

Drug and Device Product Recalls

By Megan Lauff

WHAT IS A RECALL?

DEFINITION - RECALL

- A firm's removal or correction of a **marketed** product that FDA considers to be in violation of the law it administers and against which the Agency would initiate legal action (i.e. seizure).
- 21 CFR Part 7.3(g)

DEFINITION - PRODUCT CORRECTION

- The repair, modification, adjustment, relabeling, destruction or inspection (including patient monitoring) of a product and/or promotional literature which causes the product to be violative, **without** its physical removal to some other location.
- 21 CFR 7.3(h)

RECALLS

- May be conducted voluntarily & at any time
- In response to a formal request by FDA
- As a means of protecting the public health
- Retrieving or correcting products that present a risk of injury or gross deception or are otherwise defective
- 21CFR 7.40

TYPES OF RECALLS

FIRM INITIATED RECALL

- Voluntary action initiated by a firm when it learns through its own sources that a product is defective, presents health hazard, and/or violates the FD&C Act.
- Most common type of recall
- 21 CFR 7.46

FDA REQUESTED RECALL

- Occur when there is a serious health hazard and the firm has decided not to recall a product after being advised of the hazard.
- 21 CFR 7.45

WHO CONDUCTS THE RECALL?

DEFINITION - RECALLING FIRM

- The firm who initiates a recall, or in the case of an FDA-requested recall, the firm that has primary responsibility for the manufacturing and marketing of the product to be recalled.
- 21 CFR 7.3(i)

WORKING TOGETHER

- The recall of an FDA regulated product is the responsibility of both FDA and the firm responsible for the manufacturing that product. Thus it is essential to define not only FDA's role in product recalls, but industry's as well, because ultimately the recall procedures that a firm follows actually determines its success or failure.

CORRECTION AND REMOVAL REPORTS

- Manufacturers and Importers are required to promptly report actions concerning device corrections and removals
- Maintain records of **all** device corrections and removals
- 21 CFR 806

CONTACTING THE FDA

- As soon as possible - once a firm has made the decision to recall a product especially when the situation poses a serious risk to the public
- Under 806, a firm has 10 working days to submit the Corrections and Removals Report to FDA
- Firms have 3 working days to submit FARs

DEFINITION - RECALL STRATEGY

- A planned specific course of action to be taken in conducting a specific recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall.
- 21 CFR 7.3(1)

RECALL STRATEGY

- The planned course of action to be carried out by the firm in the achievement of its recall goals.
- The FDA will review and/or recommend changes to the firm's recall strategy, as appropriate.
- 21 CFR 7.42

RECALL STRATEGY FACTORS

- Results of firm's health hazard evaluation
- Ease in identifying the product
- Degree to which the product's deficiency is obvious to the consumer or user
- Degree to which the product remains unused in the marketplace
- Continued availability of essential products

DEPTH OF RECALL

- Level in the distribution chain to which the recall is to be extended
- Depends on the product's degree of hazard and extent of distribution
- Wholesale, Retail, Consumer Levels
- 21 CFR 7.42(b)(1)

RECALL COMMUNICATIONS

- Convey the name of the recalled product
- Further distribution or use of any remaining product should cease immediately
- When appropriate, the direct account should conduct a sub-recall
- Instructions regarding what to do with the product
- 21 CFR 7.49(a)

RECALL COMMUNICATIONS

- Should be brief and to the point
- Clearly identify the product
- Concisely explain the reason for the recall and the hazard involved
- Provide specific instructions on what should be done with respect to the recalled product(s)

RECALL COMMUNICATIONS

- Should not be diluted or camouflaged by irrelevant qualifications, promotional materials, or any other statement or information that may detract from the message
- Provide a means for the recipient to report back to the recalling firm
- 21 CFR 7.49(c)(1) and (2)

PUBLIC WARNINGS

- Purpose is to alert the public that the recalled product presents a serious hazard to health.
- Reserved for urgent situations where other means for preventing use appear inadequate.

PUBLIC WARNINGS

- Issued through the general news media and/or the specialized news media or to specific segments of the population
- Should be reviewed by FDA prior to being issued
- 21 CFR 7.42(b)(2)

HEALTH HAZARD EVALUATION

- Evaluation by FDA scientists of the threat to health presented by a product, including its labeling and/or promotional literature, that is being recalled or considered for recall.
- 21 CFR 7.41

HEALTH HAZARD FACTORS

- Any disease or injury has occurred
- Any contributing factors
- Assessment of hazard to various segments of the population (infants, elderly, etc)
- Assessment of the degree of seriousness
- Assessment of the likelihood of occurrence
- Assessment of the consequences of occurrence

FDA CENTERS

- Review recall package to determine Class
 - Conduct Health Hazard Evaluation
 - Review any HHE the firm submits
 - Review draft press releases
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- District is the liaison between firm and Center

