Review Article

Drug recall: An incubus for pharmaceutical companies and most serious drug recall of history

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Abstract

There has been an increasing trend in the number of prescribed and over-the-counter drug recall over the last few years. The recall is usually due to company's discovery, customer's complaint or Food and Drug Administration (FDA) observation. The process of recall involves a planned specific course of action, which addresses the depth of recall, need for public warning, and the extent of effectiveness checks for the recall. The FDA review and/or recommend changes to the firm's recall strategy, as appropriate. The critical recall information list includes the identity of the product; summary of the failure; amount of product produced in the distribution chain and direct account. Product recalls clashes thousands of companies every year affecting: sales, testing customer relationships and disrupting supply chains. Drug recall is incubus for pharmaceutical companies. It effects the reputation of the company. The reason for the recall can be divided into two categories: manufacturing affined and safety/efficacy affined. It is essential to follow all the guidelines related to drug development and manufacturing procedure so as to minimize drug recall.

Key words: Drug product recall, guidelines, process, recall information

INTRODUCTION

A drug recall is an instance to return to the maker a batch or an entire production run of a drug product, usually due to the detection of safety issues or drug product defect. When drug products are known to have potentially harmful effect on users due to their defective quality, safety or efficacy, they may be subjected to a recall and all related information's are reported to the drug office [Table 1].[1] When Food and Drug Administration (FDA) found a violation of the laws, it issues a recall orders by which a firm remove or correct the market product. The agency would initiate legal action if the orders are not followed. There is a team responsible for coordinating all aspects related to product recall. The team is composed of endeavor to design, manufacture and sell safe and reliable products, the probability still a recall coordinator and members from the various functional areas.

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Regardless a company's best exists that dangerously defective drug product may reach the customers. These products may cause disasters, leading to adverse verdicts in drug product liability litigations. The quality management of complaints and drug product recalls are necessary to ensure the safety of customer.[2] Recalls can be either unconstrained by the manufacturer, or rarely, injunction by FDA. Recalls vary in severity and in the action that must be contracted. It is possible that sometimes a drug company may recall only a specific batch or lot. However, there are certain other cases when all batches or lots of the drug experience recall from the market.[3]

PURPOSE

This review article endows definitions, responsibility and procedure to initiate, review, classify, audit and terminate recall action. It also discusses the major drug recalls, reasons of recalls and strategies to overcome the recalls.

BACKGROUND

Recalls are a suitable alternative providence by the FDA for removing or correcting marketed consumer products, their labeling, and/or promotional literature that violate the laws administrated.[4] Firms may initiate a recall following notification of a problem by FDA or a state agency, in response to a formal request by FDA, or as ordered by FDA. Manufacturers and/or distributors may also initiate a recall

at any time to fulfill their responsibility to protect the public health from drug products that show a risk of injury or gross spoof, or are otherwise defective. The FDA drug recall and other actions have been classified as the following five categories:[5]

- Class I recall: Includes a health hazard situation where there is reasonable possibility that the use of the product will lead to serious, adverse health consequences or death.
- Class II recall: Includes a potential health hazard situation where there is a remote possibility of adverse health consequences from the use of the drug product.
- Class III recall: Includes a situation where the use of the drug product is not likely to cause adverse health outcome.
- Market withdrawal: When a product has a minor violation that would not be subject to FDA legal action "market withdrawal" occurs. The drug product is removed by the firm from the market or corrects the violation.
- Medical device safety alert: Released in circumstances where a medical device may present an unreasonable risk of substantial harm. These situations also are considered recalls in certain cases.

THE RESPONSIBILITY OF FOOD AND DRUG ADMINISTRATION

The FDA recall curriculum provides sufficient resources to process, to classify, and to publicize recalls on time. The responsibility of FDA is:[4]

- To initiate the recall process, this includes two types of the voluntary recall: FDA requested, and FDA mandated.
- Determine that the action is a recall. The process of recall involves a planned specific course of action, which addresses:
  - The depth of recall,
  - Need for public warning, and
  - Extent of effectiveness checks for the recall.

The FDA review and/or recommend changes to the firm's recall strategy, as appropriate.

