Recall Planning and Administration:

Legal and Practical Requirements for Recalls

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Table of Contents

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I. Introduction

One of the most critical decisions a manufacturer selling into the United States can make is whether to undertake a post-sale corrective action such as a recall. For unregulated products, it is only necessary for them to consider the U.S. common law of post-sale duty to warn. For regulated products, the manufacturer must consider the common law as well as the law and practices of the applicable U.S. government regulatory agency. However, it does not stop there.

There has been a significant increase in the enactment of regulatory laws around the world requiring manufacturers or product sellers to report safety issues to the government and to undertake post-sale activities. And some of these countries, such as Canada, also have an established common law for post-sale issues.

Despite the existence of all of these laws, it is not clear whether the manufacturer will be encouraged or required to recall its products from the distribution chain, including consumers, and how that recall should be implemented. This will be a critical decision, especially if the post-sale corrective actions are inconsistent from country to country.

This paper will discuss the common law and regulatory law and its application to regulated and unregulated products and then some recent developments that will be helpful in identifying best practices in undertaking recalls.

II. Common Law and Regulatory Law

A. Common Law Post-Sale Duty to Warn

Courts in the United States first enunciated a manufacturer's post-sale duty under the common law in 1959. Since that time, most courts have adopted some form of post-sale responsibility, but have differed greatly on when this duty arises and how far it goes.

It has been fairly clear for many years that this post-sale duty utilizes a negligence balancing test to decide when a duty arises and what needs to be done. Generally, the law says that the higher the level of risk of injury to consumers and the lower the level of difficulty in getting a message to those consumers, the greater the duty to at least warn them.

In the late 1990s, the new Restatement of Torts Third: Products Liability ("Restatement 3d") set forth factors to be considered in this negligence balancing test. However, the Restatement section dealing with post-sale duties only envisioned a duty to warn. In another section within the Restatement, the American Law Institute, consistent with the common law, limited the duty of a manufacturer to recall its products.

This section stated that a manufacturer has a duty to recall its product if a "governmental directive issued pursuant to a statute or administrative regulation specifically requires the seller or distributor to recall the product." Since this almost never happens, as a practical matter, there is no general duty to recall products under the common law. As a result, the additional language in this section is more relevant.

It says that a manufacturer could be held liable if they voluntarily undertake to recall the product despite the lack of a governmental directive and perform it negligently. Since virtually all recalls of government regulated products are technically voluntary, this statement of the common law must be seriously considered when deciding whether to undertake any post-sale actions.

This, of course, makes a decision by a manufacturer to recall its product in a marginal safety situation especially important. As we all know, when a recall has occurred, some plaintiffs file suit for injuries involving these products, even if the safety issue that prompted the recall had nothing to do with the incident. Many of these cases settle since manufacturers, or their insurance companies, don't want to risk an adverse verdict where doing so could encourage more injury claims as well as possible class actions.

In addition, the common law limits any requirement for a manufacturer to inform product customers about any post-sale safety improvements where the original product was properly designed and manufactured. In other words, no duty exists where the product involved in the incident was not defective when sold. This law was confirmed by the Restatement 3d which said that there is no such duty unless the balancing factors for issuing a post-sale warning are met.

As a result, manufacturers making post-sale safety improvements must evaluate the risk that a jury will consider the product without the safety improvement to be defective, thereby possibly triggering a duty to inform customers about the safety improvement or placing the company in serious potential legal risk if no notice is provided.

B. Application of Common Law to Unregulated Products

As I mentioned above, this common law is the only law that needs to be considered by unregulated products such as industrial products, construction equipment and farm equipment. Despite the lack of a common law duty to recall its products, a manufacturer of unregulated products still has a difficult decision to make as to whether or not to undertake any post-sale program, be it a post-sale safety improvement or an actual recall or retrofit program.

And, as stated above, if the manufacturer voluntarily undertakes to perform some post-sale program, it cannot do it negligently. Unfortunately, given the vagueness of the negligence standard, especially when trying to predict how a particular jury might react to the facts, manufacturers of such products need to be very careful before they undertake a program, especially where they will have difficulty finding customers.

