CLM 2021 Focus: Diversity, Equity & Inclusion, Management Liability, Medical Malpractice, Product Liability, Professional Liability, Transportation, Claims & Litigation Management Conference

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Narrative

Return to Sender: Consumer Product Recalls

I. The Product Recall

Types of Product Recall

Every year approximately 400 products are recalled by Consumer Products Safety Commission (CPSC) Food recalls range between 9 million to over 200 million per year. A recall is a method by which a product manufacturer or distributor seeks to take corrective action to alert or protect the public from a danger of which it is made aware. The recall may be a complete removal of the product from the market or some type of corrective measure.

The Food & Drug Administration (FDA) issues in excess of 200 prescription recall enforcement reports and between 30 and 40 over-the counter medication recall enforcement reports per year. In June 2021, there were twenty (20) food and drug products added to the FDA recall list and 170 entries for 2021. These included recalls for listeria, toxins, mold, labeling problems, allergens and foreign matter. There were also approximately 100 consumer products placed on product recall by the end of the first half of 2021.

Product recall can involve food, drugs, medical devices, automotive products, children's products and consumer retail products. The type of product will dictate the manner in which the recall will be conducted, the process and the governmental agency or agencies involved. The overall purpose of the recall is to protect the public from a dangerous or potentially dangerous product which is in the stream of commerece.

Product recall can be voluntary or involuntary. The manufacturer can determine that its product is in some manner defective and decide to recall the protect. An involuntary

recall is one that is required by the government or a regulatory agency. Usually, the corrective comes after public complaint.

Involuntary or Mandatory Recall

Involuntary recall usually is directed by the FDA and involves food products, drugs or medical devices. Simply put, it is the government directing the manufacturer, distributor or processor to remove a product from the market or to take a remedial measure. There are classifications of products to be considered for an involuntary or mandatory recall

Class I-A dangerous or defective product that could cause serious harm or death
Class II-A product that might cause temporary health problems or pose a threat of a serious nature
Class III-A product is unlikely to an adverse health reaction but violates FDA labeling or manufacturing laws or standards

The class designation will dictate the recall plan to be devised with the FDA and followed by the manufacturer, supplier or processor. Failure to follow the plan issued by the FDA would result in compliance orders and fines.

Voluntary Recalls

Voluntary recalls of FDA regulated products usually involve food. There are market withdrawal recalls and recalls done by the producer or manufacturer directly. The market withdrawal is initiated by the company when a product is deemed unsafe but does not violate FDA regulations. The second type of withdrawal is done by the company when it realizes the product presents a danger and recalls the product before the FDA issues a mandatory recall.

Voluntary recalls of consumer products and devices are common for automobiles, appliances and sporting goods. These are often considered advantageous to the manufacturer, supplier of processor but also the public. The manufacturer has the ability to "get out in front" of a problem and address the issue. The public is alerted to a potential problem, given guidance and a sense of transpencary. Any uncertainty can be addressed and goodwill established.

Federal Food & Drug Administration (FDA)

The FDA is the oldest consumer protection agency in the US government. Its modern regulatory function began in 1906 with the passage of the Pure Food and Drug Act. It presently regulates medical devices, food, drugs, vaccines, biologics, and provides regulatory approval and inspection services. Regarding recall the FDA is responsible for

the public health and to ensure the safety for the products it regulates. It accepts and investigates consumer complaints. It issues recalls and provides recall plans of action. All recalls are monitored through Enforcement Reports once the recall is classified. All recall data can be accessed through its weekly publication. It also provides information on manufacturer market withdrawals and safety alerts. The FDA provides industry guidance for the implementation of mandatory food recalls and direction to interested parties to issue alerts, provide warnings and notifications to the public.

The FDA regulates a host of products including food (except of meats, poultry and eggs which fall under the US Department of Agriculture) human drugs, radiation-emitting electronic devices, cosmetics, dietary supplements and tobacco products. The FDA also regulates pet foods and veterinary medicines. Presently, there are many pet-related products which are subject to recall. Like all recalls pet-related recalls can be voluntary or under mandate. However, to date a mandated recall has not been issued for pet-related products. By mid-year 2021 twelve (12) pet-related products were recalled. Pet product complaints are submitted through the same portal as all other complaints. Pet products are subject to labeling requirements, registration for drugs, food safety standards and verification.

Other Recall Agencies

There are numerous agencies with recall authority which include the Environmental Protection Agency, Federal Aviation Administration, US Coast Guard (marine vehicles and boats) Department of Housing and Urban Development, National Highway Traffic Safety Administration, United States Department of Agriculture and Food Safety and Inspection Service.

