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Recall Effectiveness: An Update

by Kenneth Ross



As we all know, recalls can be the most costly and damaging event in any manufacturer's corporate experience. Not only do they cost a great deal to implement and resolve, but they can generate many new product liability cases and make all of them harder to defend. In addition, they might even generate class-action lawsuits which can cost many millions of dollars to resolve.

An example of how expansive the problem with recalls can be is a pending class action lawsuit in California where a plaintiff claims 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. Sateway, Inc.*, No. 11-1230 (U.S. Dist. Ct., N.D. Cal., SF Div. (2011).

In addition, the increase in recalls has also created problems. Recalls have become so numerous that there is a new phenomenon called "recall fatigue" that threatens to make relatively ineffective recalls even more ineffective. This makes it harder to defend the recall to the government and in a product liability case.

Despite this, manufacturers and retailers are striving to create new ways to make recalls less costly and more effective. For example, 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 then follows up with a letter. This results in the vast majority of recalled products being returned to the store. See "*Officials worry about consumers lost among the recalls*," Washington Post, July 1, 2010.

Since recall adequacy is based on negligence, the jury gets to decide whether the manufacturer could have done more. Adopting the best practices that have been issued by government agencies and standards groups and utilized by other manufacturers is very difficult to do. There are many different ways to undertake recalls and it is hard to know exactly what would work best for a particular company and their products.

As a result, a manufacturer must try to be aware of the various ways in which recalls have been undertaken and are suggested to be undertaken so that they can adopt and be prepared to utilize techniques that are effective, not too costly, and defensible. In addition, when defending the adequacy of a recall, considering the "best practices" employed or suggested by others can be helpful in arguing that you did a non-negligent job of recall.

While relying on the government's regulations and guidelines and approval of your recall will not provide a certain legal defense to a claim of negligent recall, it can be helpful in bolstering an argument that you did all that was necessary. As a result, it is useful to learn about new developments and new research on what is effective.

I have previously written several times before about the issue of product recalls and how to make them more effective. I want to devote this column to further information about new developments in the standards and international areas and about several studies released by the U.S. federal government on how to improve product recalls.

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improve product recalls.

ISO Standard on Recalls

In a prior article, I mentioned the imminent passage of a new ISO standard (ISO 10393) entitled "**Consumer product recall - Guidelines.**" This standard is in its final form and should be finalized and issued this year. 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. 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.

Organization for Economic Co-operation and Development (OECD)

In another development, the 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 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.

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.

- Medical devices



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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.

- 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

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

recalls from 2000 through 2009 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 percent to 75 percent—for all passenger vehicles with safety defect calls, with an average across all years of about 65 percent.

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. See <http://www.expertrecall.com/nissan-takes-recall-notification-to-the-next-level/>.

- 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.

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.

Kenneth Ross is a former partner and now Of Counsel in the Minneapolis, Minnesota office of Bowman and Brooke LLP where he provides legal and practical advice to manufacturers and other product sellers in the area of warnings, instructions, safety communications, recalls and all areas of product safety and product liability prevention. Mr. Ross can be reached at 952-933-1195 or kenrossesq@comcast.net. Other articles on these subjects can be accessed on www.productliabilityprevention.com.

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