Table 1: Difference between drug recall and drug withdrawal

Drug recall	Drug withdrawal
A drug recall is an act taken by a firm to dislodge a drug product from the market that FDA considers to be in violation of the law. A drug may be recalled due to factors such as issues related to packaging, manufacturing, or contamination	In seldom cases, FDA may need to reassess and change the drug product's approval decision. A decision that a drug should no longer be marketed depends upon the nature and frequency of the adverse events and how the drug's benefit and risk balance compares with treatment alternatives. When FDA recognizes that the drug's benefits no longer outweigh its risks, the agency will ask the manufacturer to withdraw the drug[6]

FDA: Food and drug administration

- The FDA categorizes the recall action by determining that the action meets the definition of the recall. The information is reviewed by FDA in detail.
- It is the responsibility of FDA to notify the firm about necessary changes in its recall strategy, including the need for press releases, and the classification of the recall.
- The recall process is monitored, and audit is carried out by FDA so as to ensure that the recall action has been effective.
- FDA also determines that when a recall should be terminated. It provides written notification for termination action to the recalling firm.

In the case, the firm fails to recall violative product or when recall action fails, FDA may take regulatory action in consultation and co-ordination with the district compliance branch, the appropriate center recall and compliance staffs.

SETTING UP FOR RECALL

Food and Drug Administration deduces its recall regulations by specifying measures a "rational firm" can take to minimize disruption in the event of a recall.[7]

1. FDA suggests setting and maintaining "current written contingency plan" for use in starting and affecting a recall in accordance with agency guidelines. The "written contingency plan" should be according to the standard operating procedure (SOP) that set forth what steps must be taken, in what series, and by whom, as soon as a potential recall situation has been recognized. These steps include:
   a. Evaluation of the information received,
   b. Identification of the nature and source of the problem,
   c. Determination of its breadth and depth,
   d. Evaluation of the potential health consequences,
   e. Decide whether to recall,
   f. Decide whether FDA should be notified,
   g. Develop a recall strategy,
   h. Communication of that strategy to FDA and work with the agency as appropriate to shape it,
   i. Implement the recall, and
   j. Conduct effective examination.
2. FDA instructs companies to sufficiently code regulated drug products in order to make corrective lot identification possible and to allow effective recall of all violative lots.
3. FDA encourages the maintenance of drug product distribution records essential to assist in the location of a recalled drug product. These records are kept for a period of time that exceeds the drug product's shelf-life and expected use, and that is at least as long as the retention period specified in other exercisable regulations.

The responsibilities for personnel from essentially every division of the company, with prominent roles for Quality Assurance, Regulatory Affairs, Legal Counsel, and Senior Management

are allotted. It usually helps to identify a core team that would manage the recall and assign key individuals decision-making authority at critical points during the process. It may also help to orchestrate a mock recall to test the effectiveness of the SOP. Finally, it would be prudent for the firm to review its insurance coverage for the recall event.

EXECUTION OF A RECALL

The recall execution involves the following steps:[8]

1. Determining the incumbent of recall
    - When a firm came to know about a potential recall situation, it needs to determine whether the product violates the standard guidelines and whether FDA would likely take legal action. The investigation is carried out so as to conclude whether drug recall is exigent or not.
2. Informing FDA
    - Not reporting a recall, however, can affect the firm's rapport with the agency. Postulating the agency's input in the planning process can also inhibit an enforcement action after the fact, if the agency concludes the recall lacked adequate depth or breadth. FDA actuates companies to endow notification of recalls, however, and it expects to be involved in the planning of any Class I recall. There may be certain cases where it is suitable not to notify the agency of a Class III recall, and some (fewer) situations where it is suitable not to notify of a Class II recall.
3. Evaluating the health hazards
    - A firm must evaluate the health hazard presented by the product when faced with a potential recall. An assessment of the health hazard should take into account:
        - Whether any disease or injuries have already occurred from the use of the product;
        - Whether any existing medical conditions could mask the risk from the product and whether products used to treat these conditions could contribute to (or lessen) the risk from the product;
        - The risk to various identifiable segments of the population, the relative frequency of use within each segment, and the risk to vulnerable groups like infants, children, elderly, pregnant women, and surgical patients;
        - The degree of seriousness of the hazard;
        - The likelihood of the occurrence of the hazard; and
        - Short-term and long-term consequences of the hazard.

It may be worth noting that whether users could be brought under closer medical supervision and whether any medical interventions (for example, medical monitoring) could lower the likelihood of harm.

