



Health Hazard Evaluation and Recall

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What is a “recall”?

- A removal or correction of a violative product
 - Correction: on-site repair, modification, adjustment, relabeling, inspection, or destruction of a product
 - Excluding market withdrawal (removal or correction of a product with minor or no violation), stock recovery (product that has not been released for use), and routine servicing
- Violative product, if:
 - Not safe and effective for the intended use – i.e., adulterated (FDCA § 501) or misbranded (§ 502)
 - Presenting a risk of health hazard to users

Types of recall

- Firm-initiated (voluntary) recall (21 CFR 7.46)
 - Most effective and efficient way to recall a product
- FDA-requested recall (21 CFR 7.45)
 - Refusal by firm to conduct a recall
 - Product posing risk of health or gross deception
- FDA Medical Device Recall Authority (21 CFR 810)
 - Reasonable probability of serious health risk or death
 - Stepwise: (1) cease distribution and notification order; (2) regulatory hearing; (3) mandate/ vacate recall order

Why recall a product?

- Alternative to recall: FDA-initiated court action (e.g., seizure, injunction)
 - If firm refusing to conduct FDA-requested/ordered recall
 - If ineffective recall, or continuing violation
- A need for recall may arise even for the best product
 - Most IVD recalls: product failures/malfunctions due to improper or inadequate design, control, manufacturing, labeling, or user error
 - Often prompted by user complaints, internal findings, FDA inspections, MedWatch and international vigilance reports

Recall process

- What generally happens in a medical device recall:
 - Fact gathering
 - Root cause determination
 - Assessing potential health hazard
 - Formulating an effective recall strategy
 - FDA notification
 - Reports of Corrections and Removals (21 CFR 806)
 - Recall classification – (FDA)
 - Monitoring recall progress
 - Terminating a recall – (FDA)

Health hazard evaluation (HHE)

- Firm should conduct an HHE for the product being recalled or considered for recall
 - To accurately assess health and safety implications
 - To articulate a coherent and effective recall strategy
- FDA also conducts an HHE on the violative product
 - To classify the recall by relative degree of health hazard
 - To evaluate adequacy of firm's recall strategy
 - To guide FDA recall enforcement actions (e.g., public warning, levels of effectiveness checks/audit checks)

Elements of an HHE

- Disease or injuries already occurred due to the violative product
- Existing conditions exposing people to health hazard
- Populations exposed to the violative product, including those at greatest risk
- Degree of seriousness of health hazard
- Likelihood of occurrence of health hazard
- Consequences (immediate/long-range) of health hazard

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/default.htm>

FDA's HHE

- Risk assessment
 - As if violative product is still in the market
 - As if corrective action has not been taken by firm (or FDA)
 - As if users may not be able to detect product failure or malfunction, unless clearly obvious
 - Ineffective controls, user ignoring error messages
 - “Worst case” scenario if information is incomplete
- Risk not necessarily lower even if:
 - Lack of reported injuries or deaths
 - Cause of failure attributed to “user error”

FDA's HHE

- Mitigating factors allowed
 - e.g., back-up system or other appropriate tests available, test used for long-term risk/prognostic assessment
- May be updated as situation unfolds
- May use a precedent recall with similar product problem and risk profile
- Convene *ad hoc* HHE committee
 - Potentially a Class I recall or high visibility case
 - Additional technical/medical expertise needed
 - When in doubt...

FDA's HHE

- Adverse health consequences and injuries may include
 - Errors in patient management
 - Lengthening or delay in medical intervention
 - Significant psychological/emotional distress
- Likelihood assessment
 - Often difficult to estimate frequency of failure and injury
 - Past experiences with similar recalls
 - Additional investigations/studies by the firm
 - No quantitative definition for “reasonable” or “remote” probability

Recall classification (assigned by FDA)

- Class I: *reasonable probability* that use of, or exposure to the violative product will cause serious adverse health consequences or death
- Class II: use of, or exposure to the violative product may cause *temporary* or *medically reversible* adverse health consequences, or *remote probability* of serious adverse health consequences
- Class III: use of, or exposure to the violative product is *unlikely* to cause adverse health consequences

