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**Medical Device Recalls:  
Unique Challenges and Opportunities**

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# Today's Discussion

- When should a recall be conducted?
- What is (and isn't) a recall?
- When must a recall be reported?
- What distinguishes a product enhancement from a recall?
- How can common recall pitfalls be avoided?
- What systemic actions can be taken to ensure recalls are conducted properly?

# When Should a Recall Be Conducted?

# Legal Analysis

- A device is adulterated and/or misbranded if it fails to comply with its specifications, even if the noncompliance is minor. See, e.g., 21 U.S.C. § 351(h).
- Marketing an adulterated or misbranded device is a prohibited act. 21 U.S.C. § 331(a).

# Factors to Consider in Recall Decision

- Potential health risk to the patient/user is by far the most important consideration in determining whether to conduct a recall.
- Thus, a comprehensive health hazard evaluation (HHE) typically should be the first step taken when a systemic problem is identified.
  - It makes sense to follow the HHE process that FDA uses. *See* <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm126206.htm>

# Other Factors to Consider in the Recall Decision

- Whether the problem causes the product to fail to meet its fundamental functional requirements or reasonable user expectations.
- Whether the problem relates to a significant characteristic of the device that was described in the 510(k) or PMA.
- Whether failure to recall will impact customer relationships.

# What Is (and Isn't) a Recall?

# “Recall”

- 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” and “Removal”

- **“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); 21 C.F.R. § 806.2(d))
- **“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. § 806.2(i))

# Exclusions from the Definition of “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); 21 C.F.R. § 806.2(h))
- **“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 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); 21 C.F.R. § 806.2(l))

# Three Recall Classes

- **“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))
- **“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)(3))

# When Must a Recall Be Reported?

# Regulatory and Policy Framework Governing Recalls

- 21 C.F.R. Part 7 Subpart C – Recalls.
- 21 C.F.R. Part 806–Reports of Corrections and Removals.
- FDA Guidance Documents:
  - “Methods for Conducting Recall Effectiveness Checks” (June 16, 1978).
  - “Guidance for Industry: Product Recalls, Including Removals and Corrections” (November 3, 2003).
  - “Draft Guidance. Distinguishing Medical Device Recalls from Product Enhancements and Associated Reporting Requirements” (February 22, 2013).

## 21 C.F.R. Part 7 – Recalls

- Part 7 is guidance, not law. Recalls conducted pursuant to Part 7 are “voluntary.”
- In Part 7, FDA requests that firms notify the Agency immediately when they decide to conduct a recall.
- Part 7 defines key recall-related terms and provides guidance on how to conduct a recall.

# 21 C.F.R. Part 806 – Reports of Corrections and Removals

- Part 806 has the force of law.
- Part 806 sets out the circumstances under which “voluntary” recalls must be reported to FDA.

# Purpose

- The requirement to report certain corrections and removals was added to the FDC Act in 1990 because Congress was concerned that firms were conducting voluntary recalls without notifying FDA, and that mandatory reporting of certain recalls was necessary to enable FDA to take prompt action against dangerous devices.



# Under Part 806, Reportability Turns on “Risk to Health”

- A report under Part 806 is 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 FDC Act caused by the device which may present a **risk to health**.
- Report must be submitted within 10 working days of initiating the correction or removal. (21 C.F.R. § 806.10(b))

# “Risk to Health”

- Definition in Part 806 tracks the definitions of Class I and Class II recalls in Part 7. Thus, “Risk to Health” means:
  - A reasonable probability that use of, or exposure to, a violative product will cause serious adverse health consequences or death; or
  - That use of, or exposure to, a violative 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))
- Part 806 does not require reporting recalls categorized as Class III under Part 7.

# Where to Look in Order to Answer the “Risk to Health” Question

- Health Hazard Evaluation
- MDR reporting history
- FDA’s assessment of health risk of similar recalls by competitors

# Actions Exempt from Reporting Under Part 806

- Actions taken by device manufacturers or importers to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the FDC Act caused by the device;
- Market withdrawals;
- Routine servicing; and
- Stock recoveries. (21 C.F.R. § 806.1(b))

# Records Must Be Kept for Corrections and Removals That are Not Reportable

- Record must include all communications regarding the correction/removal, and:
  - Brand, common or usual name, classification, product code if known, intended use;
  - Identification number (e.g., model, catalogue, or code number);
  - Description of events giving rise to correction/ removal; and
  - **Justification for not reporting to FDA.** (21 C.F.R. § 806.20)

# Consequences of Noncompliance

- FDA enforcement action.
- Increased product liability risk.
- Noncompliances can taint FDA's perception of a manufacturer, creating a climate of distrust.

