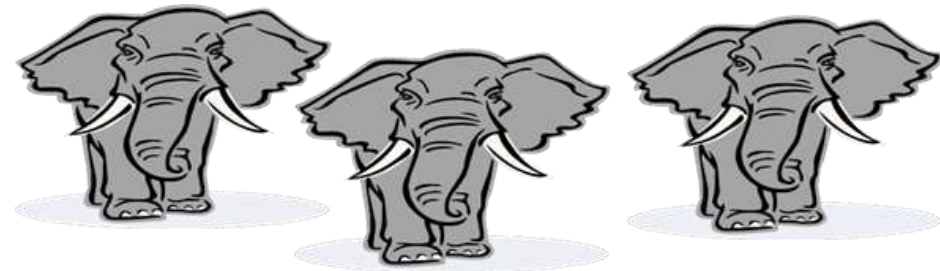


Challenges: Conducting the HHE

- What triggers an HHE at the company? How is the HHE escalated?
- Who conducts and is responsible for the HHE?
 - Who provides clinical input? Who must be at the table?
 - Who might provide data but not determine the risk to health or likelihood?
 - Who has the final say and sign off on the HHE?
- Common sticky assumptions
 - Defect is “easily recognizable” by healthcare provider
 - “Work-arounds” will consistently prevent patient harm
 - Problem is misuse or inexperience (“Experts have no problems”)

Elephants in the Room

- FDA weighs **seriousness** of injury more heavily than estimates of the likelihood of harm
- **What numbers count?**
 - In reports to the public, FDA nearly always reports numbers of injuries, not estimates of probability
 - Occurrence of actual injuries to a few is weighted heavily





Challenges: Conduct of the Recall

- What about benefit–risk?
- Product scarcity if device is recalled (removed)?
- Should HHE be provided when company notifies FDA of the recall?
- When does the clock start for Part 806 report?
- When is a press release needed?
- When is an “update bulletin” to users an under-the-table recall?
- What is difference between a “Safety Alert” and a recall (correction)?

Panel Discussion and Q&A



"We've considered every potential risk except the risks of avoiding all risks."