I have served as a recall adequacy expert in litigation for a number of years. One of my most interesting cases illustrates the risk of a voluntary recall of an unregulated product. A manufacturer of an industrial product experienced a product failure in the test lab shortly after the product was first sold. Out of an abundance of caution, the manufacturer decided to recall the approximately 200 products that had already been sold. They were able to retrieve approximately 198 of these products. Customers for the last two products failed to respond to the recall letter and the manufacturer eventually gave up trying to retrieve the remaining products. Unfortunately, over 10 years after this recall, one of the remaining products was involved in an incident where an individual was seriously hurt.

One of the claims alleged by plaintiff was that the recall was inadequate and that the manufacturer was negligent in that it did not succeed in retrieving the product involved in this incident. Since the accident occurred so long after the recall was completed, it was difficult for the manufacturer's employees to reconstruct what happened and what actions they undertook to locate all of the products to be recalled. Unfortunately, during a move of one of the manufacturing plants, many of the documents concerning this recall were misplaced or thrown away. Therefore, this manufacturer was unable to document that the recall letter was actually sent by them or received by the employer of the injured employee.

First, I questioned whether a recall was necessary in the first place. There had been a failure in the lab and the manufacturer decided to make some safety improvements in the product going forward. However, there had been no incidents with any product users at that point and therefore one reasonable decision could

have been not to recall the product, but to keep a close eye on any post-sale incidents indicating any future risk of injury.

Again, the manufacturer thought that they were acting in the best interests of safety even if they had little reason to believe that their product was defective or that anyone would be hurt in the future. Given the lack of helpful evidence on the recall letter and the seriousness of the injury, the manufacturer was presumably sufficiently concerned about the reaction of the jury to the post-sale safety improvement and the recall that the case ultimately settled for a significant sum.

I've wondered how the case would have played out if the manufacturer had not undertaken a recall and instead was defending this one incident. The manufacturer could have argued that there was nothing wrong with the original product even though the design change made future products safer. The lack of any accidents, except for the one involved in the litigation, would have supported this argument.

C. U.S. Regulated Products

Regulated products in the U.S. are mainly governed by the Consumer Product Safety Commission, the Food and Drug Administration, and the National Highway Traffic Safety Administration.

All of these agencies have fairly well developed regulations on when a manufacturer has a duty to report a possible safety issue to that agency. The reporting responsibility is based on the existence of a possible future risk of serious injury or death or a high risk of many minor injuries.

However, after the report is made, the question then becomes when a corrective action is necessary and how far it goes. There are differences among the agencies in determining whether a consumer level recall is necessary. The FDA classifies a reported safety issue as class I, II or III. This classification helps the FDA and the manufacturer to develop a recall strategy, including whether consumers need to be notified and the rate of recall effectiveness that should be achieved through consumer notification.

Once a report is made to the CPSC, the Recall Handbook provides some guidance as to whether a recall from the consumer level is necessary and if one is undertaken, what elements constitute an adequate consumer notification program. The CPSC Recall Handbook says:

> When a company reports to the Commission, the staff of the Division of Recalls and Compliance undertakes the same product hazard analysis as that requested of firms. First, the staff considers whether the product contains a defect. If the staff believes there is a defect, it then assesses the substantiality of the risk presented to the public, using the criteria listed in section 15 (that is, pattern of defect, number of defective products distributed in commerce, severity of the risk, likelihood of injury and other appropriate data). In determining preliminarily whether the product in question creates a substantial product hazard, the staff applies hazard priority standards to classify the severity of the problem.

The staff internally classifies the hazard as Class A, B, C, and D, although they don't usually inform the manufacturer of that classification. On this point, the Recall Handbook goes on to state:

> The hazard priority system allows the Commission staff to rank defective products uniformly. For example, a Class A hazard rating is reserved for product defects that present a strong likelihood of death or grievous injury or illness to the consumer. Should the staff make a preliminary determination that a product creates a substantial product hazard, the hazard priority system also provides a guide for selecting the level and intensity of corrective action.

Most reports to the CPSC are based on the existence of a "defect" and a "substantial product hazard." However, many times companies report if there is a defect or possible defect even though the company does not believe that there is a substantial product hazard.

