

Product Recalls— A Potential Corporate Tragedy



One of the most important and costly decisions any manufacturer can make is undertaking a recall of its product. Recalls,

which usually result from accidents in the field, can generate more claims, lawsuits, possible class actions, and, depending on the product, government entanglements.

While there generally is no common law duty to recall a product, once a manufacturer voluntarily undertakes a recall, it can be liable if it does so negligently. In addition, a duty to recall a product exists in regulatory laws enacted in the United States and in many foreign countries. The last few years have seen a proliferation of new safety regulatory laws in foreign countries that require manufacturers to report safety issues to government agencies and possibly to undertake recalls.

As a result, the number of recalls and the number of reports to government agencies has increased significantly. Even with unregulated products, manufacturers have become more aware of the risks of not fixing safety problems that come to their attention. These can be used as the basis for a product liability case, usually also involving possible punitive damages. And, this theory, known as postsale duty to warn, lasts for the life of a product. Therefore, any time during the life of a product a manufacturer might learn of a risk in the field that needs fixing and decide that it should send a warning to product users or recall the product.

This article will discuss the ways in which a company can become organized and prepared to meet its post-sale duties and to undertake a field corrective action program or a recall. Given the growing



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importance of these subjects, various government agencies and other concerned entities recently have developed and proliferated guides, standards, and best practices in the United States and elsewhere. Taken together, these provide a good basis for a manufacturer to establish procedures and personnel necessary to meet its legal and practical obligations.

Recall Preparation

One of the most difficult things that I've ever done is to decide whether to encourage a manufacturer to prepare for a recall when the manufacturer first begins to design a product. This is not something that most manufacturers want to do. They are spending their time trying to produce and sell a product. Preparing for a recall is viewed as wasted effort since no one will admit that a recall likely will occur. Unfortunately, after a manufacturer sells a product, it is too late to do many of the things discussed below.

Some of the most significant elements to build into a product's design, manufacturing, and distribution processes are product marking and traceability procedures that are used before manufacture, during manufacture, and during distribution. To the extent possible, products, and especially safety-critical components, should be marked or coded so that anyone, including customers, can easily identify a recalled product and remove it or a component so that they can return or repair it.

This is not easy to do, and many manufacturers, especially those that have never had to recall their products, will wonder if the effort is worth it. Of course, in the event of a recall, this traceability will allow a manufacturer of a finished product or component part to narrow the affected population of products and more easily identify the population of customers. The customer might even be able to return the affected part and replace it with a new one. In that case, everyone benefits, from the manufacturer to the retailer to the consumer.

The next important consideration is for a manufacturer, in cooperation with all entities in the distribution chain, to design and maintain an effective database that can identify different types of entities, including product users, if possible. These databases must be updated periodically.

Manufacturers have new and interesting ways to accomplish this. In the past, manufacturers have relied on a customer sending in a warranty registration card. This has not worked well in the past. The ability now to register online with a manufacturer has made it a lot easier. And the

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enormous growth of retailer customer loyalty programs and membership retailers has made it much easier to trace products to specific customers. Also, I think that "QR" codes, quick response barcodes, can be programmed so that scanning the code with your smart phone will send someone's contact information to a manufacturer.

One of the most important and difficult tasks a manufacturer has before selling a product is to set up a communications network so that everyone who may need it will receive appropriate safety information. A manufacturer has a number of readily available sources of information anywhere its product is sold. Personnel should be trained to ensure that sufficient information is gathered concerning warranty claims, injury or damage claims, accidents, near misses, and customer complaints so that potential problems can be identified as early as possible.

Personnel should be trained to identify and clarify the information received so that it is accurate and substantiated. A manufacturer does not want to gather and maintain inaccurate and overstated complaints and claims that make it appear that a problem exists when, in fact, it does not. In addition, a company must decide which claims to follow up on and how to do so. Does the company need to see and analyze a product? Does it need to interview the product user or claimant?

Postsale information, some of it unsubstantiated or even incorrect, can be posted by consumers on the Internet, including to the new U.S. Consumer Product Safety Commission (CPSC) database. A company needs to monitor this and follow up when necessary. Ignoring such information can be risky, but following up on all alleged safety issues could be time-consuming, fruitless, and misleading. The goal is to separate the valid information from all of the information that is available and received.

