What Companies Must Know About Product Recalls

By **Kelly Jones Howell and Judi Abbott Curry** (August 2, 2023)

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Whether it is leaking inhalers important to asthmatics or "Baby Shark" bath toys for children, product recalls continue to be a fairly common occurrence.

Recalls can be voluntary, or mandated by a government regulatory agency, such as the U.S. Food and Drug Administration, the U.S. Consumer Product Safety Commission or the U.S. Environmental Protection Agency.

The scope of a particular recall will vary depending on the product, how it is regulated and the set of facts around the incident.

For example, in the case of the inhalers, Cipla Ltd. initiated a voluntary recall on July 6, due to a market complaint for one single albuterol sulfate inhalation aerosol inhaler, where leakage was observed through the inhaler valve due to a container defect.[1]

Out of an abundance of precaution, the company recalled all six batches manufactured using the same lot of valves, stating:

> There is a reasonable probability that failure to deliver the recommended dose to treat the respiratory symptoms of an acute asthma exacerbations such as wheezing coughing, shortness of breath and bronchospasms, due to device defect, may be life-threatening. There were no adverse events reported for Albuterol Sulfate Inhalation Aerosol 90 mcg related to this recall.

Just a couple of weeks earlier, on June 22, Zuru LLC issued a much broader recall, encompassing approximately 7.5 million "Baby Shark" toys, because, "when using the recalled bath toys, particularly in a bathtub or wading pool, a child can slip and fall or sit onto the hard plastic top fin of the shark, posing risks of impalement, lacerations and punctures."[2]

Of course, the intention is never to create a product that will be recalled — and the scope of a recall may vary greatly, depending on the product and individual facts at issue. But the days following the report of an initial incident often follow a pattern, and require quick action.

The more efficient and transparent the recall process is, the better the outcome will be for all — which is why it is important to keep a few best practices in mind.

Recalls 101

Generally, recalls are made when there is a potential risk of harm from a product. They are generally initiated to protect health and safety, preserve brand reputation, and avoid or mitigate litigation.

In the case of FDA-related recalls that can affect manufacturers of FDA-regulated products like food, drugs, medical devices and cosmetics, they are designated by class:

- 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.

- Class II: A situation in which 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.

- Class III: A situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

- Market Withdrawal: Occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal.

As for the CPSC, the agency is charged with protecting consumers from potential hazards commonly associated with consumer products. Consumer products that fall under the CPSC's jurisdiction range from children's toys and childcare articles to household products, as well as products such as fireworks and lawn mowers.

Many products commonly used by consumers, however, do not fall squarely within the CPSC's jurisdiction. These include, for example:

- Pharmaceuticals and medical devices, regulated by the FDA;

- Cars, trucks, motorcycles and tires, regulated by the National Highway Traffic Safety Administration;

- Firearms and ammunition, regulated by the Bureau of Alcohol, Tobacco, Firearms and Explosives; and

- Pesticides and disinfectant products, regulated by the EPA.

CPSC-related recalls require manufacturers, importers, distributors and retailers of consumer products to report any of the following situations immediately:

- A product that could create a substantial risk of injury to consumers;

- A product that creates an unreasonable risk of serious injury or death;

- A product that fails to comply with an applicable consumer product safety rule or with any other rule, regulation, standard or ban under the Consumer Product Safety Act, or any other statute enforced by the CPSC;

- An incident in which a child, regardless of age, chokes on a marble, small ball, latex balloon, or other small part contained in a toy or game and, as a result of the

incident, the child dies, suffers serious injury, ceases breathing for any length of time or is treated by a medical professional; and

- Certain types of lawsuits.

Whether or not a product falls under the regulation of the CPSC is an inquiry that should be evaluated and researched, if not immediately obvious.

And regardless of whether a recall is voluntary or mandated, all parties in the distribution chain may be affected — from raw material suppliers, manufacturers and distributors to the end consumers.

Communications During a Recall

Interaction With the Client

An attorney-client relationship is important for any product recall situation.

Counsel will want to establish lines of communication with the client, and identify primary points of contact for effective teamwork. It is crucial to be available, responsive, calm and clear with clients. In the event of a recall, clients will provide a wealth of information necessary to identify next steps and properly advise the client.

Clients, working alongside counsel, should identify all necessary stakeholders, provide essential facts about the product and the need for recall, and gather all available records. It is important also to evaluate the need for a legal hold and the scope of that hold.

Counsel should identify capabilities the client already has in place for recall action plans, including resources and experience. In an advisory role, counsel should also develop internal employee communications and advise the client on what not to say — e.g., no admissions or binding declarations.

Additionally, counsel should conduct a review of potentially applicable insurance policies, to ensure the company provides timely notice of potential claims and determine if there is potential coverage for losses incurred.