DEFINITION - RECALL CLASSIFICATIONS

- The numerical designation (I, II, or III) assigned by the FDA to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.
- 21 CFR 7.3(m)

DEFINITION - RECALL CLASSIFICATIONS

- CLASS I
- 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.
- Highest Level
- Usually require a press release
- 21 CFR 7.3(m)(1)

DEFINITION - RECALL CLASSIFICATIONS

- CLASS II
- A situation in which the 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)

DEFINITION - RECALL CLASSIFICATIONS

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

EFFECTIVENESS CHECKS

- Conducted by the recalling firm
- Verify that all consignees have received the notification/communication about the recall and have taken the appropriate action
- If not conducted, the firm is not meeting its obligation/responsibility to the consumer
- 21 CFR 7.42(b)(3)
- Methods for Conducting Effectiveness Checks

RECALL STATUS REPORTS

- Recalling firm is requested to submit periodic recall status reports so that an assessment can be made regarding the progress of the recall.
- Frequency will be determined by the relative urgency of the recall.
- Normally - monthly
- 21 CFR 7.53

RECALL STATUS REPORTS

- Should contain the following information:
 - number of consignees notified, date, and method
 - number of responders and quantity on hand
 - number of non-responders
 - amount of product returned or corrected and quantity accounted for
 - number and results of effectiveness checks
 - estimated time frame for completion

THOUGHTS

- A firm can first make an initial decision whether an action is a recall; however, FDA makes the final decision as to whether the firm's actions constitutes an FDA recall.
- FDA has the responsibility for deciding when a firm's action is or is not a recall.
- A voluntary recall does not preclude FDA from invoking any of its regulatory powers