I have reported in the past to the CPSC on behalf of clients where there is a defect but they have not had any incidents and had no reason to expect that any would occur. In these cases, they argued that no consumer level corrective action was necessary because there was no substantial product hazard and the CPSC agreed. In other situations, I have reported on behalf of clients where incidents have occurred, but we did not believe there would be any future incidents or if any incidents occurred, the injuries would be minor. In those cases, we also argued that no consumer level corrective action was necessary, and the CPSC agreed.

III. ISO Standard on Recalls

In 2013, a new standard from the International Organization for Standardization entitled ***"Consumer product recall - Guidelines"*** was finalized and issued. This standard (ISO 10393) 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. This is critical as a lack of preparation will always result in a potentially inadequate recall.

In the standard, there are extensive suggestions on how to develop a recall strategy, recall objectives and recall process as well as how to develop a communication plan. I believe that these procedures are more extensive than the procedures suggested by consumer product government agencies in the U.S., Canada, the European Union (EU) and Australia and therefore should be considered as a company develops a recall program. The company should strive to meet or exceed the requirements and good suggestions made by these various entities.

IV. Organization for Economic Co-operation and Development (OECD)

In 2012, the OECD launched a global recalls portal. This Internet database will enhance information sharing across jurisdictions and support regulators who are undertaking corrective actions. The OECD believes that the portal will be beneficial for consumers and businesses in that consumers can check products that they have purchased and businesses can improve tracking of emerging hazards from around the world involving similar products.

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

This recall portal is phase 1 of an OECD project whose goal is to enhance information sharing on consumer product safety. Additional elements of the project involve developing mechanisms to coordinate international product safety initiatives more effectively and to support regional and global efforts to promote harmonization of standards and highlight emerging issues.

In addition, the OECD will be using the Internet to publish studies of hazards, update regulatory activities and establish a web directory of safety experts. Last, the OECD wants to pool information on product hazards that could develop a confidentiality protocol for sharing research information and enhancing international cooperation on traceability.

These efforts should be tracked by any company selling globally as they might prove to be helpful in learning about hazards early and publicizing recalls quickly.

V. U.S. Government Accountability Office (GAO)

The GAO issued three reports in 2011 and 2012 making recommendations about how recalls could be improved for medical devices, food and motor vehicles. The GAO analyzed recalls implemented by the FDA and NHTSA and made recommendations for improvements. Regarding consumer products, the GAO issued two reports in 2012 concerning the CPSC, but none of them dealt with product recalls.

Anyone interested in recalls should be interested in these reports even if they deal with products that you do not deal with. Some of the observations, findings and recommendations have a broad application to all kinds of products subject to recall, even those in non-regulated industries.

A. Medical Devices

The first report was issued by the FDA in June of 2011, entitled ***"Medical Devices: FDA should enhance its oversight of recalls."*** GAO interviewed FDA officials and examined information on medical device recalls from 2005 to 2009. Based on these interviews and a review of FDA documentation, the GAO made recommendations for developing enhanced procedures and criteria for assessing the effectiveness of recalls and documenting the agency's basis for terminating individual recalls.

This report was undertaken at the request of Congress which was concerned with the effectiveness of the medical device recall process in that there had been reported incidents where individuals were seriously injured or died due to defective devices that have been recalled.

The GAO evaluated 3510 recalls from 2005 to 2009 with some interesting statistics on time to complete the recall as well as the kinds of products most subject to recall (cardiologic being the highest and infusion pumps the most prevalent for general hospital and personal use devices). In addition, they classified the root cause of these recalls and came up with process control, device design and component design and selection as resulting in the highest number of recalls.

The FDA found gaps in the medical device recall process which limited their effectiveness and timeliness. In particular, the FDA's procedures for overseeing recalls were unclear, and the FDA had not established criteria, based on the nature or type of devices, for assessing whether firms corrected or removed a sufficient number of recalled devices. Also, the FDA did not document its justification for terminating recalls and sometimes took too long to terminate.

