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2017

PRODUCT
RESOURCE
GUIDE

PREPARING FOR AND IMPLEMENTING PRODUCT RECALLS



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By Kenneth Ross

As this article is being written, there is news that Takata Corporation, the Japanese airbag manufacturer, has filed for bankruptcy in the U.S. courts because of its airbag recall in the U.S. and elsewhere. After the bankruptcy is complete, this company, which has been in business for many decades, will no longer exist. And there will still be millions of cars that need their airbags replaced. In addition, Takata has agreed to pay a \$1 billion fine to the government, and three of their employees have been criminally indicted.

While this is an extreme example of a disaster that can befall a manufacturer as a result of a recall, it is a red flag about the importance of companies doing what they can to avoid recalls, and to have an effective way to accomplish a recall when, and if, one is necessary.

This article will discuss the ways in which a company can be organized and prepared to meet its post-sale duties and to undertake a field corrective action program or a recall. Given the growing importance of this subject, there has been a recent proliferation of guides, standards and best practices developed in the U.S. and elsewhere. Taken together, these can significantly help a manufacturer establish procedures and train its personnel as necessary to meet its legal and practical obligations.

RECALL PREPARATION

Some of the most significant elements to build into the 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 the component to be returned or repaired.

This is not easy to do and many manufacturers, especially those who 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 the manufacturer of the finished product or component part to narrow the affected population and more easily identify the affected population of customers. The customer might even be able to remove 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 the manufacturer, in cooperation with all entities in the distribution chain, to design and maintain an effective database so that different types of entities, including product users if possible, can be identified. These databases must be updated periodically.

There are new and interesting ways in which this can be accomplished. In the past, manufacturers have relied on the customer sending in a warranty registration card. This hasn't worked well. The customer's ability now to register online with the manufacturer has made it a lot easier. And the enormous growth of membership retailers, such as Costco, and retailer customer loyalty programs has made it much easier to track product purchases to specific customers. Also, QR codes on the product or the packaging can often be programmed so that scanning the code with your smartphone will automatically send your contact information to the manufacturer.

One of the most important and difficult tasks is for the manufacturer to set up a communications network before sale so that appropriate safety information is received. A manufacturer has a number of readily available sources of information anywhere its product is sold and used. Personnel should be trained to ensure



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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. The 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 doesn't. In addition, the company must decide which claims to follow up on and how to do so. Do they need to see and analyze the product? Do they need to interview the product user or claimant?

Post-sale information, some of it unsubstantiated or even incorrect, can be posted by consumers and others on the Internet. This information needs to be monitored and followed up where 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 out the valid information from all the information that is available and received.

The manufacturer must understand all legal reporting and recall requirements for each country in which its products are being sold. The requirements have grown recently and are different from country to country. The result is that there may be a reporting responsibility in one country and not another, resulting in an uneven pattern of required recalls. In addition, there may be differences in the ways in which different government agencies expect the manufacturer to announce and implement a recall. Coordinating reports and recalls in multiple jurisdictions is a significant challenge that can be very detailed and time-intensive.

Entities in the supply chain must consider appropriate contractual provisions that anticipate potential

recalls or other corrective actions. Therefore, any company buying products or services for inclusion in their product needs to consider which entity will be financially and procedurally responsible in case that component part or service is defective. In addition, every entity within the distribution chain - dealer, distributor, and retailer - is potentially responsible for any accidents involving products that should have been recalled. Therefore, the contracts between these product sellers and the manufacturer are critical in establishing the duties and obligations and responsibility 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 the manufacturer don't mind discussing warranties with their customers, but raising the possibility of the product being recalled and who is responsible 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 they will be fully financially responsible for any defects in that component part. And many times, it is difficult to determine what caused the problem - the component part itself, the selection of the part, the installation of the part or its use.

POST-SALE PREPARATION

Every entity in the supply chain needs to expect that a recall may be necessary at some point. Importantly, they need to have experienced technical and legal personnel who routinely evaluate post-sale data and information and decide whether to report to the government and undertake a corrective action or to undertake a corrective action even if no government agency is involved. If adequate pre-sale planning has occurred, gathering and analyzing the information and implementing the corrective action 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 whose main job is to evaluate post-sale information and make decisions concerning reporting to government agencies and undertaking corrective actions such as recalls. Decisions in this area are multi-functional and lend themselves well to the kind of brainstorming that can be accomplished in a committee meeting. This is particularly true because information about post-sale issues are coming into different parts of the company and therefore several members of the committee might have information relevant to the post-sale analysis that can be discussed.

There should be well-defined procedures for the committee, 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 the committee has in making decisions concerning corrective actions. For example, do they have the final decision or are they merely making recommendations to upper management?

