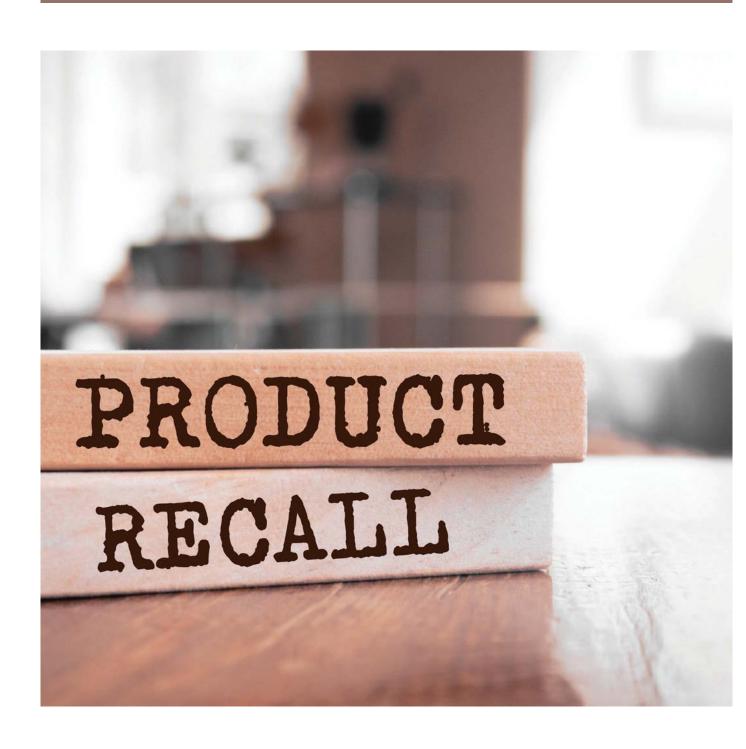
CREATING AN EFFECTIVE AND DEFENSIBLE PRODUCT RECALL

Recent Requirements Can Be Helpful



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by Kenneth Ross

he recent news is replete with stories about product recalls being undertaken because of safety issues. In addition, there have been a number of recent jury verdicts based on injuries or deaths caused by a product that has been recalled, should have been recalled, or is in the process of being recalled. Needless to say, recalls can have a significant adverse effect on a manufacturer's or product seller's reputation, financial condition, relationship with retailers, and the ability to successfully defend a product liability case.

The law makes it easy for an injured party to claim that a recall was inadequate and that this inadequacy contributed to their injury. In addition, government entities in the U.S. and Europe are beginning to demand that companies do more things that should make their recalls more effective.

This article will discuss the law concerning recalls and recent government efforts to improve the effectiveness of such actions.

THE LAW

Court-made law ("common law") that has been adopted by most states in the U.S. is generically referred to as the "post-sale duty to warn." It states that a manufacturer may have a duty to warn consumers about hazards revealed after sale if consumers were not initially warned when the product was first sold. In addition, some state legislatures have enacted statutory laws that create a post-sale duty for products sold in that state.

This duty is based on negligence, which occurs after the product has been sold. Negligence is usually decided by a jury and is based on an allegation that the manufacturer failed to exercise reasonable care and that this failure resulted in injury, damage, or loss. In other words, could the manufacturer have done more after sale to initiate the recall or corrective action earlier or done something to make it more effective, thus preventing the injury from occurring? Unless you are completely successful in your recall, you can always do more. However, since each jury gets to decide what is negligent, there really is no guidance for the manufacturer as to what "reasonable care" is and how effective the recall must be.

The common law and state statutory laws generally refer to "a duty to warn" and do not establish "a duty to recall." The law that pertains to the U.S. Consumer Product Safety Commission (CPSC) also does not require that the manufacturer always recall its product. The CPSC says that if the product has a defect that could create a substantial product hazard, the manufacturer must offer one of three remedies – replacement, repair, or refund of the subject product's purchase price.

In addition to the duty to warn, the common law also says that if a manufacturer voluntarily recalls its product, it can be held liable for injury or damage if the recall was done negligently. Virtually all recalls done under the supervision of a government agency are voluntary, and none are 100% effective. Therefore, the question is how to implement a recall that will not be considered negligent.

Another consideration when designing the recall or corrective action is whether you are providing a sufficient remedy to the consumer from a safety and economic standpoint. For example, if you are repairing the product, are you doing it for free? Or are you repairing the part or product but should be replacing it?

