Drug Recall Policies and Procedures

DESPITE the very thorough approval process required for drugs, unexpected side effects and manufacturing defects can occur. When a harmful situation is discovered in which a drug violates the laws administered by the Food and Drug Administration, a recall is the most effective means of removing the harmful drug from the marketplace.

Objective:

Summarize drug recall policies and procedures.

Key Terms:

- adverse drug reaction (ADR)
- cause analysis
- Centers for Disease Control and Prevention (CDC)
- clinical trial
- drug recall
- efficacy
- Food and Drug Administration (FDA)
- Illinois Department of Public Health (IDPH)
- Institute of Medicine (IOM)
- National Drug Code (NDC)
- New Drug Application (NDA)

Recall Policies and Procedures

The **Food and Drug Administration (FDA)** is the federal agency responsible for ensuring that drugs, vaccines, and medical devices are safe. Although the approval process for drugs is quite thorough, it is impossible to fully prove that a drug is safe for use. No matter how many people participate in a **clinical trial** (a study that assigns human participants to evaluate a drug), the number is just a fraction of how many people will use the drug once it is approved. There is always a risk that the drug may produce an adverse drug reaction (ADR). An

adverse drug reaction (ADR) is any negative consequence to a patient from taking a particular drug.

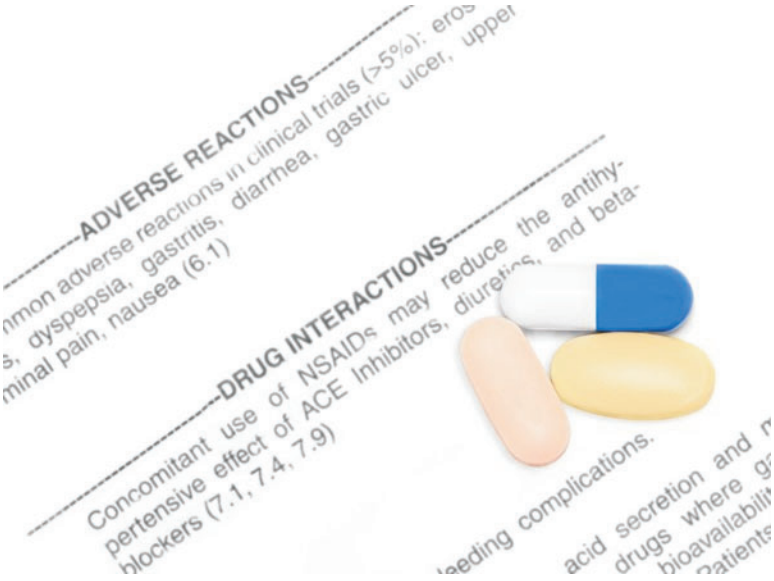

FIGURE 1. An adverse drug reaction (ADR) is any negative consequence to a patient from taking a particular drug.

REVIEW DRUG RECALL POLICIES

Institute of Medicine (IOM)

The **Institute of Medicine (IOM)** is a nonprofit organization that works outside the framework of the government to provide evidence-based research for public health. In 1999, the IOM called for a nationwide mandatory reporting system for state governments to collect information about adverse medical events resulting in death or serious harm to consumers. By 2015, each of 27 states had adopted a formal adverse event reporting system. A list of standardized reportable events was established in 2002 and updated in 2011. There are 29 reportable adverse events, including "patient death or serious injury associated with the use of contaminated drugs, devices, or biologicals provided by a healthcare setting."

Illinois Department of Public Health (IDPH)

In 2005, Illinois passed a mandatory adverse event reporting law requiring hospitals and ambulatory treatment centers to report information on serious adverse events based on the list of 29 reportable events to the Illinois Department of Public Health (IDPH). The **Illinois Department of Public Health (IDPH)** is the state organization in Illinois that works with communities to promote health, prevent diseases, and ensure access to healthcare for all individuals. The Illinois Adverse Health Care Events Reporting Law of 2005 was designed to facilitate error identification and reduction and to adopt corrective action plans in response to errors.

FIGURE 2. The Illinois Department of Public Health (IDPH) works to protect citizens from adverse health hazards and to promote healthy lifestyles.

According to the law, an event must be reported within 30 days of discovery, and a

report must be generated identifying the facility but not the patients involved. Then, the facility must conduct a cause analysis of the event and must implement a corrective action plan. **Cause analysis** is a systematic process of identifying a problem and finding a way to prevent it.