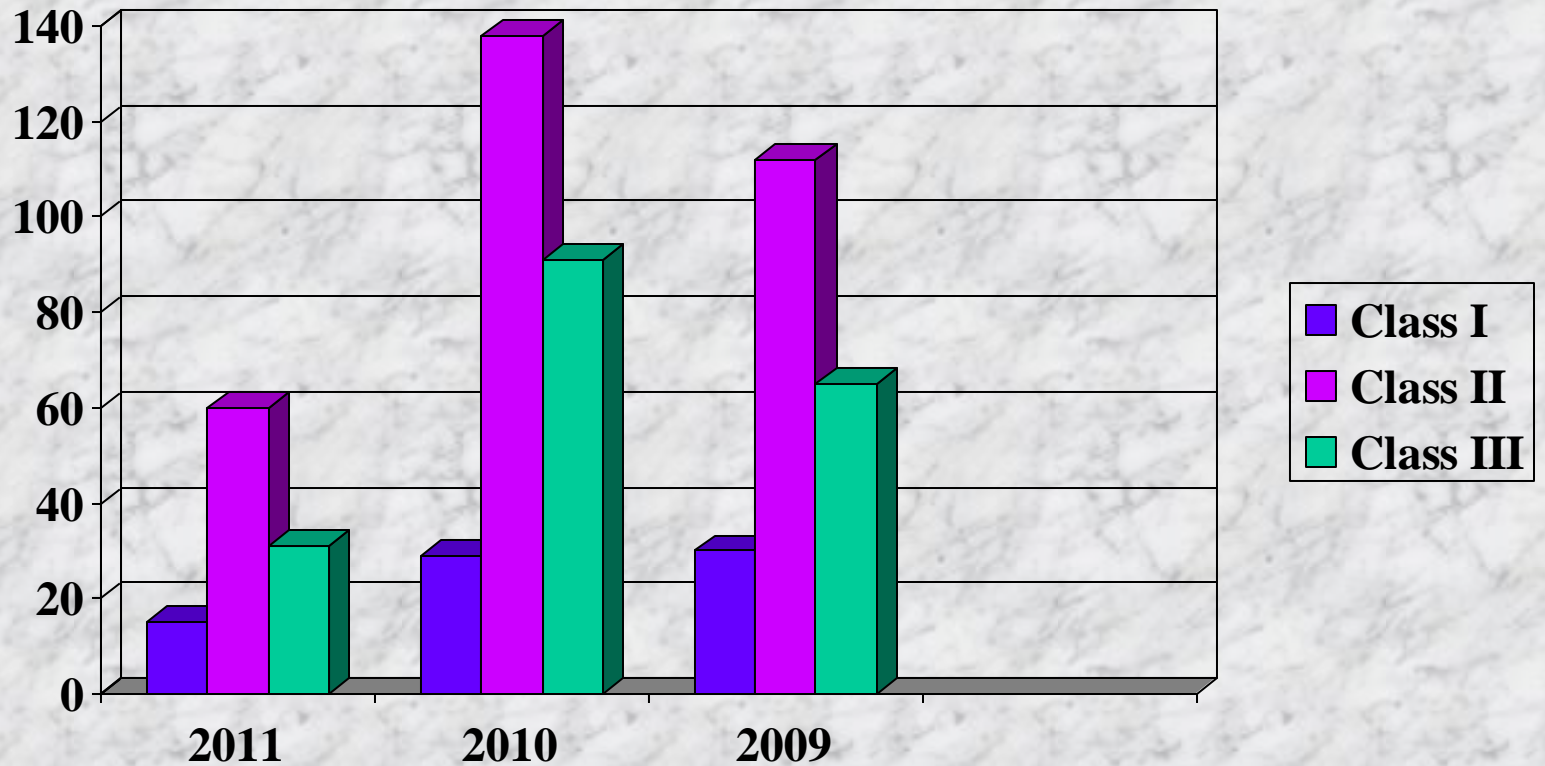
THOUGHTS

- When a firm decides to initiate a product removal or correction, it should proceed with the action and not wait for FDA to determine whether that action is a recall.
- Don't think that the "voluntary" nature means it is unimportant for FDA to be aware of and monitor for appropriateness.

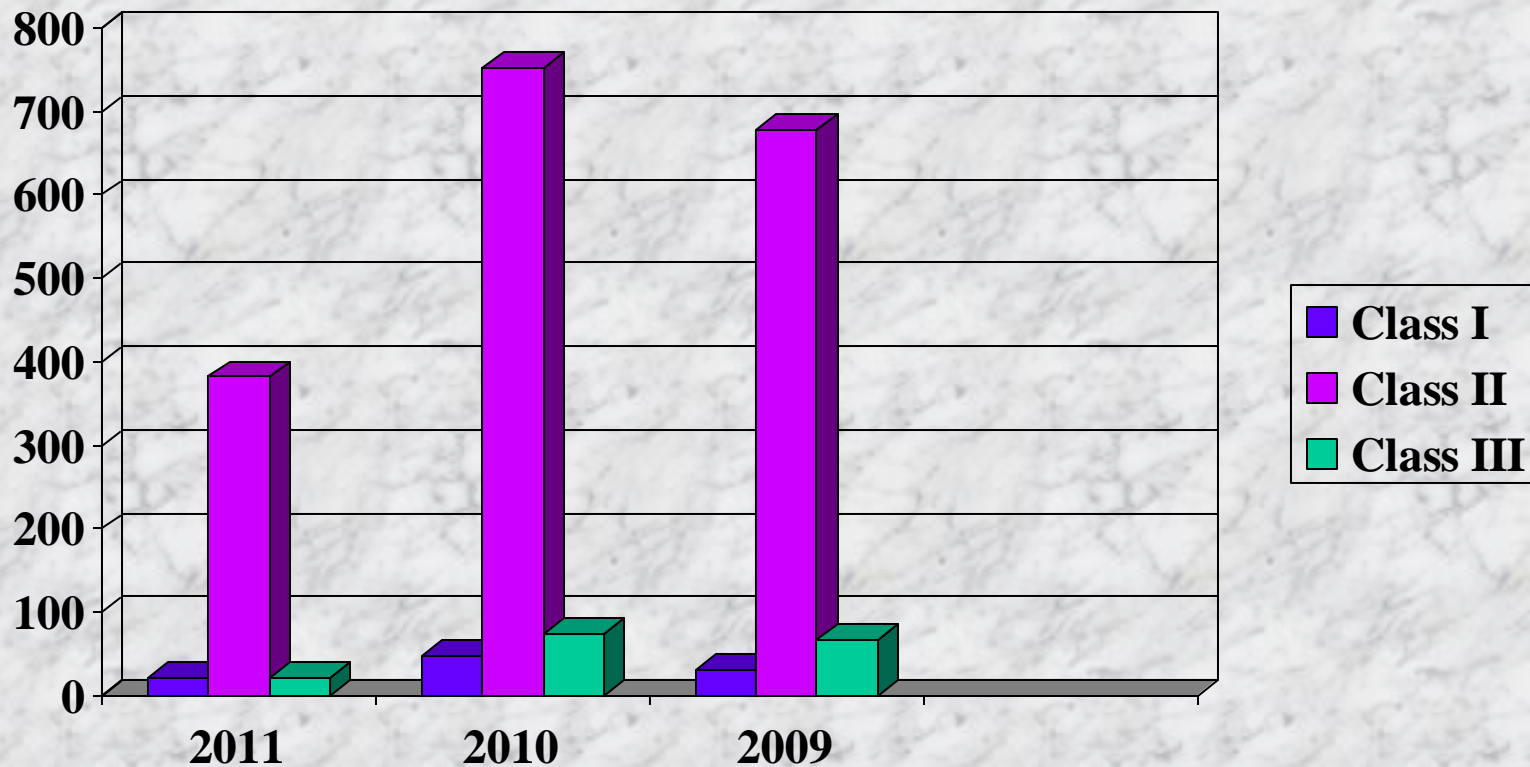
QUESTIONS

- Anytime you have a question call me at (215) 717-3749.
- Or email at megan.lauff@fda.hhs.gov
- Philadelphia Recall Coordinator is
 - Deborah Haney
 - 302-573-6447 ext 112
 - Deborah.haney@fda.hhs.gov