Interaction With Agencies

Product recalls must be reported to the agency handling the type of product in question. It is important to identify the agency that must be reported to, in order to understand what to report, how to report it, when to report it and who else needs to be involved.

Each agency may have their own procedure or internal process with guidelines for communication and additional steps to take. This is important to think about prior to any product recall, to determine what records should be kept for all communicating functions.

Expert Retention: During and After the Recall

Experts are a crucial aspect to navigating the recall process. First, identify the key issue that needs an expert. You may potentially need more than one expert, depending on the issues at hand.

Expert communications are, however, not automatically privileged material that is not discoverable. Communications between a company and expert may not be protected under the attorney-client privilege.

It is important to remember that including legal counsel on a communication with a consulting expert does not automatically trigger that protection.

If you claim privilege or work-product protections, it is your burden to prove, if challenged. This varies by jurisdiction, so it is imperative to know the case law of the relevant jurisdiction.

The best way to protect consulting expert material from disclosure is through retention letters or deputizing memos. Retention letters between the outside counsel and the expert that clearly identify the purpose for retaining the expert — e.g., "to assist in providing legal advice to client regarding recall response" — are useful to help protect privilege down the line.

Deputizing memos also assist in identifying core post-recall investigators, and expanding the legal team.

External Notification

It is important to properly notify parties involved and potentially affected by recalls, and to communicate the issue. Notification should take place as soon as possible, in a clear, concise, consistent and accurate manner.

Who to Notify

When a recall occurs, make sure to identify what regulatory agency may need to be notified, and then develop a plan to notify that agency and all stakeholders.

Regulatory agencies have specific guidelines that must be adhered to when a product recall occurs, so communication is key to properly correcting a situation. Avoid communicating with the public until a feasible corrective action plan is approved by the regulatory agency.

Once that occurs, make sure all public communications follow the regulatory guidelines.

Stakeholders must also be notified. Key stakeholders to consider are:

- Consumers;
- Suppliers;
- Distributors;
- Sales representatives;
- Everyone in the supply chain;
- Business partners;
- Investors;
- Insurance carriers;
- Internal employees, to ensure consistency; and
- Elected officials.

What to Include in a Notification

A product recall notification should include:

- The name of the recalling company;
- The product name and description;
- A photo of the product, if possible;
- The package size and type;
- Any product codes, dates and lot numbers;
- Volume;
- Geographic area; and
- Instructions for how to return the product, or properly dispose of it.

When to Notify

Time is of the essence! Notify the regulatory agency as soon as possible, once a product recall is issued.

Once the agency approves the corrective action plan, notify all others immediately.

Don't forget to take into account long-term business strategy and brand reputation in notifying about product recalls.

How to Notify

The most effective way to notify is to use multiple channels to reach all those potentially affected. Examples of communication channels to consider:

- Company and government websites;
- Press releases;
- TV, radio, newspaper and other news reports;
- Social media posts;
- Mailers or letters;
- Postings in stores; and
- Electronic notifications — e.g., emails, texts, phone calls, faxes.

The goal is to make sure everyone is informed. This may require utilizing additional communication sources, and potentially translating the notice if the product is distributed internationally.

After the Recall

After the recall process, work continues. First, keep an open dialogue with your key stakeholders — the regulatory agency, consumers, retailers and media, when appropriate.

Be sure they know you are open to continued communication, to foster a sense of goodwill. Brand loyalty is often at stake.

Second, it is important to take every chance possible to reinforce your commitment to safety. Always turn to your public relations and marketing experts to help spread that

message to key stakeholders.

Finally, conducting a postmortem of your efforts is helpful to assess the impact on your internal processes and teams. Be mindful of revisiting relationships with retailers and suppliers during this time.

Based on what is discovered from the postmortem, decide whether any updates to the recall response plan are needed.

Final takeaways in the case of a product recall:

- Be consistent in your communication;
- Conduct a focused and prompt investigation;
- Have a comprehensive litigation hold;
- Protect privilege when possible;
- Do not admit causation in company statements;
- Secure the evidence — i.e., the recalled product; and
- Obtain the right type of subject-matter experts.

Keep in mind that a robust recall can moot or provide defenses to many lawsuits.

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[1] See https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/cipla-issues-voluntary-nationwide-recall-six-batches-albuterol-sulfate-inhalation-aerosol-90-mcg-200.

[2] See https://www.cpsc.gov/Recalls/2023/Zuru-Recalls-7-5-Million-Baby-Shark-and-Mini-Baby-Shark-Bath-Toys-With-Hard-Plastic-Top-Fins-Due-to-Risk-of-Impalement-Laceration-and-Puncture-Injuries-to-Children.