Health Hazard Evaluation and Recall

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Tan Nguyen MD, PhD, RAC
FDA/CDRH/OIVD/DCTD-DIHD

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 – e.g., adulterated (FDCA § 501) or misbranded (§ 502)
  - Presenting a risk of health hazard to users

21 CFR 7.3

Types of recall

- A need for recall may arise even for the best product
  - Product failures/malfunctions due to inadequate design, control, manufacturing, labeling, or user error
  - Often prompted by user complaints, internal finding, MedWatch/international vigilance reports, FDA inspection
- 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

Types of recall

- 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 or vacate the recall order
- 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

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, level of effectiveness checks, audit check)

21 CFR 7.41

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
- Immediate/long-range consequences of health hazard

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

21 CFR 7.41

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

21 CFR 7.3(m)

FDA's approaches to HHE

- Assessing adverse health consequences of a recall
  - As if violative product still in the market
  - As if corrective action not yet taken by firm (or FDA)
  - As if users not able to detect product failure or malfunction
  - Assuming worst case scenario if incomplete information
- Risk of violative product not necessarily lower even if:
  - Lack of reported injuries or deaths
  - Cause of failure attributed to "user error"
- Mitigating factors allowed

FDA's approaches to HHE

- Adverse health consequence may include
  - Errors in patient management
  - Lengthening or delay in medical intervention
  - Significant psychological/emotional distress
- Severity of adverse health consequences
  - Magnitude of error in test result
  - Patient population(s) most at risk
  - Risk from incorrect or delayed test result on diagnosis or treatment (e.g., inconsequential harm → death)

FDA's approaches to HHE

- Assessing likelihood of adverse health consequence
  - Often difficult to estimate frequency of failure and injury
  - No quantitative definition for "unlikely," "reasonable," or "remote" probability
  - Whether the test result being a sole basis for, or a major, or a minor contributor to medical decision
  - Likelihood of harm to patient from the resulting decision
- Probability of harm = [Severity, Likelihood]

FDA's approaches to HHE

- FDA may use HHE from a precedent recall with similar product problem and risk profile
- FDA may classify a recall by "policy"
  - e.g., unless otherwise indicated, removal of a hitherto uncleared product is a Class II recall
- FDA may convene an *ad hoc* HHE Committee, if:
  - Potentially a Class I recall, or high visibility case
  - Additional technical/medical expertise needed

Recall strategy

- Depth of recall
  - Degree of health risk, extent of product distribution, amount unused, ease of identification
- Targeted public warning/notification when necessary
  - 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 by FDA to monitor recall effectiveness
- Shortage may modify recall strategy (risk-benefit)