II Consumer Products Safety Commission (CPSC)

The CPSC was created in 1972 by the Consumer Products Safety Act and administers regulatory laws such as Federal Hazardous Substances Act, Flammable Fabrics Act, Child Safety Protection Act, Drywall Safety Act and Children's Gasoline Burn Prevention Act. It has jurisdiction over thousands of products used in schools, households, and in recreation. Its mission is to keep consumers safe through prevention, response and communication. As part of its mission it addresses consumer products safety recalls and awareness of these recalls. Information regarding product hazards is communicated to the CPSC through incident reports, consumer complaints, company-self reports and social media. It is responsible to outreach and messaging about products which pose unreasonable risks of injury and death. Like the FDA, the CPSC is empowered under various statutes to order product recalls. Its powers extend to the manufacturer, imports, distributors and retailers.

Under the CPSC there is a requirement that once there is reason to believe that a product fails to comply with a safety rule or voluntary consumer safety standard it must immediately notify the Commission. Reports are marked confidential. A report must be filed if there are at least three (3) civil suits during a two (2) year period and each suit alleges that the product was involved in a death or grievous bodily injury. The Commission will evaluate the hazard presented into the following Classes:

Class A-Risk of death or grievous injury or illness is likely or very likely or serious injury or illness is very likely

Class B-A risk of death or grievous injury or illness not likely to occur but is possible, or when serious injury or illness is likely, or moderate injury or illness is very likely

Class C-A risk of serious injury or illness is not likely, but is possible or when moderate injury or illness is not necessarily likely, but is possible.

Fast Track Product Recall Program

The Commission provides for a program which allows a company which reports a potential product defect and with twenty (20) days of the filing of the report implements with the CPCS a consumer-level voluntary recall. The recall must be conducted to the satisfaction of the Commission. This program allows the company to recall the product without a determination by the CPSC that the product defect created a substantial risk of harm. This is a corrective plan of action which usually involves product repair, replacement or a refund.

What is Involved in a Recall

CPSC Guidelines of For Full Product Recall

The Commission provide guidelines for full product recall. The company should be able to address the causes of the product defect, the location of the unsafe products, the distributors or retailers, identity of owners, preparation of press releases, establish toll free hotlines, address the situation of the company's website, deploy manpower, mechanics of product return or replacement, and reporting to the Commission during the recall process.

The News Release

The company is encouraged to submit a plan which will address all of the areas and to work in conjunction with the Commission through joint press releases, videos, and social media. Unilateral releases are discouraged. The nature and content of a recall press release is strictly governed and must contain certain information such as the identity of

the company, the geographical location of manufacturer, the identity of all significant retailers, the exact name, model number, size and sku's of the product and include high resolution of the product and a concise summary of the reasons of the recall.

Video News Release-The VNR is a tape version of the written release. The Commission provides guidance on how to produce a VNR

Posters-Guidelines for posters including brief-eye catching descriptions of the hazards. Bold colors and font size that provides strong contrast, with information such as toll-free numbers.

Social Media-CPCS encourages the use of all available social media including the company's website, Facebook and Twitter accounts.

Other Forms of Communication-Letters Bulletins Newspaper and other forms of notice.

The Plan for Recall

Both the FDA and CPCS require the company to submit a product recall plan. The is essential to compliance and to protect the company from future liability and costs. A proper plan minimizes the impact of the recall and serves to reduce the impact on potential business interruption. Both agencies provide guidance to draft a plan. The CPCS plan should be drafted by key personnel who will participate in the recall process. The plan should address:

The reason of the recall
The identity of the recall committee and each individual's responsibilities in well-defined terms including a recall coordinator.
The recall discovery phase-the first step, the isolation of the problem
The recall decision-the scope and assessment of the recall and what will be done
Recall actions-including 24-hour plan, product recovery, disposal
Recall termination

The plan should also provide all essential information such as contact numbers of key personnel, samples of forms of communications, time lines of communication, press releases, notices, and other references.

The FDA food recall plan should include the ability to recognize a problem immediately. Each and every food business operator must have an up-to date food recall plan. The plan must identify:

The recall procedure
Roles and responsibilities of personnel and management team
Recall action and documentation
Decision to recall

Notification of product recall
Regaining control over stock
Recall status report
Post recall report
Termination of a recall
Follow up action

Recall Procedures

Within the company there should be a plan and process for recall procedures. There recall team should be clearly identified and each person's role clearly outlined such as decision making, technical advisory, media communication, accounting, legal counsel and complaint investigation. The company's internal process should be set forth such as product evaluation, location of products, notification and product remedies. There are outside companies and agencies which will provide recall related services and direction to companies involved in the process.

General Concepts

According the CPSC there are certain things a company can do to ensure a successful recall. These include preparation, monitoring the market, reporting any problem immediately, self-evaluation of the products, having a team in place and draft notifications at the ready and assigning responsibilities to key employees in the event a recall is necessary.

III Insuring the Recall Risk

Product Recall Insurance

Product recall insurance is available to cover the expenses involved with a recall. The coverage is typically purchased by manufacturers of foods, beverages, toys, etc. The coverage can cover the cost of notification, shipping of the recalled products, disposal costs and restocking. While this is normally first-party coverage, it can be purchased to cover third-parties. The intent is to protect the company from the financial losses resulting the expenses of the recall. The coverage is when the policy holder becomes aware of a health risk or danger to the end user. The recall can be either voluntary or involuntary.