4. Developing and implementing recall strategy
    - Each recall is uncouth and postulates its own recall strategy. A "recall strategy" is the planned specific curriculum of task to be taken in conducting a specific recall, which addresses the depth of the recall, necessity for public warnings, and the extent of effectiveness scrutinize for the recall.
    - The strategy must customize the individual situation of the particular recall and must take into account among other relevant factors which includes:
        - The results of the health hazard evaluation;
        - The ease in identifying, isolating, and removing the violative product;
        - The degree to which the products deficiency is obvious to the consumer or user;
        - The amount of product remaining on the market; and
        - The need for continued availability of essential product.
    - The recall strategy should specify the requirement of "public warning" and if so whether that warning would issue through generalized or special news media.
    - The strategy should identify the methods which have to be used for "effective investigation checks," which are intended to verify that recipients of the recalled drug product have received notice of the recall and have taken appropriate action in response.
5. Recall communication
    - A recalling firm is amenable for explicitly notifying each of its affect direct accounts about any recall it initiates. However, it should convey:
        - That the product is subject to a recall;
        - That further distribution or use of the product should stop immediately;
        - When appropriate, that the recipient should in turn notify the next party in the chain of distribution of the recall; and
        - What to do with the product.
6. Narration to FDA
    - A recalling firm is expected to provide periodic status reports regarding the progress of the recall to FDA. Unless otherwise set forth by the agency or inappropriate for the recall in question, a status report should have:
        - The number of recipients of the drug product notified of the recall and the method of notification;
        - The number of recipients responding to the recall and the number of drug products each recipient had in its possession upon receipt of the recall notification;
        - The number of recipients that did not respond;
        - The number of drug products returned pursuant to the recall;
        - The number and results of effectiveness checks conducted by the firm; and
        - The approximated completion date for the recall.
7. Terminating a recall[9]
    - A recall may be abolished when all reasonable endeavor have been made to remove or correct

the drug product in accordance with the recall strategy, and it is prudent to assume that the drug product subjected to the recall has been removed and proper disposition or correction has been made corresponding with the degree of hazard of the recalled drug product. Termination of a Class II or III recall does not require any prior approval by the center. In every case, written reportage that a recall is abolish will be issued by the appropriate District office to the recalling firm. FDA will not terminate a recall until the firm has brought the drug product into compliance or disposed of it in a conceded manner.

RECALL ENTERPRISE SYSTEM

The Recall Enterprise System (RES) is a database that involves the full array of communications amid the agency's district offices and headquarters related to drug product recalls.[10] It allows FDA staff to perusal a recall event and sees the timeline of concerning agency activity.

The FDA recall personnel utilizes RES, which is an electronic data system used to submit, update, classify, and terminate recalls. Districts don't capture and track Market Withdrawals or Safety Alerts in the RES system.

Basic recall guidance and steps remain essentially same from those used prior to the initiation of RES. RES User Guides contain the detailed information required for the use of RES. Electronic copies of the guides are given to field and center recall coordinators.

UNDERLAY OF DRUG RECALL

A drug product recall may be:

- Testament by a regulatory agency as an outcome of a violation of government act, standard or other mandatory regulations.
- Postulated to avoid potentially serious additional drug product liability claims or losses.
- Connoted by the analysis of field invigilating reports and feedback that may point to drug product tampering, near miss incidents, accidents or consumer complaints.
- Admonished by new acquaintance based on additional research and drug product testing.
- Required when characteristics of the drug product don't meet the advertised claims for safety or effectiveness.