# Consequences of Noncompliance

- Failure to comply with Reports of Corrections and Removals requirements “misbrands” the devices in question. (21 U.S.C. § 353(t)(2))
- Introducing an “adulterated” or “misbranded” device into interstate commerce is a “prohibited act.” (21 U.S.C. § 331(a))
- In addition, failure to comply with Reports of Corrections and Removals requirements is an independent “prohibited act” under the FDC Act. (21 U.S.C. §§ 331(q))

# What Distinguishes a Product Enhancement From a Recall?



# FDA's New Draft Guidance

- On February 22, 2013, FDA issued a draft guidance entitled “Distinguishing Medical Device Recalls from Product Enhancements and Associated Reporting Requirements.”
  - The draft guidance is “intended to clarify when a change to a device constitutes a medical device recall, to distinguish those instances from product enhancements that do not meet the definition of a medical device recall, and to identify the associated regulatory reporting requirements for each.”
  - The draft guidance “seeks to address concerns that firms may have about making product enhancements.”

# Product Enhancement Defined

- The draft guidance defines “product enhancement”:
  - “Product enhancements include, but are not limited to, changes designed to better meet the needs of the user, changes to make the product easier to manufacture, and changes to the appearance of the device that do not affect its use. A product enhancement is both (1) a change to improve the performance or quality of a device, and (2) not a change to remedy a violation of the [FDC Act] caused by the device. A product enhancement is not a medical device recall.”
- And distinguishes a product enhancement from a recall:
  - “FDA generally considers devices that fail to meet specifications and devices that fail to perform as intended to be of a quality below what they purport or are represented to possess, which would render them adulterated . . . . Changes to or removals of these devices to correct these violations would generally constitute recalls.”
  - “A change made to improve a level of safety performance that was known, predicted, and stable at the time the device was cleared or approved does not typically mean that the underlying product was violative. A change to improve the performance or quality of a legally marketed, non-violative device is a product enhancement and not a medical device recall.”

# Reportable Product Enhancements?

- The draft guidance states that product enhancements intended to reduce a risk to health must be reported under Part 806:
  - “[A]s long as your change is initiated to reduce a risk to health posed by your device, even if your change is not a recall, you must submit an 806 report . . .”
  - “An 806 report submitted for product enhancements should be identified as such by the manufacturer. **If FDA concurs with your assessment that the correction or removal is a product enhancement, the agency will not treat the report as a recall but will determine the appropriate premarket and postmarket actions necessary to address the information contained in the 806 report.**”
- FDA’s final guidance is expected to provide clarity on the reportability of product enhancements.