There were some anomalies noted by the GAO report – the majority of recalls are class II yet class I recalls more than doubled between 2008 and 2009, and many recalls have been ongoing for 5 years – that could not be explained by the FDA. In addition, there were concerns expressed by manufacturers about the length of time it can take FDA to classify recalls and the confusion that can be created, especially when the recall starts off as class II and then the FDA classifies it as class I.

And GAO identified a variety of inconsistencies in how recall audit checks were implemented and documented, especially when an investigator concludes that the audit was effective or ineffective. The FDA admitted that there are no detailed instructions or requirements for conducting audit checks. This gap is fairly significant in that no criteria or guidance is provided by the FDA on the desired percentage of recalled products that must be corrected or removed. Medical device firms said that the percentage was not the key to the FDA, as long as they made three attempts at communicating with customers and device users about the recall.

Generally, the FDA agreed with the GAO's recommendations and has convened a working group to analyze each of the recommendations and develop improvements in their processes for analyzing, implementing and terminating recalls.

B. Motor Vehicles

Also, in June 2011, the GAO issued a report entitled ***"Auto Safety: NHTSA has options to improve the safety defect recall process."*** This report was requested by Congress who raised questions about the recall process, including the sufficiency of NHTSA's oversight authority and whether vehicle owners are being effectively motivated to comply with recalls.

The GAO interviewed the auto industry, auto dealers and auto customers. They made recommendations about how to improve the recall process and recall completion rates. First, they suggested that NHTSA could modify the way that manufacturers present information in safety defect notification letters and publicize information resources, like NHTSA's website, so that vehicle owners are better motivated and informed. Secondly, NHTSA may be able to use manufacturer's data to identify what factors make some recalls more or less successful than others so that NHTSA can better target the monitoring of recall campaigns and identify best practices. Finally, expanding NHTSA's recall authority may help identify more defective vehicles and improve recall completion rates.

The report contained some interesting information concerning the way the NHTSA assesses a recall's effectiveness from the quarterly reports filed by manufacturers. The agency generally uses an internal guideline on completion rates to assess whether a second notification is warranted. The minimum completion rate identified by the NHTSA in the GAO report is 10% after the first quarter of the recall campaign, 20% after the second quarter, 30% after the third quarter and 65% at the end of the sixth quarter, the last report necessary to be filed.

There are a number of other factors which impact the effectiveness rate and completion rate of a vehicle recall. But the agency officials who were interviewed told the GAO that they do not analyze such trends in determining the completion rate data of recall campaigns.

Interestingly, the GAO analyzed the authority granted to various other government agencies in the U.S. and in foreign countries to compare those with the authority granted to the NHTSA. The foreign agencies analyzed were in Canada, Germany, Japan and the UK.

In their interviews with manufacturers, some identified difficulties in notifying vehicle owners about safety defects. For example, there was mention that not all vehicle owners keep their address information up to date with state motor vehicle registration offices. In addition, the older the vehicle, the more changes of ownership and mailing addresses occur, making it more difficult to identify the current address of the current owner.

One of the more useful portions of this study describes focus groups with vehicle owners who discussed new or additional methods of communicating recall information that might help increase recall completion rates. The focus groups identified elements of a recall letter which may lead to higher rates of response:

- a clear explanation of the severity of the defect, including an explanation that does not use jargon, which can be confusing. For example, instead of using the acronym "ABS," focus group participants would prefer the words "anti-lock brake system."
- the word "urgent" to indicate the seriousness of the defect.
- a question-answer format because, as one participant described, it spells out the issue, provides an immediate answer, and allows recipients to pick and choose the parts that are most necessary to read.

- an apology from the manufacturer.
- the owner's vehicle identification number (VIN) information. As one participant explained, including a VIN in the body of the defect notification letter clarifies whether this recall applies to the owner's vehicle.
- readable font size.
- an indication of whether there is any cost involved with the recall remedy.

NHTSA acknowledges that it has not developed a standard template for notification letters because each recall is different. But, they also believe that adding more content to the letters could be distracting and that the current requirements provide sufficient information concerning the defect, the recommended actions, and the remedy.

Interestingly, none of the almost 90 participants in the focus group said they were familiar with www.safercar.gov and more noted that they use Google when they search for information related to safety defects. GAO felt that a centralized database (developed by NHTSA or another party) that allows consumers to search for recall information by VIN would allow vehicle owners to determine if their specific vehicle is affected by a recall. And, the agency is in the process of purchasing software to facilitate a VIN-based search engine on its Web site.