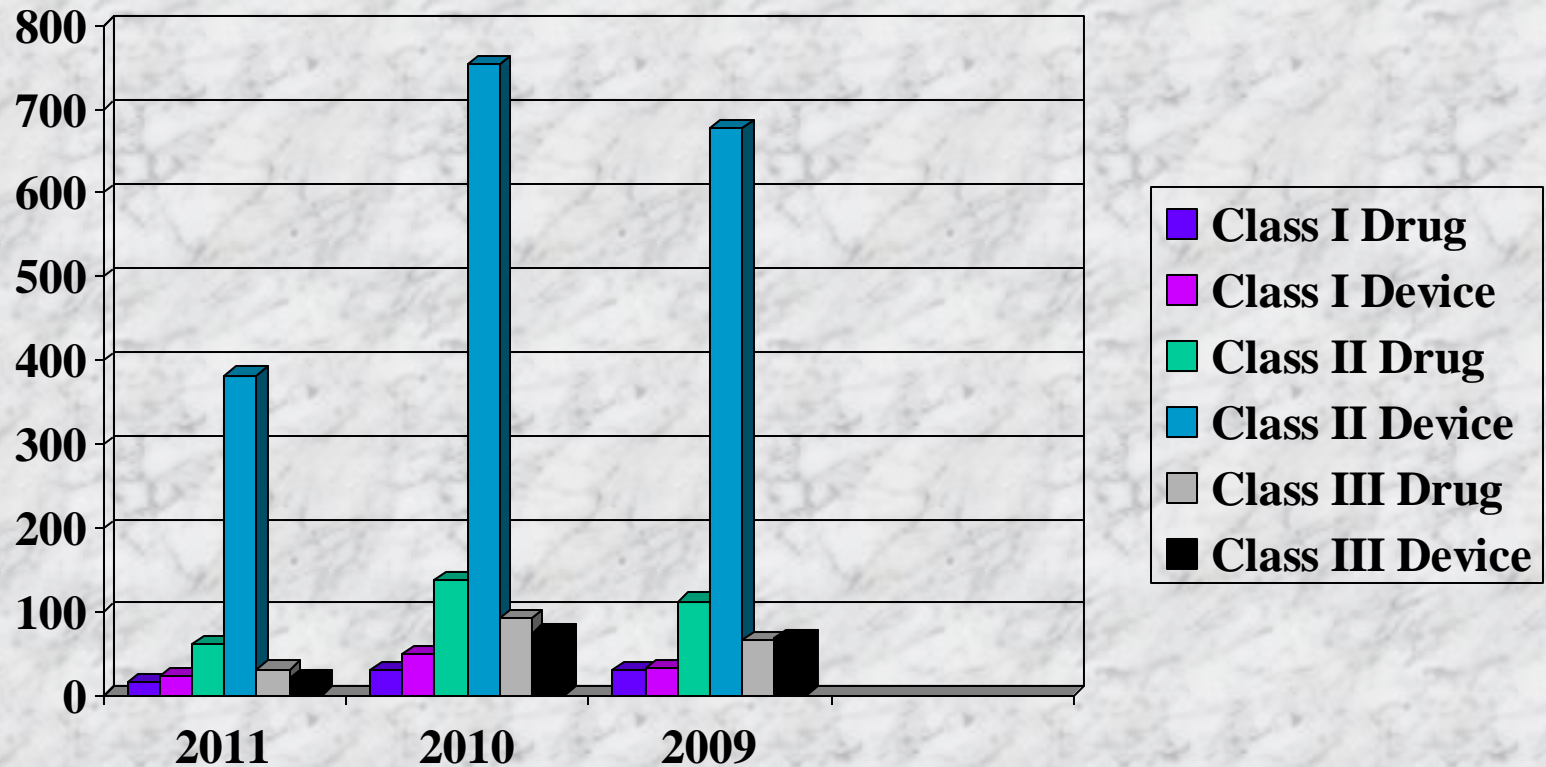
DRUG RECALLS



DEVICE RECALLS



DRUG & DEVICE RECALLS



WEBSITE

- WWW.FDA.GOV
- FDA Weekly Enforcement Report
- Press Releases