A manufacturer must understand all legal reporting and recall requirements for each country in which it sells a product. The requirements have grown recently and are different from country to country. Consequently, a manufacturer may have a reporting responsibility in one country and not another. This may result in a recall in one country and not in another. In addition, different government agencies may expect manufacturers to announce and implement a recall in different ways. Coordinating multiple jurisdiction reports and recalls is a real challenge that is very detailed and time intensive.

Entities in a supply chain must consider contracts in anticipation of potential recalls or other corrective actions. Therefore, any company buying products or services for inclusion in a product needs to consider which entity should be financially and procedurally responsible in case that component part or service is defective. In addition, every entity in the distribution chain—dealer, distributor, and retailer—is potentially responsible for any accidents involving products that a manufacturer should have recalled. Therefore, the contracts between these distributors and the manufacturer are critical to establishing the duties and obligations and responsibil-

ities of each of these parties in the event of safety problems in the field.

Unfortunately, most of the time, purchase and sales contracts deal with warranty matters, extra-contractual damages, and remedies, but rarely recalls. Marketing personnel from a manufacturer do not mind discussing warranty with their customers, but raising the possibility of a product recall and who is responsible for that is not something that is considered helpful during the sales process. In addition, buying component parts from a small company can be difficult if that company believes that it will be fully financially responsible for any defects in that component part. And many times, it is unclear what caused a problem—a component part itself, the selection of the part, the installation of the part, or the use of the part.

Postsale Preparation

Every entity needs to have experienced technical and legal personnel who routinely evaluate postsale data and information and decide whether to report to a government and undertake a corrective action or to undertake a corrective action even if no government agency is involved. If adequate presale planning has occurred, gathering and analyzing the information and implementing the program will be less difficult and more organized than if no planning occurred. Everyone will know what to do and when to do it.

Virtually every manufacturer should have a functioning product safety committee the main function of which is to evaluate postsale information and make decisions concerning reporting to government agencies and undertaking corrective actions such as recalls. Decisions in this area are multifunctional and lend themselves well to the kind of brainstorming that decision makers can accomplish in a committee meeting. This is particularly true because different parts of a company will each receive information about postsale issues and so several members of a product safety committee might have information relevant to a postsale discussion, and sometimes, other members may not have the same information.

A product safety committee should have well-defined procedures as well as a list

of the people who should always participate and those who will participate on an as-needed basis. It is important to decide what power a product safety committee has to make decisions concerning corrective actions. For example, does it have the final decision or will it merely make recommendations to upper management?

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Legal counsel should definitely be involved in this committee since most of the discussions will be sensitive and could become the basis of a product liability case and even a claim for punitive damages. While it is not a good idea for legal counsel to try to make all of the writings of this committee privileged, counsel should provide some guidelines to committee members on what to write and what not to write and should review the minutes of the meetings and documents with recommendations.

Some manufacturers should consider running mock recalls. While these would not involve sending notices to consumers, the mock recalls might include notices to the first tier of distribution or possibly even further. The purpose of sending notices such as this is to mainly test the accuracy of the addresses—mail, e-mail or fax—that a company has for each of its direct customers. A company wants to be in a position to be able to immediately stop production, stop shipping, and stop sales of all products subject to a recall. Therefore, having the ability to communicate quickly to immediate customers, the distributors, and for these customers to be able to quickly communicate to their customers, meaning retailers, is important.

While it is still important to be able to communicate with the end-use customer eventually, a mock recall would not attempt this. However, if end-use customers send registration cards to a manufacturer, it might periodically send them a letter or an e-mail to test the accuracy of their addresses. Then, when the time comes for a manufacturer actually to communicate with them about a recall, most if not all of the addresses that it has will be current and accurate.

One other task that a manufacturer should undertake is to develop templates for various types of communications that it will want to send out in the event of a recall. If a manufacturer sells regulated products, it will want to look at the recall guides for those products to find the templates provided by the appropriate government agency or agencies. A manufacturer can then use these as the basis for template communications, recognizing that government-generated template models are a minimum standard, and a company might need to exceed the requirements of that agency.

A company might want to consider testing the template communications with sample users or even personnel in the company. A company wants to know whether the communication makes it clear that this is a safety-related matter it is important that customers comply, and what the company wants them to do is understood. In addition, a company might want to ask end-use consumers how they wish to receive such communications if any are necessary in the future.

The use of social media has significantly increased in the recent past. That is fine if a consumer is willing to receive information through these means and has signed up to do so. That is one reason why asking consumers how they wish to receive this information could be very valuable. Some may be willing to receive it by letter, others prefer e-mail, and others prefer Facebook, Twitter, or text messages.