Recall strategy

- Depth of recall
 - Degree of health risk, extent of product distribution, amount unused, ease of identification
- Public warning (notification)
 - e.g., news media, trade press, "*Dear Doctor*" letter
- Effectiveness checks to verify notification and action
 - Level A: 100%; B: 11-99%; C: 10 %; D: 2%; E: none
- Audit checks (FDA) to monitor recall effectiveness
- Shortage may modify recall strategy (risk-benefit)

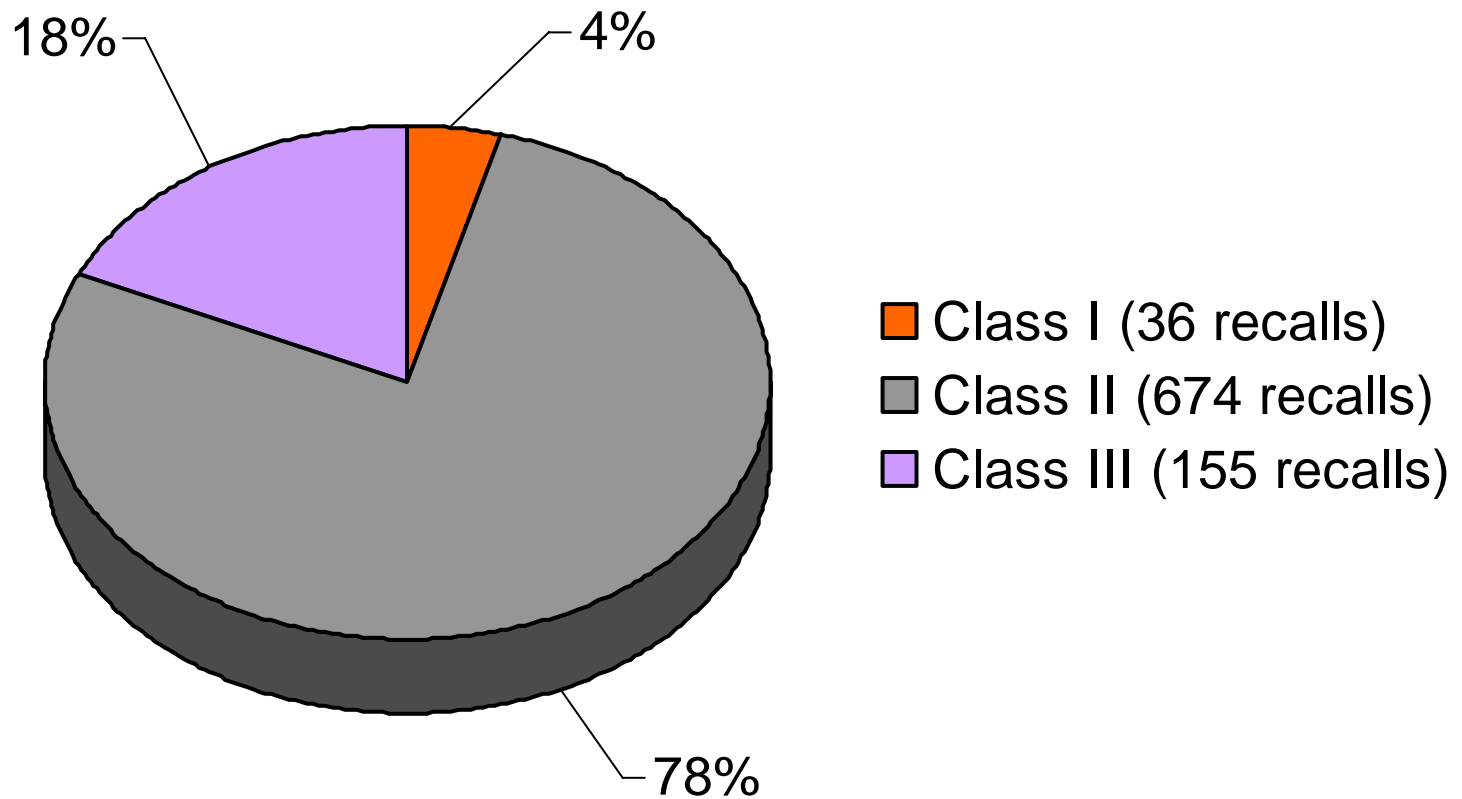
To facilitate a recall

- Maintain updated contingency recall plan
 - Customer contact information
 - Complete product distribution records (kept longer than expected product life) to help locate the product
 - Product information, production logs, lot release data, etc.
 - Methods for returning/disposing of violative product
- Use sufficient product code for positive identification
- Follow Quality System Requirements (21 CFR 820)
 - To implement corrective and preventive actions