# How Can Common Recall Pitfalls Be Avoided?

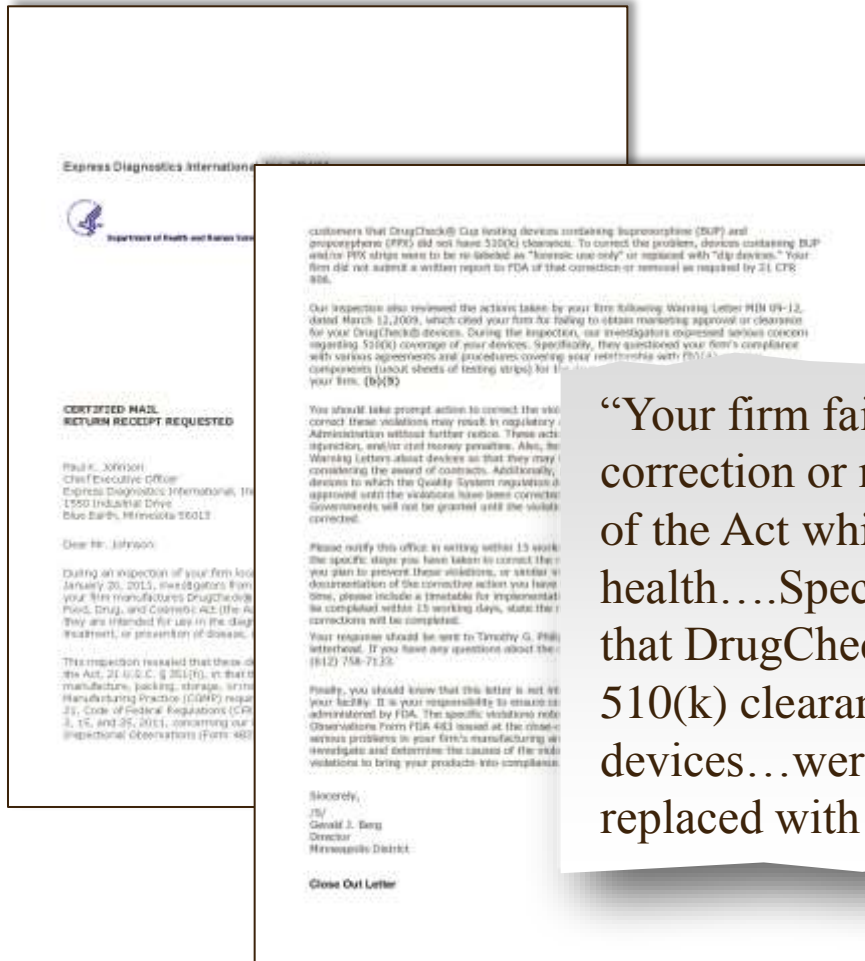
# Do Not Delay

- FDA has cited firms in Warning Letters for allowing too much time to elapse between identifying a systemic issue and initiating a recall.
  - It is important to have in place written procedures addressing the Health Hazard Evaluation process; Part 806 reporting and record-keeping obligations; and the conduct of recalls.

# Understand FDA's Interpretation of Key Definitions

- For example:
  - **“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 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); 21 C.F.R. § 806.2(1))
  - **“Risk to Health”**-
    - A reasonable probability that use of, or exposure to, a violative product will cause serious adverse health consequences or death; or
    - That use of, or exposure to, a violative 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))

# FDA Interprets “Risk to Health” Very Conservatively



“Your firm failed to submit a written report to FDA of a correction or removal...initiated to remedy a violation of the Act which might present a risk to health....Specifically,...your firm notified customers that DrugCheck Cup testing devices...did not have 510(k) clearance. To correct the problem, devices...were to be re-labeled as ‘forensic use only’ or replaced with ‘dip devices.’”

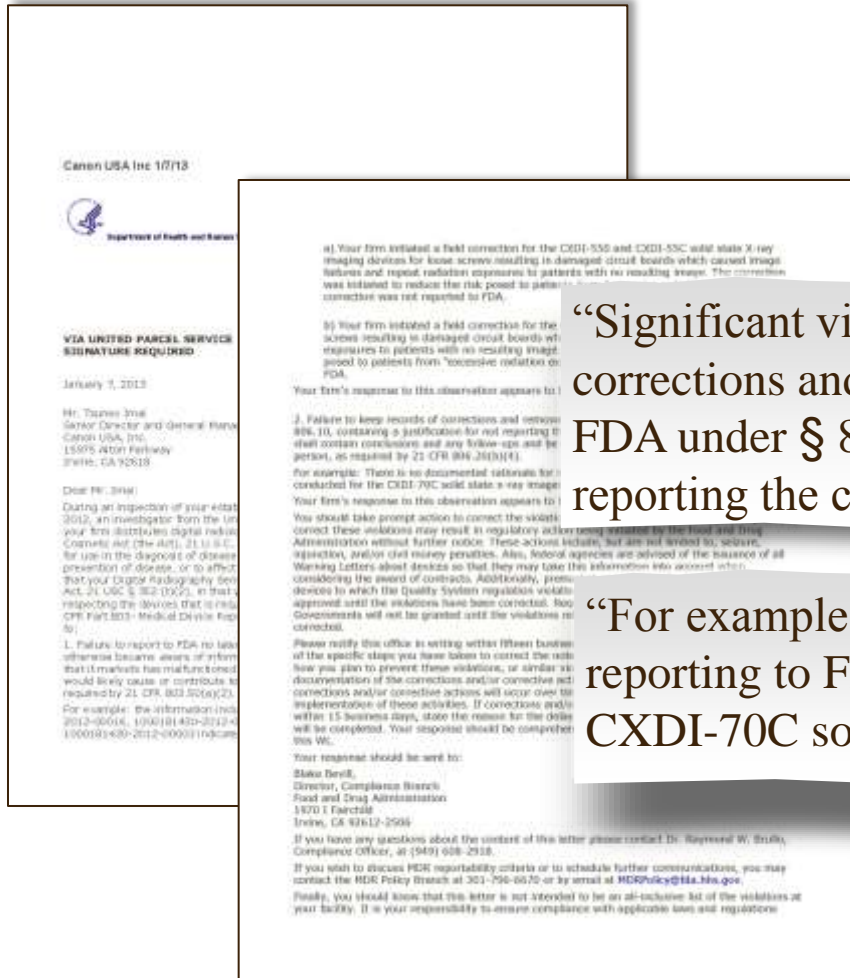
Warning Letter to Express Diagnostics International, Inc., March 24, 2011