General Liability Insurance

General liability insurance coverage applies to losses for bodily injury and property damage, personal and advertising injury liability and medical payments. It coverages claims caused by the business or product. Therefore, general liability coverage would not cover the expenses involved in a product recall, but could cover losses caused by a defective product.

Business Interruption Coverage

Business interruption coverage, covers income following a disaster. The insurance covers loss of profits. There are a number of events which would trigger the coverage such as fire, destruction or other covered peril. Therefore, business interruption coverage would not cover expenses caused by a product recall.

Other Insurance Considerations

There are possible other liability considerations surrounding product recall. Attorneys are often involved, therefore there could be malpractice considerations. There are CGL considerations generally for defective products. There are issues regarding failure to recall a product.

IV Legal Considerations of Recall

Common Law-Failure to Recall

Generally, there is no common law liability for failure to recall a product unless a company was ordered to recall and failed to do so as directed by the governmental authority or a company undertook a recall and did so negligently. Please note that liability can still attach for the defect productive, however an independent duty to recall is not created. Liability for a negligent undertaking requires a plaintiff to establish all of the elements of a negligence claim.

Subsequent Remedial Measures Federal Rule of Evidence 407

Subsequent remedial measures are not admissible to establish negligence, a defective product warning or a defective product design. The policy behind the rule is to encourage companies to undertake steps to ensure product safety. It is generally accepted that evidence of a product recall is not admissible to establish product defect or a manufacturer's negligence.

Legal Effects of a Recall

Strategically a recall can be a benefit to a client or policy holder. There are public relations considerations and consumer confidence issues. In personal injury claims a

recall could aid to decertify a class or stop a court from certifying a class. Issues of proximate cause or comparative fault must be considered if an individual continues to us a product despite the recall.

Notable Recalls

There are several notable recalls. The most famous may be the in 1982 Johnson & Johnson recalled 31 million bottles of Tylenol as a result of product tampering. This landmark recall changed product packaging for over-the counter medications. It resulted in anti-tampering legislation. It was also an example of damage control and a return to consumer confidence campaign. The company's response was thought to be straight forward and honest. It completely removed the product from retail shelves and discontinued the manufacture of capsules. The capsules were not reintroduced to the market until the following year and began triple sealing it packages.

Other notable recalls included the 2005 Bextra recall and the subsequent Vioxx recall. In 2009 the Peanut Corp of America, a privately held company experienced a food borne contamination which killed nine (9) people. Recently, the Samsung Galaxy Note 7 recall for overheating batteries sparked revised airline regulations. There was the Volkswagen diesel engine emission, or dieselgate recall. The Takate Air Bag recall which cost the company $24 billion.

The Ford Pinto is probably one of the most notable products which should have been considered for a product recall early after it was introduced to the market. However, the original model year was 1971 and the CPSC was not established until 1972. While Ford denied knowledge of the product defect, the issue of defective gas tank would most certainly demand an immediate recall today. Ford did not recall the Pinto until 1978 and later apologized for its handling of the Pinto's exploding gas tank. The Pinot was also the subject of ten (10) additional recalls including faulty seat belts, contaminated brake fluid and a throttle problem.

The biggest recall is the Habro Easy Oven which occurred in 2007 following complaints of burn hazards. Other newsworthy recalls including the Ford cruise control recall of 2009, Firestone tire recall of 2000, Toyota gas pedal and floor mats in 2010 and Red Dye # 2 in the 1970s.

The recent Peloton Tread+ treadmill recall involved the recall of $2000 to $4000 treadmills in the spring of 2021. Customers began reporting issues and concerns with the treadmills in 2019. There was one (1) death and at least 70 reported injuries caused by people or pets being pulled under the tread at the rear of the treadmill. Another reported problem was the touchscreen was not stable and fell causing injury. The CPSC encourage Peloton to recall the product but it resisted. In May of 2021 Peloton issued a voluntary recall with a full refund to its customers. The recall came on the heels of two

(2) class action lawsuits filed against Peloton. One suit alleges that Peloton knowing sold an unsafe and inherently dangerous product. The other suit was brought by the company's investors who alleged that Peloton failed to disclose material facts regarding the company's business.

In June of 2021 Peloton released "Tread Lock" to those who continue to use its treadmill. Tread Lock prevents unauthorized users from turning on the treadmill without a four (4) digit access code. Tread Lock completely disables all Peloton treadmills. It is deployed through Peloton's "Run Free" program. Prior to June of 2021, Run Free was a free computer program for Peloton users. After June of 2021, with a three (3) month introductory free period, users will have to pay $39.99 per month. Failure to pay the monthly fee will render the treadmill useless.