One new series of lawsuits that have recently been filed involve class actions alleging that the recall remedies are inadequate and, therefore, the consumer has suffered some economic loss. These lawsuits can be filed even though there have been no incidents resulting in injury or damage. Most of the class-action lawsuits filed for an "inadequate remedy" have been against automobile manufacturers who have recalled their products, but most of these lawsuits have been dismissed by the court. However, there have also been cases filed against consumer product manufacturers that are still pending.

One recent case was brought against a bicycle parts manufacturer.1 The complaint states:

"Even though Shimano has finally acknowledged the widespread issue, it is working hard to limit the cost of fixing the issue at the expense of consumers. Rather than offering to issue refunds or replacements for all of the Defective Cranksets, Shimano has taken the unconscionable position that only '(c)onsumers whose cranksets show signs of bonding separation or delamination during (an) inspection will be provided a free replacement crankset . . . that the dealer will professionally install'."

The plaintiffs go on to allege:

"This proposed remedy is a nightmare for riders and bike shops. Owners are left without usable bicycles while they get in line with hundreds of thousands of other impacted cyclists to schedule and await an inspection. When the inspection finally happens, a local bicycle mechanic is tasked with making a complex engineering judgment to determine whether the crankset shows sufficient deterioration to merit replacement."

The plaintiffs conclude by alleging that:

"Plaintiffs and the other Class members were deprived of having a safe, defect-free crankset installed on their bicycles, and Defendants unjustly benefited from the sale of these products and from the unconscionable limitations on the recall remedy now offered."

Plaintiffs are asking for reimbursement of all of the expenses that consumers could be subjected to as a result of this recall which would include a refund for the purchase price of the defective crankshaft.

Manufacturers should think about designing the remedy so that there is little risk that consumers will file a class action alleging that they suffered economic loss.

PRE-SALE PREPARATION

Below are some actions that companies can take to have a more effective and defensible recall or other post-sale corrective action.

Various entities in the supply chain should try to establish procedures before the product is designed and sold so that after the sale, each organization can easily and efficiently obtain and analyze information, make decisions about any appropriate post-sale remedial programs, and implement any necessary programs.

Some of the most significant elements to build into a product's design, manufacturing, and distribution processes are traceability and marking procedures that are used before and during the manufacturing process and during distribution. To the extent possible, products, and especially safety-critical components, should be marked or coded so that in the event of a recall, the part can be traced to a specific product or part and can be easily replaced or repaired.

This traceability allows the manufacturer of the finished product or component part to narrow the affected population and clearly identify the population to the government, retailers, and customers.

One of the most important and difficult tasks for the manufacturer is setting up a communications network before the sale so that appropriate safety information is received if there is an issue after sale.

A manufacturer has many readily available sources of information anywhere its product is sold. Personnel at the component supplier, the dealer, and the OEM should be trained to ensure that sufficient information is gathered concerning warranty claims, injury or damage claims, accidents, near misses, and customer inquiries or complaints so that actual or potential problems can be identified.

Personnel should be trained to identify and clarify the information received so that it is accurate, substantiated, and properly documented. The manufacturer does not want to gather and maintain inaccurate and overstated complaints and claims that incorrectly make it appear that a problem exists.

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? Do they need to see the location of the incident?

POST-SALE PREPARATION AND IMPLEMENTATION

As a manufacturer obtains and analyzes post-sale information, it must determine whether any post-sale action is necessary at any point in time. This includes reporting to the CPSC and possibly undertaking some form of recall, repair, or replacement.

Analyzing the information and deciding what it means is the most critical phase of this process. It is recommended that manufacturers conduct a risk assessment prior to selling their products. This process identifies the risk, the probability of the risk occurring, the potential consequences if it occurs, and methods to minimize the risk.

Before sale, the manufacturer should make a best guess on the probability of the risk occurring. Of course, it is difficult to estimate the probability of an event occurring when it has never happened before. After sale, when events occur, a new risk assessment should be conducted by both the manufacturer and any applicable component supplier. This is easier since you are now aware of safety-related incidents and potential vulnerabilities.

