Recall: A Difficult Decision

By
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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 article will discuss the common law in the United States as well as recent activities of the Consumer Product Safety Commission in encouraging manufacturers to undertake consumer level recalls.

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 Products Liability 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.

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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 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.

<u>Application of common law to unregulated products</u>

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.

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.

<u>A change in CPSC policy?</u>

The CPSC staff has publicly stated for years that they prefer manufacturers to report if in doubt as to whether there is a defect or a substantial product hazard. In addition, they have told manufacturers that a significant percentage of reports do not result in a corrective action and, therefore, manufacturers shouldn't be afraid to report because they are concerned that such a report will result in a recall.

Despite these assertions, there are some indications that some CPSC compliance personnel have become more aggressive in their position on the need for consumer level recalls and that more recalls are being undertaken where there is no reasonable and substantiated belief that there is a

future substantial product hazard. In other words, the CPSC staff, when analyzing a product that has a defect that could possibly pose a risk of serious injury or death, is not engaging in any serious probability analysis and merely concluding that a recall is necessary. In addition, there is evidence that, with certain products, the CPSC staff believes a recall is necessary if there has been a serious injury or death, even where there is arguably no defect in the product. Last, the staff has exhibited a bias in favor of recalls even where the risk of injury is miniscule. The example is lead paint recalls.

The possible reasons for these changes are multi-faceted. The CPSC now has five Commissioners, with the "Democratic" commissioners now being in the majority. In addition, the new chairman is demonstrably a more aggressive safety regulator and has appointed new senior personnel at the Commission who share her vision. All of this translates into an agency that is under a great deal more pressure to do more to advance safety than the Commission was perceived to have done under the prior President. This is a political reality and not a criticism.

With more recalls being undertaken where the product has never had an incident or where the product does not have an apparent defect, an issue has arisen that the media has referred to as "recall fatigue." This allegedly results in important recalls being less likely to be noticed or being noticed but ignored. This syndrome of "crying wolf" might make it harder to achieve a high return rate, thus creating significant potential liability for negligence under the common law in the event of an accident.

An illustration of this possible change in philosophy involves a baby product made by a number of manufacturers. One manufacturer was made aware of a death involving their product. No claim was made. After being informed by the CPSC of this death, the CPSC told the manufacturer that nothing more needed to be done. Three years later, the CPSC became aware of more deaths involving other manufacturers of this type of product and decided to issue a safety alert. The safety alert pointed out the risks of injury or death where the product user did not follow the warnings and instructions provided by the manufacturer. In addition, the alert clearly described to users how to use these products safely.

Three months later, the CPSC changed its position and decided that all manufacturers of these products should recall their products from consumers instead of relying on the safety alert that they had just issued three months earlier. It was intimated that the reason for the change in position was that the new Commissioners were taking a tougher stance on evaluation of future risk. I have no confirmation that this was true.

Remember that generally a defect and substantial product hazard or non-compliance with a safety standard is necessary to justify a recall. In the case of these products, it was arguable that the CPSC did not believe that these were defective products or they would not have issued a safety alert three months earlier.

This manufacturer had been selling thousands of products over 15 years and was only aware of one incident, albeit a death caused most likely by the consumer not following the clear warnings and instructions. There was no reason to believe that any further injuries or deaths would occur and, in fact, the manufacturer had changed its warnings and instructions to be consistent with those included by the CPSC in their safety alert.

The CPSC staff basically told manufacturers that if there was a death with this product, it must be recalled even without clear proof of defect or any determination of future probability of harm. In other words, a death equaled a recall. The manufacturer argued that the safety alert was much more effective in enhancing the safety of this product in that parents would not return the product or stop using it even if they became aware of the recall. This is a product that has been in use for many years and, like most products, can result in harm if not used properly and in accordance with the manufacturer's instructions.

It does not make sense to require the recall of a product where the consumer does not follow the warnings and instructions and an injury or death could result or has resulted. If that was the case, most products would have to be recalled and there would be no way to more safely design them.

The result of the staff position was that this manufacturer went out of business because they were unable to continue to sell their products. Four months later, the CPSC changed their position again and said that manufacturers of these products would not have to recall their products. Instead, the CPSC issued another safety alert and is supporting the passage of a voluntary safety standard. Unfortunately, this was too late for at least one manufacturer who today remains out of business.

This issue was also raised at the recent annual meeting of the International Consumer Product Health and Safety Organization ("ICPHSO"). I argued at one of the sessions that there have been too many recalls, especially involving situations where there have been no incidents or just minor incidents. Surprisingly, some manufacturers stood up and argued that they had been strongly encouraged and even "bullied" into doing recalls by the CPSC even though they did not believe that there was any risk of substantial harm.

In other words, these manufacturers were confirming the supposition that some staff are not engaging in risk assessment in deciding whether the manufacturer should undertake a consumer level recall. Instead, they equate a defect with a recall if there is <u>any</u> chance of a serious injury or death. In the past, manufacturers have argued that if there is a defect in the product and no known incidents have occurred, that a consumer level recall is not necessary.

We all understand the pressure on the CPSC to have a product recalled when there is any chance of a serious injury or death. It is an easy decision for them but one that puts the manufacturer in a very difficult position. They would first try to resist a recall requested by the CPSC. And, if they decided to undertake a recall after further encouragement by the CPSC, this could slightly increase safety, but more likely result in serious legal risks and huge costs if class actions are filed or incidents occur. It seems today that almost any serious recall results in a class action or shareholder lawsuit.

At the ICPHSO meeting, the CPSC discussed some of these issues privately and publicly. Their statements confirmed differences of opinion within the staff and between the staff and the commissioners over the question of when a recall at the consumer level is appropriate.

If the CPSC continues to encourage recalls in marginal safety situations, it could cause some manufacturers to decide not to report such matters to the CPSC. If there is a defect, but the manufacturer does not believe that there is a substantial product hazard, they have no duty to report. As I said above, many manufacturers have reported anyway in the belief that the CPSC

would agree with their analysis and not require a recall. If this changes, then manufacturers could rightfully decide not to report.

Conclusion

This possible change in philosophy at the CPSC, when combined with the new reporting laws in various foreign countries, will create new angst among manufacturers. They want to do the right thing from a safety standpoint, but do not want to undertake a corrective action that is unnecessary, costly, and does not enhance safety. This could adversely affect the manufacturer, suppliers, retailers, and consumers.

The CPSC and other government agencies should announce any change in the way they intend to analyze the need to undertake consumer level recalls and allow manufacturers to comment. Final decisions by the CPSC and manufacturers should be made that comport with the law and regulations and with what is in the best interests of everyone concerned.