# Thoroughly Document Non-Reportability Rationales

- FDA frequently challenges firms on their decisions not to report recalls under Part 806
  - Thus, for unreported recalls, it is critical to have in place a comprehensive rationale demonstrating why the recall was not initiated to reduce a risk to health.
  - The rationale should be consistent with other records (e.g., MDR, complaint).



# Warning Letter Example



“Significant violations include... Failure to keep records of corrections and removals not required to be reported to FDA under § 806.10, containing a justification for not reporting the correction or removal action to FDA...”

“For example: There is no documented rationale for not reporting to FDA the correction and removal conducted for CXDI-70C solid state x-ray imager device.”

Warning Letter to Cannon USA Inc., January 7, 2013

# Avoid “Back Door” Recalls



# The Problem

- Firms sometimes undertake actions in the field without realizing these actions are “corrections” or “removals” that must be analyzed for reportability under Part 806.
  - FDA may view such actions as “back-door” recalls.

# Back-Door Recalls

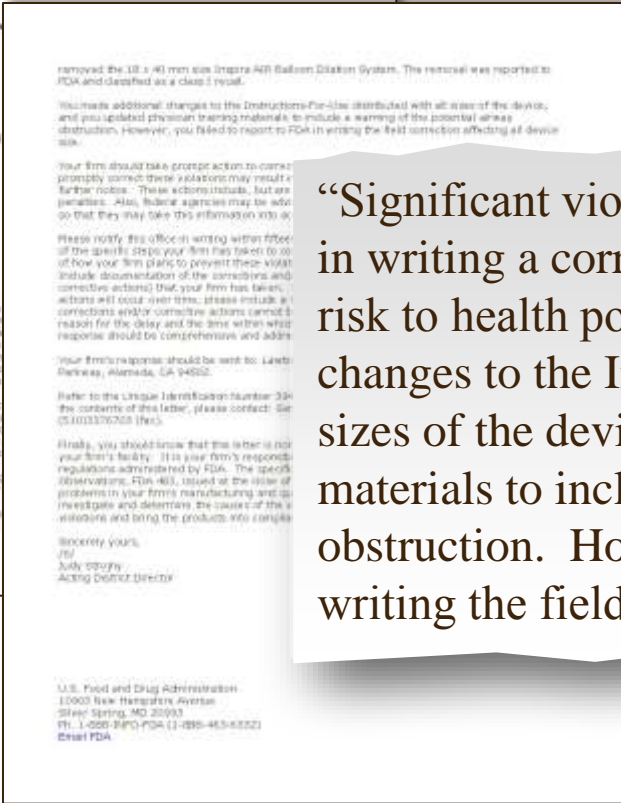
“Corrections and removals continue to be an issue, these under-the-table recalls, the silent recalls, these activities that are occurring . . . Notices go out telling doctors or patients to do this, or do that, that constitute a correction, or other activities that constitute corrections. I continue to be dismayed in regard to the number and scope of these things that are popping up. More instruction, more education, more outreach certainly is needed there.”

- Timothy Ulatowski, Former Director, Office of Compliance, CDRH (speaking at the February 2008 Food and Drug Law Institute Annual Conference on Enforcement & Litigation)

# Common Fact Patterns

- Combining a product “upgrade” with a correction/removal.
- Distributing a “market bulletin” or “technical advisory”
  - Informing customers of recent device problems and advising them of techniques that should be used to help prevent those problems.
- Deploying sales representatives to inspect devices in the field to determine whether a known systemic problem is present.
- Exchanging defective devices for those customers who complain, without systematically removing the potentially defective devices from the field.