Table 2: Major drug recalls

Tylenol[11]	Prescribed for	Maker	Financial damage	Recalled (year)
Tylenol	Used for the relief of fever as well as aches and pains associated with many conditions	Johnson and Johnson	27.5% decrease in revenue from OTC/Nutritionals in the US	Recall was issued in 1982
Atorvastatin[12]	Statin-type cholesterol-lowering drug	Ranbaxy		2012
Mibefradil (Posicor)	Used to treat high blood pressure or chest pain (angina)	Roche	Analysts had projected $2.9 billion in sales within 4 years	1998 (after 1-year on the market)
PPA	Used for everything from dieting to cold medication to treatment of psychological disorders	No principal manufacturer, widely manufactured across the industry	Untold millions, if not billions (one manufacture alone settled for $15 million)	In 2000 (at least 60 years on the market)
Terfenadine (Seldane)	Antihistamine without causing drowsiness	Hoechst Marion Roussel, now Aventis	In addition to its legal expenses, the loss of market share alone to drugs such as Loratadine (Claritin) was steep	1997, after 13 years on the market
Troglitazone (Rezulin)	Antidiabetic and antiinflammatory drug	Warner — Lambert	Warner — Lambert grossed $2.1 billion in sales before recall	2000 (after 1-year on the market)
Valdecoxib (Bextra)	Treat arthritis and pain from other inflammatory disorders	Pfizer	Over $2 billion in legal awards and expenses	2005, after just 1-year on the market
Rofecoxib (Vioxx)	Prescribed to more than 20 million people as a pain reliever for arthritis	Merck	Nearly $6 billion in litigation-related expenses alone	2004 (after 5 years on the market)
Cerivastatin (Baycol)	Treatment for high cholesterol	Bayer	Litigation-related damages	2001 (after 4 years on the market)
DES	To prevent miscarriages and other complications during pregnancy	Multiple manufacturers, DES was never patented as it was created with British public funds	Steep, but difficult to quantify because each manufacturer paid out legal damages correlated with its respective market share (a new way of awarding damages in these cases)	1975, after 37 years on the market
Fenfluramine/ phentermine	Weight loss	Wyeth-Ayerst Laboratories	Awards to victims close to $14 billion, making it one of the most costly products liability cases in history	1997 (after 24 years on the market)

Source: The data is collected from: http://xfinity.comcast.net/slideshow/finance-worstdrugrecalls/cerivastatin-baycol/, http://features.blogs.fortune.cnn.com/2013/05/15/ranbaxy-fraud-lipitor/. PPA: Phenylpropanolamine, DES: Diethylstilbestrol, OTC: Over-the-counter

PRETEXT MADE ON PRODUCT RECALL

Nevertheless the company's best efforts to design manufacture and sell safe and authentic products, the possibility still exists that dangerously defective products may reach the consumer. A recall is an expensive undertaking even where patient safety is not at stake, not only in apparent costs, but also disservice to the reputation and the risk of litigation [Table 2]. It should be intone that the reason cited in a recall report may not reflect the root cause of an event, as establishing this generally requires the manufacturer to fetch an investigation into the incident to a close.[13] A number of factors can result in a drug to be recalled [Table 3].[14,15] A recall may be issued if a medicine:

- Cause health hazard
- Is mislabeled or packaged poorly
- Is potentially contaminated
- Is not what it says
- Is poorly manufactured

ENFORCEMENT REPORT OF 2013 BY FOOD AND DRUG ADMINISTRATION

According to the FDA enforcement report of 2012 in the fourth quarter, there were total 81 drug and pharmaceutical recalls.[16] Out of 81 recalls, four recalls were over-the-counter (OTC) products and seventy seven affected prescription medications. The FDA enforcement report of 2013 in the first quarter reveled that there were total 107 drug and pharmaceutical recalls.[17] The figure has increased by 32% as compared with the previous quarter and is higher than the average number of events of last year that is, 2012. The second quarter of 2013 showed 241 drug and pharmaceutical recalls according to FDA enforcement report. An increase of 127% from the previous quarter was osbserved in the second quarter. The FDA enforcement reported 171 drug and pharmaceutical recalls in the third quarter of the year 2013. In the third quarter, there was a decrease of 29% as compared with the previous quarter. Nationwide recalls in the fourth quarter were total 52 drug and pharmaceutical recalls, as documented in FDA enforcement reports [Figure 1 and Table 4].[18]

Chart is representing quarterly data of drug recalls. X-axis represents quarters of year and Y-axis represents the number of recalls.