On completion rates, the GAO report said:

> our analysis of NHTSA's completion rate data for passenger vehicle recalls from 2000 through 2008 found considerable underlying variation in completion rates in several areas. Overall, we found that annual recall completion rates varied substantially by year—from about 55% to 75%—for all passenger vehicles with safety defect recalls, with an average across all years of about 65%.

And GAO noted that "the agency does not currently use the data it collects to conduct a higher-level analysis across all campaigns to systematically look for potential factors related to higher or lower recall completion rates that might be helpful in identifying successful recall campaigns because conducting such analyses is resource intensive." NHTSA responded and said that "they were currently re-evaluating how they used their data and would consider ways that additional data analysis could help increase recall completion rates."

There was discussion about the difficulties of rental car companies and used car sellers getting information about the defect recall and changes that could be made to provide better information to them and to users and purchasers of both rental cars and used cars. In 2011, Nissan announced that they were partnering with Carfax to get more information out about car recalls to purchasers of used vehicles over the Carfax network.

C. Food

The last report by the GAO on recalls was published in July of 2012. Its title is ***"Food Safety: FDA's Food Advisory And Recall Process Needs Strengthening."*** This report was generated at the request of Congress in the Food Safety Modernization Act (FSMA). In this report, the GAO examined the government's authority to order product recalls, examined the challenges FDA faces advising the public about food recalls, and identified ways to compensate the food industry for erroneously ordered food recalls and advisories.

In its conclusion, the report stated:

> The agency has taken steps to begin meeting these challenges but has yet to fully address recommendations from GAO and others to fashion a comprehensive food recall communication policy and related implementation plans.

The steps taken by the FDA to better communicate recalls are detailed in the agency's ***Strategic Plan for Risk Communication*** which was issued in the Fall of 2009. One of the major challenges is to provide timely and accurate information to all potential purchasers of the food to be recalled. Unlike most other products, the government cannot wait until injuries or illness manifest themselves, but, must take proactive steps in anticipation of these problems. And sometimes, the safety notice or recall turns out to be premature or even unnecessary.

In the GAO report, they describe a methodology to test draft recall communications with users that was developed by the FDA. The FDA felt that it was difficult to anticipate how consumers would understand and evaluate certain communications unless it had been tested beforehand. This is interesting and not something commonly done by any other government agency or manufacturer before a recall notice or safety alert is issued.

The GAO report also states that the FDA has not fully implemented a recommendation from GAO's 2004 report concerning recall communications. In 2004, the GAO stated that press releases and web postings may not be effective in adequately communicating recalls. GAO stated that USDA had improved its method of sending out recall communications (*i.e.* through Twitter) but that the FDA had not consulted with USDA nor have they made any significant improvements.

The ability of food producers and retailers to post notices in grocery stores, include QR codes on food packaging and, in other ways, directly communicate with consumers, has been greatly enhanced over the years. For example, using a grocery stores' loyalty program to communicate recall information seems like a sensible and cost-effective improvement.

VI. Conclusion

Manufacturers should be aware of all good ideas provided by anyone to come up with the best recall program possible and appropriate for the risk that exists. Going outside the industry in which they are involved might yield useful results. The government agencies, in the U.S. and elsewhere, do talk to each other about issues of common interest. Hopefully, improving recall procedures and effectiveness rates is or will be one of those subjects.

But there are also companies developing more recall applications through social media that will help manufacturers get recall notices to those consumers who are interested in receiving this information. See http://www.recallsplus.com/; http://wemakeitsafer.com; http://www.safetybook.org. Manufacturers need to keep track of these developments and utilize those services that make sense for their products.

When manufacturers who sell globally recall their products, it is important that they be successful in all countries, not just the U.S. Continuing accidents and injuries and inadequate recall completion rates in other countries can have an adverse effect on U.S. products liability litigation. It could even trigger further follow-up recall efforts required by the U.S. government agency. Therefore, best practices being developed anywhere in the world are appropriate to consider adopting.