21 CFR 7.42

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

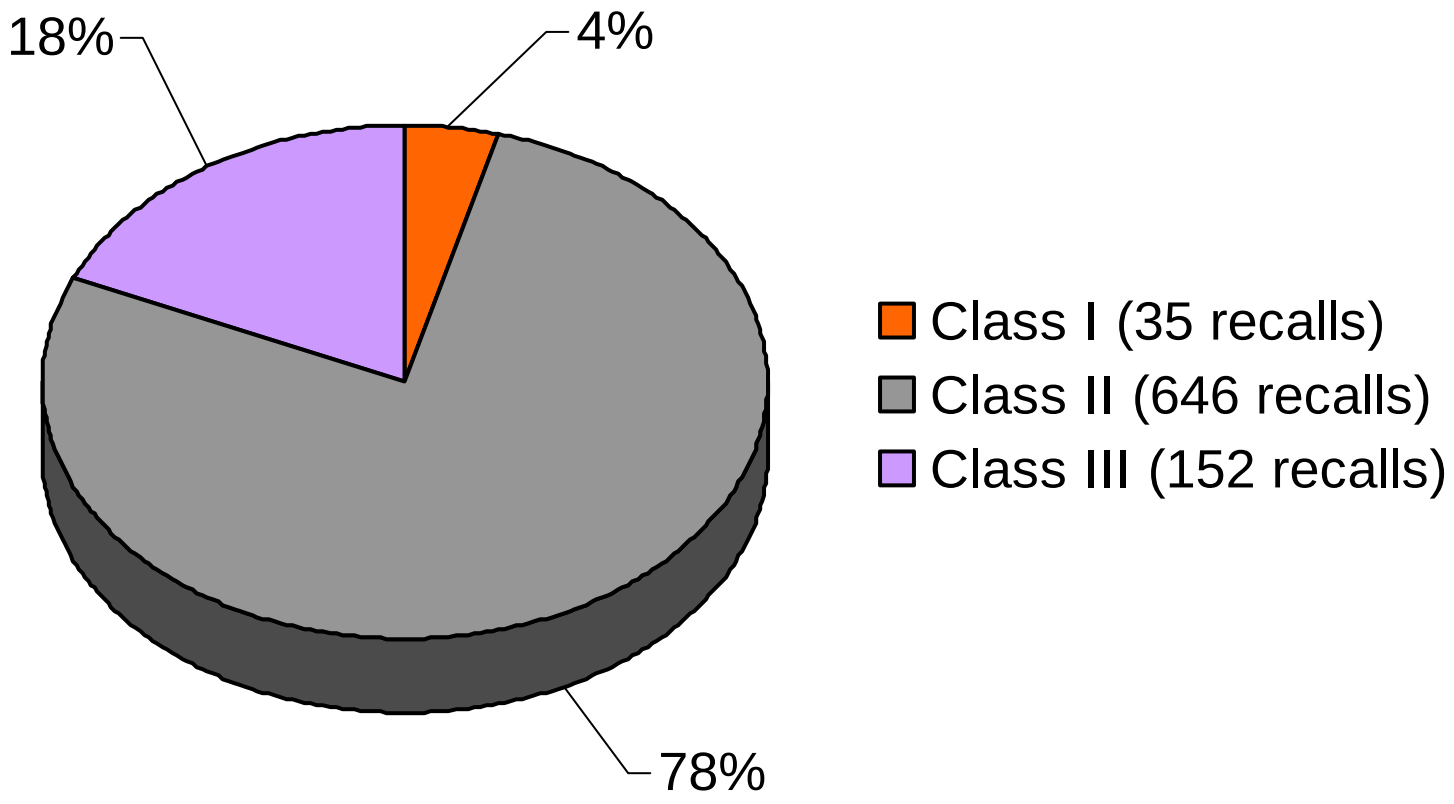
21 CFR 7.59

Termination of recall

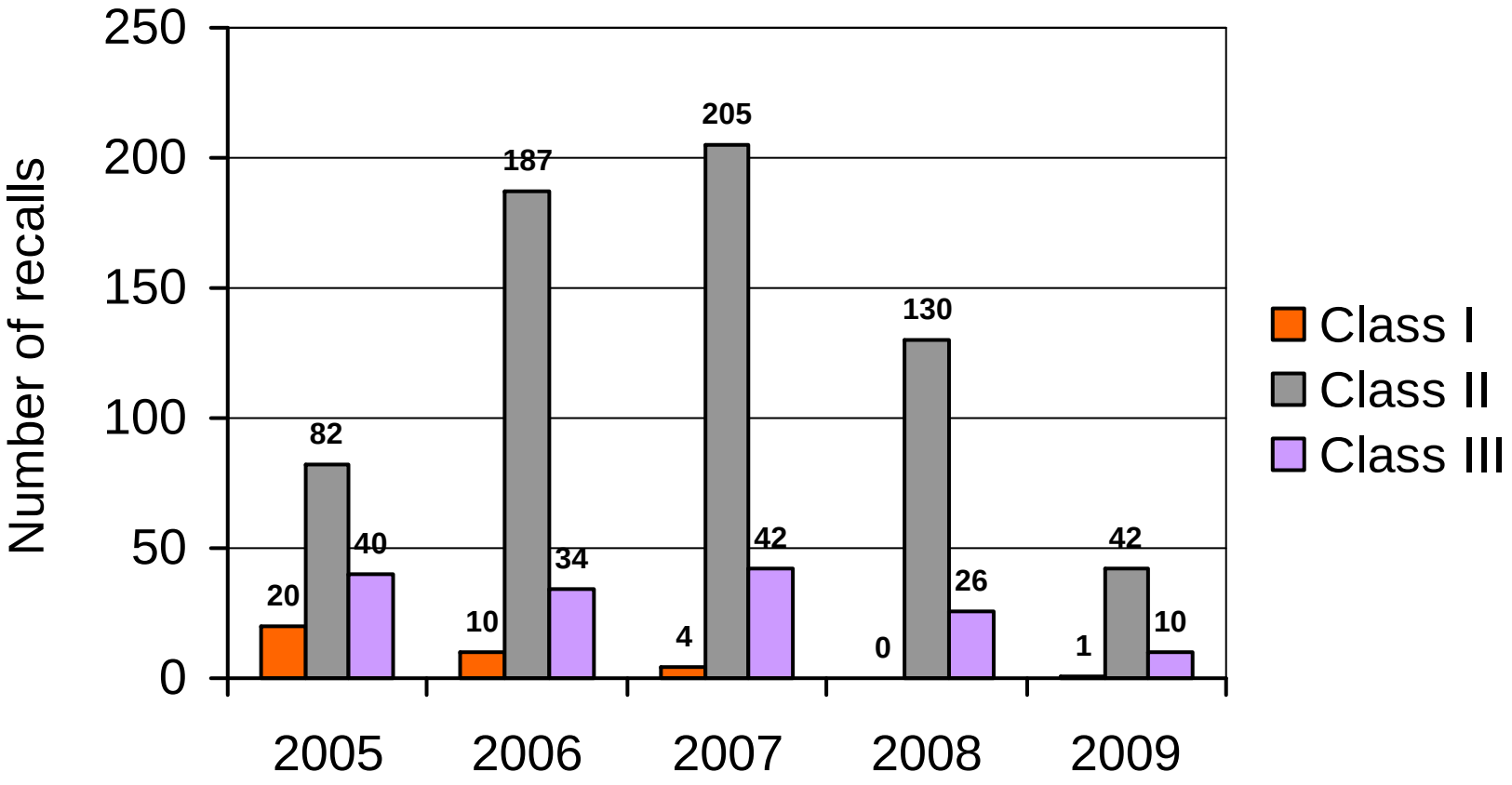
- FDA will terminate a recall when
  - All reasonable efforts have been made to remove or correct the product
  - Reasonable to assume that the violative product has been removed, and proper disposition/correction has been made
- Firm may request FDA to terminate its recall
  - Submit request in writing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

21 CFR 7.55

IVD recalls by class (2005-2009)



IVD recalls by year (2005-2009)



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Thank You!