DENOTATIONS TO AVERT PRODUCT RECALL

The drug recall leaves worst impression on pharmaceutical company's financial situation.[19,20] Apart from that, market image of that company also suffers. There are certain contentions to subdue drug recall. The management system to overcome the drug recall involves:

- Ensuring compliance with industry and government regulations and standards

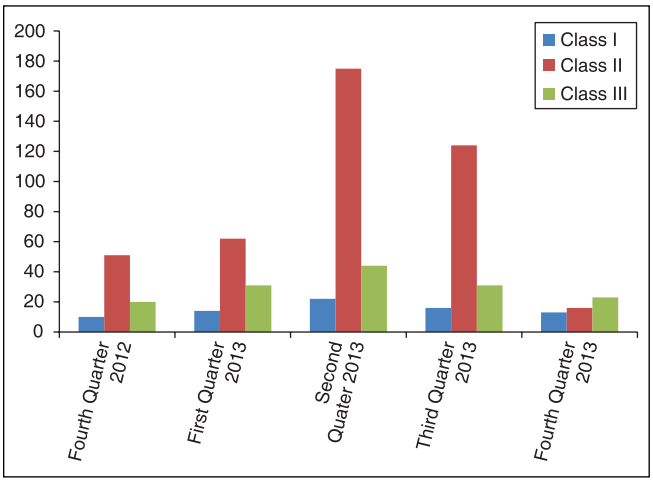

Figure 1: Statistical representation of Quarterly data of drug recall

Table 3: Cause of drug recall

Manufacturing affined drug recall	Safety/efficacy affined drug recall
Marketed without an approved NDA/ANDA	Super potent drug
Chemical contamination	Super potent drug
Failed impurities/degradation specifications	Microbial contamination of nonsterile products
Defective container	Adverse drug reaction(s)
Nonsterility	Presence of foreign substance
Labeling: Label error on declared strength	
Presence of particulate matter	
CGMP deviation	
Failed dissolution specifications	
Failed stability testing	
Failed content uniformity specifications	

CGMP: Current good manufacturing practice, NDA: New drug application, ANDAs: Abbreviated new drug applications

Table 4: Quarterly data of drug recall

Drug recall class	Number of recalls
2012 fourth quarter	
Class I	10
Class II	51
Class III	20
2013 first quarter	
Class I	14
Class II	62
Class III	31
2013 second quarter	
Class I	22
Class II	175
Class III	44
2013 third quarter	
Class I	16
Class II	124
Class III	31
2013 fourth quarter	
Class I	13
Class II	16
Class III	23

- Reducing risk of customer exposure by improving on time action

- Providing legal protection as well as drug product and corporate brand protection through improved response times
- Decreasing cycle time and production/operation costs by speeding up quality and process efficiency
- Reducing risk of missing or incomplete data through closed-loop product recall decision-making process
- Providing flexible yet monitored environments through fully configurable process workflows
- Improving other quality and operating processes by integrating with other enterprise-level control systems
- Increasing operational transparency
- Increasing accountability though assignments, process step sign-offs and automated audit trails.

The risk management program can work as an aid to anticipate the reasons for recall. The risk can be managed by using three strategies.[21]

Reducing risk

During the initial phase of drug development and manufacturing, there should be a strict quality control measures to prevent recall. To handle a recall, crisis-management procedure should exist.

Assuming risk

Laying down all the possibilities due to which a recall can occur is another strategy to predict and resolve the recall issue.

Transferring risk

The third party, who could be a supplier or insurer, who is capable of share risk and to pay for the costs of drug recall, could help to overcome recall loss.

CONCLUSION

There has been an increasing trend in the number of prescribed and OTC drug recall over the last few years. The recall is usually due to company's discovery, customer's complaint or FDA observation.[18] The critical recall information list includes the identity of the product; summary of the failure; amount of product produced in the distribution chain and direct account. Drug recall is incubus for pharmaceutical companies as it effects the reputation of the company. The most common reason that account for product recall is manufacturing affined. This inference that the production sequel didn't followed the current Good Manufacturing Practice guidelines. Another reason involve safety/efficacy affined which suggest that the safety data was not appropriate, or some kind of biasing was involved during drug development time. It is essential to launch the drug in the market after assuring the safety and efficacy of the new intervention so as to minimize drug product recall. Major drug recall list of the history suggest that lots of carelessness is involved during the drug development and manufacturing period. The long list of drug recall on FDA website is evidence that still industries are not following the standard guidelines issued by FDA. The process of recall execution is followed by FDA and firms in very efficient manner. This execution step is effective enough to protect consumer's health from a particular drug that requires recall. Therefore, even after launch of the drug in the market, it is essential to carry out postmarket surveillance and investigate the drug performance in the market.

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