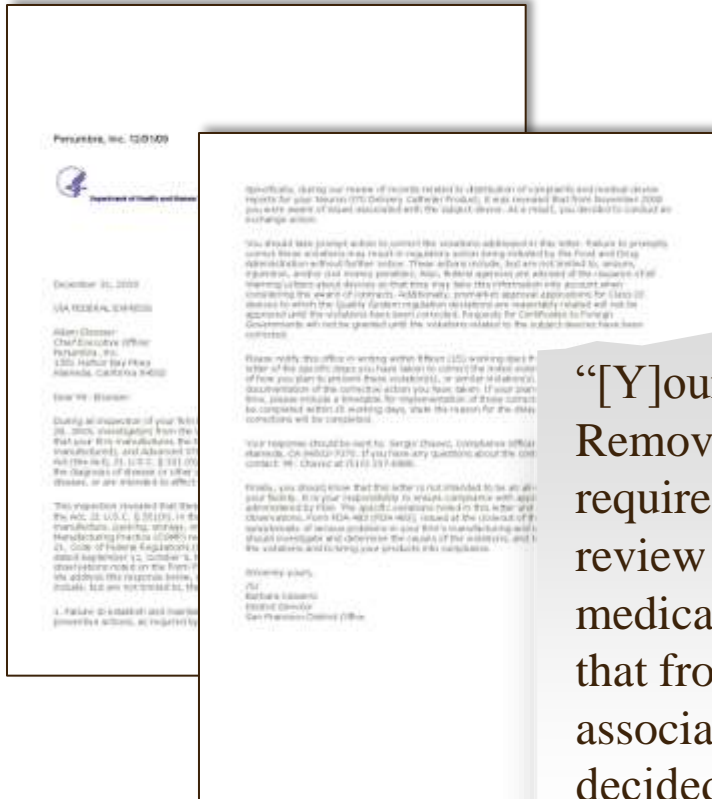
# Warning Letter Examples



“Significant violations include... Failure to report to FDA in writing a correction or removal, conducted to reduce a risk to health posed by a device... You made additional changes to the Instructions-For-Use distributed with all sizes of the device, and you updated physician training materials to include a warning of the potential airway obstruction. However, you failed to report to FDA in writing the field correction affecting all device size (sic).”

Warning Letter to Acclarent, March 20, 2013

# Warning Letter Examples (cont'd)




“[Y]our firm failed to submit its Report of Correction and Removal within the required ten day time frame as required by 21 CFR 806.10(b). Specifically, during our review of records of complaints and distribution of complaints and medical device reports for your [device], it was revealed that from November 2008 you were aware of issues associated with the subject device. As a result, you decided to conduct an exchange action.”

Warning Letter to Penumbra, December 31, 2009



# Warning Letter Examples (cont'd)

- Example: Failure to submit report of Correction and Removal
  - “Safety reminder” to health care practitioners
  - Upgrade of software
  - Disposable kit work-around



“For example, the report of your corrective actions (CAPAR 50001564 Action Update) dated December 28, 2010, indicates that your firm received 45 reports of alleged air injections during procedures in which the Avanta system was in use, between January 1, 2007, and July 24, 2009. As a result of these alleged air injections, Medrad instituted the following corrective actions:

- a) Issued an ‘Important Product Safety Reminder: User diligence in reducing air embolism risks with the Avanta Quick Set Up Guide for MPAT and SPAT purging;’
- b) Released an advanced single patient disposable set with a new pressure isolation valve making the priming process simpler to perform; and
- c) Upgraded the software and set up procedure in the graphical user display to allow one step priming of both SPDS lines.

There is no evidence that Medrad submitted a report of Correction and Removal in response to the corrections.”

Warning Letter to Medrad Inc., May 17, 2011



# What Systemic Actions Can Be Taken to Ensure Recalls Are Conducted Properly?

# Recommendations

- Develop Part 806, Health Hazard Evaluation, and recall procedures that incorporate FDA law, regulations, and guidance.
- Comprehensively train regulatory and quality personnel on Part 806, with particular focus on the expansive definitions of “correction” and “removal.”
- Train sales, marketing, and customer service personnel on core Part 806 concepts.
- For software driven devices, focus attention on the potential Part 806 implications of software “upgrades.”
- Do a reality check and get guidance in gray areas.

Thank You!

Questions and Answers