Newly formed companies are developing social media recall applications that will help manufacturers send recall notices to those consumers who are interested in receiving this information. *See* RecallsPlus, <http://www.recallsplus.com/>; WeMakeItSafer,

<http://wemakeitsafer.com>; SafetyBook, <http://www.safetybook.org>. Manufacturers need to keep track of these developments and use those that make sense for their products.

Ultimately, I believe that almost everyone will be willing to receive communications in some electronic form, making it quicker and less costly to send recall notices or safety alerts. In addition, when stores have established loyalty programs for frequent customers, it makes it much easier to identify these customers and the products that they purchased. Costco uses the data gathered through cards carried by its millions of wholesale club members and calls them within 24 hours if they have purchased a recalled item. The company follows up with a letter. This results in Costco customers returning the vast majority of recalled products, 90 percent with some products, to the stores.

And failing to use available technology could even become the basis of a lawsuit. In a pending class action lawsuit in a federal court in California the plaintiffs claim that a grocer's failure to use its customer loyalty program to warn consumers about recalled food constitutes an unfair and deceptive act and a failure to warn. See *Hensley-Maclean v. Safeway, Inc.*, No. 3:11-cv-01230-RS (N.D. Cal., San Francisco Div., 2011).

Postsale Implementation

Many government agencies both in the United States and foreign countries have developed guidelines for implementing recalls. The U.S. Consumer Product Safety Commission has a recall handbook while the U.S. Food and Drug Administration (FDA) has guidelines and regulations for food, drug, and medical device recalls. The U.S. Department of Agriculture has recall guidelines for food, and the U.S. National Highway Traffic Safety Administration has them for motor vehicles and accessories. Therefore, if a company sells regulated products in the United States, it will want to look at the relevant agency's recall guidelines for help.

However, other agencies might have some useful guidelines that a company could consider in implementing its own recall program. Sometimes, due to the way that a manufacturer distributes products and the type of consumers who purchase them, another agency's guidelines might

overlap. So, for example, the FDA might regulate a home health care medical device but the manufacturer might actually sell it like a consumer product through drugstores.

The European Union and the governments of Canada and Australia have developed various recall guides, especially for consumer products. Some of these guides

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may actually be useful in structuring a recall program in the United States. For example, the European Union has a very good postsale risk assessment analysis requirement that could easily be used by a manufacturer in analyzing postsale risk in the United States.

The Organization for Economic Cooperation and Development (OECD) launched a global recalls portal on October 19, 2012. This Internet database will enhance information sharing across jurisdictions and support regulators who are undertaking corrective actions. The OECD also believes that the portal is beneficial to consumers and businesses because consumers can check products that they have purchased, and businesses can improve the tracking of emerging hazards from around the world involving similar products to various countries.

The OECD also believes that the portal will be of value to countries that do not have an electronic system on recalls as of yet. The portal initially is gathering recall data from the United States, Canada, Europe, and Australia. Additional countries will be added to the database.

In addition, during 2013, the International Organization for Standardization (ISO) will issue a new standard (ISO 10393) providing guidelines for consumer product recalls. This standard does a good job of describing the types of personnel who should be involved in establishing a product recall team, as well as the procedures that should be in place so that a company is prepared to undertake consumer product recalls. It also talks about recall objectives and how to develop a recall strategy and a recall process as well as how to develop a communication plan. All aspects of a good recall program are contained in this ISO standard.

Since the recall process is very similar no matter what the product is, whether a company makes consumer products, medical devices, drugs, motor vehicles, or industrial machinery, considering this ISO standard and the various government agency guidelines will help a company to come up with the best program for that company and one that incorporates the "best practices" used or suggested by entities with recall expertise. In that way, a company will implement a program that is easier to defend.

Conclusion

Compliance with the government's requirements and approval of your corrective action program is not a defense in a product liability case brought in the U.S. or most likely anywhere else. Therefore, thinking about the defensibility of the program as it is being implemented will help the company anticipate challenges to the program's adequacy and allow them to respond to suggestions that they could have done more and prevented the accident that is the subject of the lawsuit.

There have been significant developments, procedurally and technologically, around the world that should help the manufacturer do a better job in a more cost-effective way. But the manufacturer should plan for a recall as it is designing the product and before sale. Doing so will reap huge benefits if the worst happens and a recall occurs. This will help prevent the recall from turning into a corporate tragedy that hampers the company's activities or threatens to put it out of business. 