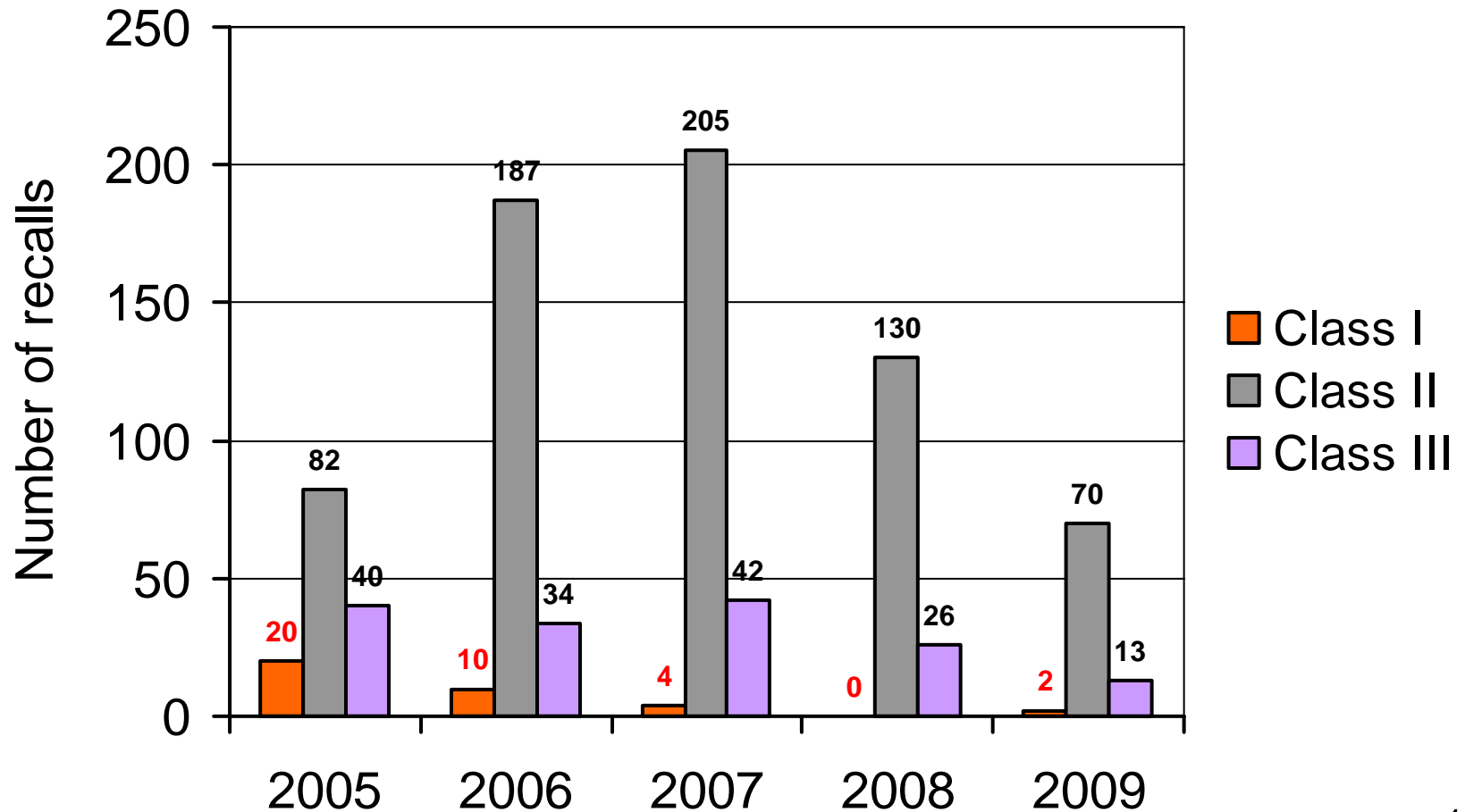
Termination of recall

- FDA will terminate a recall when
 - All reasonable efforts have been made to remove or correct the product
 - Reasonable to assume that the violative product has been removed, and proper disposition/correction has been made
- Firm may request FDA to terminate its recall
 - Submit request in writing showing recall is effective
 - Provide most current recall status report