Legal counsel should be a member of this committee and provide advice as required, since most of the discussions will be sensitive and could become the basis of a product liability case and a governmental enforcement action. While it is not a good idea for legal counsel to make the writings of this committee legally privileged and confidential, it can and should provide some guidelines to committee members on what to write and what not to write, and on the process for reviewing meeting minutes and documents with recommendations.

Some manufacturers may want to consider conducting mock recalls. While these would not involve sending notices to consumers, it might include notices to the first tier of distribution or possibly even further. The purpose of sending notices like this are to mainly test the accuracy of the addresses – mail, e-mail or social media – that are available. In cases in which a company needs to immediately stop production, shipping and sales of all products subject to the recall, it is important to have the capability to quickly communicate to immediate customers (i.e. distributors) and for customers to be able to quickly

communicate to their customers (i.e. retailers).

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

One other task that should be undertaken is to develop templates for various types of communications that you will want to send out in the event of a recall. If you sell regulated products, you will want to look at the recall guides for those products to find the templates provided by the appropriate government agency. You can then use these as the basis for your template communications, recognizing that these represent the minimum requirements of an agency, and that you might choose to exceed those requirements.

You might also consider testing your template communications with sample users or even personnel within your own company. You want to know whether the communication makes it clear that this is a safety-related matter, that their compliance is important, and that the communication clearly states what you want them to do. In addition, you might want to ask end-use consumers how they would like to receive such communications if any are necessary in the future.

The use of social media has significantly increased in recent years. That is fine if the 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 would like 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.

Some new companies are developing recall applications using social media which will help manufacturers get recall notices to consumers interested in receiving this information. Manufacturers need to keep track of these developments and utilize those that make sense for their products. Ultimately, almost everyone should be willing to receive communications in some electronic form, thus making it quicker and less costly to send out recall notices or safety alerts.

In addition, where stores have established loyalty programs for frequent customers, these make it much easier to identify customers and the products they've purchased. One membership chain uses the data gathered through cards carried by its millions of members to contact them within 24 hours of a product recall if they have purchased that item. The company follows up with a letter. This results in the vast majority of recalled products (as high as 90 percent with some products) being returned to the store.

POST-SALE IMPLEMENTATION

Guidelines for implementing a recall have been developed by many government agencies in the U.S. and elsewhere around the world. The U.S. Consumer Product Safety Commission has a recall handbook, while the U.S. Food and Drug Administration has guidelines and regulations for food, drug and medical device recalls. The U.S. Department of Agriculture has recall guidelines for food, as does the U.S. National Highway Traffic Safety Administration for motor vehicles and motor vehicle accessories. Therefore, if you are selling regulated products in the U.S., you should look at the relevant agency's recall guidelines for help.

However, other agencies might have some useful guidelines that you could consider in implementing your own recall program. Sometimes, products overlap in the way they are distributed and the type of consumers who purchase them. So, for example, a home health care medical device might be under the jurisdiction of the FDA but sold as a simple consumer product through retail drug stores.

The European Union (EU) and the governments of Canada and Australia have developed various recall guides, especially in the area of consumer products. Some of these guides may be useful in structuring your recall program in the U.S. For example, the EU has a very good post-sale risk assessment analysis requirement that could easily be used by a manufacturer in analyzing post-sale risk in the U.S.

In addition, the International Organization for Standardization (ISO) issued a new standard (ISO 10393) in 2013 that provides guidelines for consumer product recalls. This standard does a good job of describing the types of personnel who should be involved in the establishment of a product recall team, as well as the procedures that should be in place so the

company is prepared to undertake consumer product recalls. It also discusses how to develop a recall strategy, recall objectives 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 similar regardless of whether the product is a consumer product, a medical device, drugs, motor vehicles or industrial machinery, considering this ISO standard and the various government agency guidelines will be helpful in coming up with the best program for your company and one that incorporates the "best practices" employed by or suggested by entities who are experts in product recalls. That way, you should be able to implement a product recall program that is likely to be more effective and easier to defend in cases of post-recall litigation.

CONCLUSION

Compliance with the government's requirements and approval of your corrective action program is typically not a defense in a product liability case brought in the U.S. or most other jurisdictions. Therefore, thinking about the defensibility of the program as it is being implemented will help your company anticipate potential challenges to the program's adequacy, and allow you to respond appropriately to potential legal challenges that arise from product-related accidents.

There have been significant developments, procedurally and technologically, around the world that can help manufacturers do a better job in a more cost-effective way. But a manufacturer must think about and carefully plan recall procedures even as it works on designing new products. Doing so can reap huge benefits if the worst happens and a recall occurs. It can also serve to prevent a product recall from becoming a corporate tragedy that hampers the company's activities or threatens to put it out of business. 