Next, the findings must be submitted to the IDPH, which analyzes the report, the cause analysis, and the corrective action plan and communicates its conclusions to the facility. The public health department also includes information about adverse events in its annual report.

SUMMARIZE DRUG RECALL PROCEDURES

When a drug is found to have potentially harmful effects on consumers due to its defective quality, safety, or efficacy, it may be subjected to a recall. **Efficacy** is the ability to produce a desired or intended result. A **drug recall** is an action taken by a firm to remove a product from the market. A recall may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority (Source: U.S. Food and Drug Administration).

A recall removes from the marketplace a drug that is found to be in violation of laws administered by the FDA. Recalls are the most effective means of protecting the safety of the public.

A recall takes place to protect the public health and well being from a drug that presents a risk of injury. The company responsible for the drug's manufacture and distribution conducts the recall. In some situations, the company must conduct a recall in a manner specified by the FDA. In other situations, the FDA may mandate a company to recall a drug.

The FDA's Role in Drug Recalls

The FDA's role in a recall is to assess the adequacy of the decision to recall the drug and to monitor the progress and effectiveness of the recall. A recall is put into one of three categories according to the level of hazard involved.

In a Class I recall, there is a reasonable probability that use of the product will cause or lead to serious health problems or death. Examples of Class I recalls are:

- Label mix-ups on a lifesaving drug
- A defective artificial heart valve
- A food with undisclosed allergens

In a Class II recall, there is a reasonable probability that use of the product will cause a temporary or medically reversible health problem. An example of a Class II recall is the recall of a drug that is under strength but that is not used to treat life-threatening situations.

In a Class III recall, there is little likelihood that the drug will cause any adverse health reactions, but FDA labeling or manufacturing laws have been violated. Examples of Class III recalls are:

- Minor container defects

- An off taste
- An off color

Four Phases of an FDA Recall

PHASE 1: Initiation of a Recall

A recall may be initiated as a result of reports or complaints about quality, safety, or efficacy of a drug from a variety of sources. The manufacturer, pharmacists, research institutes, medical practitioners, consumers, and/or the Centers for Disease Control and Prevention (CDC) may refer reports to the FDA. The **Centers for Disease Control and Prevention (CDC)** is the leading national public health institute of the United States.

The following information is included in the initiation of a recall:

- Name of the reporting individual
- Nature of the problem, with an explanation in detail as to how the product is defective
- Explanation as to how the defect affects the performance and safety of the product
- Explanation of how the problem was detected

Details of the product include the following information:

- Name of the product and description, including active ingredients, dosage form, strength, package size, and route of administration
- Batch number, lot number, and expiration date
- Intended use or indications of the product
- **New Drug Application (NDA)** (the document that contains details of the entire history of the development and testing of the drug)
- **National Drug Code (NDC)** (the identification of the manufacturer, the drug, and the package size)

The manufacturer information includes the following:

- Company name and address
- FDA registration number

Information about the total volume of recalled product includes the following:

- Total quantity produced
- Dates produced
- Distribution pattern, wholesalers, retailers, and consumers

PHASE 2: Determination That the Action Is a Recall

When a company is notified about an issue with a drug, it needs to determine whether that drug violates the standard FDA guidelines. An investigation is carried out to determine if a recall is required. The company evaluates the health hazard presented by the drug when faced with a potential recall. An assessment of the health hazard should take into account whether any diseases or injuries have occurred from the use of the drug and what short- and long-term consequences are possible.

Then, the FDA reviews the information submitted and formalizes the recall by determining that the situation meets the definition of a recall.

Next, the FDA assigns the recall a classification number.

The FDA indicates the level in the distribution chain to which the company will extend the recall. The company must indicate whether the method of notification will be by mail, phone, or email.