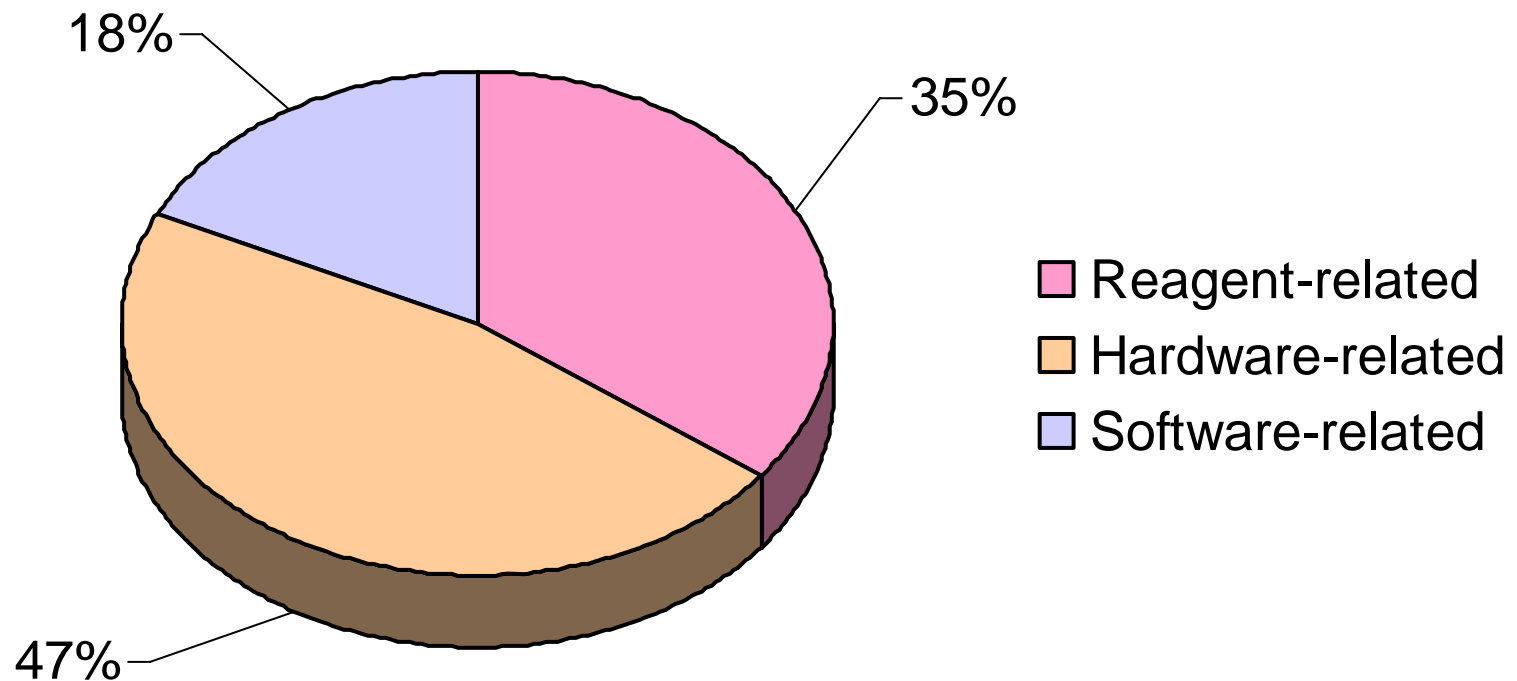
IVD recalls by class (2005-2009)



IVD recalls by year (2005-2009)



Reasons for IVD recalls (2009)



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