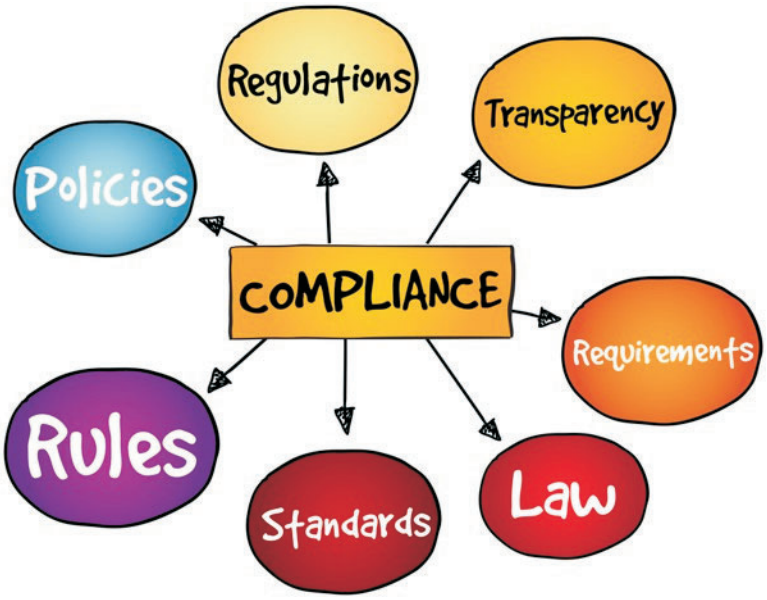

FIGURE 3. All companies are required to follow the guidelines set forth by the FDA in conducting product recalls.

PHASE 3: Notification and Public Warning

In a situation in which the drug may pose a significant health hazard and the recalled drug has already reached the consumer, a press release is usually appropriate.

The FDA posts information about recalls on its website, http://www.fda.gov. In addition, recalls will be included on the FDA's weekly Enforcement Report webpage at http://www.fda.gov/safety/recalls/enforcementreports/default.htm.

Notifications are flagged in large bold print as **Urgent Drug Recall**.

PHASE 4: Monitoring and Auditing the Recall

First, the recalling company is requested to submit periodic recall status reports to the FDA. The FDA uses these reports to assess the progress of the recall. It is the recalling company's responsibility to assure that the recall is effective.

Then, the company should conduct effectiveness checks. The purpose of an effectiveness check is to verify that the customer received the recall notification, understood the notification, and followed the recall instructions.

Next, in addition to effectiveness checks conducted by the company, the FDA may also contact customers as a means of assuring that the company is following recall policy.

FURTHER EXPLORATION...

ONLINE CONNECTION:
Pharmakon Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of All Sterile Compounded Products Due to FDA Concern of Lack of Sterility Assurance

When a company's products pose a serious threat to consumers, that company is responsible for issuing a press release to notify consumers of the health hazard. Although the FDA does not endorse any company, it will post the company's announcement on its website as a public service. Visit the FDA website at http://www.fda.gov/safety/recalls/ucm496838.htm to read the press release issued by Pharmakon Pharmaceuticals, Inc.

In a serious threat to consumers, a press release may be warranted to notify consumers of the health hazard.

Finally, a recall is terminated when the FDA determines that all reasonable efforts have been made to remove the drug in accordance with the recall strategy. The FDA issues written notification to the recalling company that a recall has been terminated.

FIGURE 4. The FDA uses a checklist of documentation and information to evaluate, classify, monitor, and audit product recalls.

Summary:

The Food and Drug Administration (FDA) is the federal agency responsible for making sure that drugs, vaccines, and medical devices are safe. Though the approval process for drugs is quite thorough, it is impossible to fully prove that a drug is safe for use. When a drug is found to have potentially harmful effects on consumers due to its defective quality, safety, or efficacy, it may be subjected to a recall.

A recall removes from the marketplace a drug that is found to be in violation of laws administered by the FDA. Recalls are the most effective means for protecting the safety of the public. The FDA's role in a recall is to assess the adequacy of the decision on the recall of the drug and to monitor the progress and effectiveness of the recall.

Checking Your Knowledge:

1. Explain the role of the FDA in a drug recall.
2. Explain the role of the Illinois Department of Public Health (or any state health department) in a recall.
3. Differentiate between the three classes of drug recalls.
4. List six pieces of information that are included in Phase 1 of a recall.
5. Explain how a company notifies the public of a drug recall.
6. How is a recall terminated?

Expanding Your Knowledge:

Contact a local pharmacy. Ask the pharmacist if there have been any recent drug recalls. Then, ask the pharmacist to provide you with the name of the drug, the company that manufactured the drug, and the reason the drug was recalled. Finally, ask the pharmacist how customers were notified about the recall. Share your information with the class.

Web Links:

Clinical Trial News
http://www.drugs.com/clinical_trials.html

Medscape Drugs and Diseases
http://reference.medscape.com/

What Is a Drug Recall?
http://www.rxrecall.com/drug-recall/