Once you decide to undertake a recall or other corrective action, the process should be designed so it is as effective as possible given the information that has been obtained or could be obtained by the manufacturers, component part suppliers, or product sellers. For an earlier discussion of governmental guidances and British codes of practice on effective recalls, see my article entitled "Preparing for and Implementing Product Recalls in 2022," from the May 2022 issue of In Compliance Magazine.²

CPSC RECALL ENHANCEMENT EFFORTS

The CPSC has been talking about efforts to make recalls more effective for at least 20 years. One of their first efforts was to retain an outside consultant to study the literature on recall effectiveness and suggest ways for manufacturers and product sellers to do better.³ Then there were recall effectiveness workshops presented by the CPSC in 2017⁴ and a report issued in 2020 by the U.S. Government Accountability

Office (GAO) with recommendations on actions that could be undertaken by the CPSC to improve recall effectiveness.⁵

Then, in February 2023, the CPSC made a presentation at the International Consumer Product Safety and Health Organization (ICPHSO) Conference that discussed "Corrective Action Plan Enhancements." These enhancements have been incorporated into corrective action plan ("CAP") agreements negotiated by the CPSC and manufacturers or product sellers. The main enhancements from the CPSC this year deal mainly with the internet and social media as these are much more likely to be accessed by potential customers than in the past.

When manufacturers and product sellers file a "non-Fast Track" report with the CPSC and agree to undertake a corrective action, they most likely will receive a proposed CAP agreement that could include some or all of the following enhancements to earlier corrective action agreements:

- In addition to the issuance of a press release, the company will publicize the CAP through all social media and mobile platforms. If the company does not have a social media presence, the CPSC may demand that they establish such a presence.
- Provide at least two CPSC staff-approved direct notices to all known consumers via mail, e-mail, phone, or text messages.
- The CPSC will specify how often the company must post on Facebook, Twitter (now "X"), and Instagram and require that these posts be available for a minimum of 10 years.
- The CPSC might request that the company initiate paid social media advertising on all of its mostfollowed social media platforms.
- The CPSC might request the company take out search engine advertisements and display ads on their retailer's websites.
- The CPSC might also request that internet platforms that sold the recalled product provide two rounds of direct notice to customers who purchased the product on their internet platform.
- The CPSC may require confirmation within 30 days of the press release as to which platforms and retailers sent out CPSC staff-approved direct notice of a hazard to all known purchasers.

In addition, the CAP agreement might include a requirement for a compliance program which states as follows:

"The company will create and maintain a Compliance Program designed to ensure compliance with the CPSA and all other Acts and regulations administered by the CPSC. The company will identify a Safety Officer or Safety Committee responsible for the Firm's compliance. The company agrees to provide documentation of the program and the specific modifications to its existing Compliance Program, if any, to address any material deficiencies, within 90 days of the acceptance of this CAP."

CPSC trial attorneys are the compliance officers for these non-Fast Track filings. In December 2023, a CPSC trial attorney made a video presentation about what actions the CPSC views as contributing to an effective recall.6 It should be noted that the "requests" in the non-Fast Track CAP agreements go well beyond what has been required over the years for a Fast Track filing.

CPSC FY 2024 OPERATING PLAN

The CPSC Commissioners recently agreed to their 2024 operating plan. This plan has several goals that relate to recall effectiveness. The CPSC is seeking a response rate for all recalls of 33%. Most response rates in the past have been much lower. And the CPSC is trying to get 70% of all filing companies to agree to use social media to communicate a recall.

In addition, the CPSC identified the following priority activities for FY 2024:

- Examine mechanisms to improve recall effectiveness by exploring measures of consumer awareness of recall information either by direct contact or secondary means.
- Encourage commitments from recalling firms to communicate recall information to consumers in Spanish and additional languages commonly spoken in the United States.
- Conduct a study on consumer behavior in response to product recalls and implement the study's recommendations.
- Work with firms to maximize communications about recalls through multiple communication channels and the use of technology.

- Prioritize resources to improve its recall monitoring process and conduct follow-up activities with firms, as appropriate.
- · Work with a variety of stakeholders to be able to better understand consumer behavior in the recall context and to increase recall response rates.
- · Seek mandatory recalls where firms will not take corrective actions voluntarily.
- Expand the recall monitoring program to identify recalling firms that are appropriate targets for an expanded recall announcement, a renewed investigation, or enforcement action.

EUROPEAN UNION

Increasing the effectiveness of recalls remains a top priority for the Commission of the European Union (EU) and is explicitly addressed in the recently enacted EU's General Product Safety Regulation (Regulation (EU) 2023/988) which will come into force on December 13, 2024. Rutger Oldenhuis, a leading EU recall expert, summarizes this priority as follows:

"In the EU, enhancing the efficiency of product recalls continues to be a key focus for the EU Commission and is explicitly addressed in the upcoming EU General Product Safety Regulation (Regulation (EU) 2023/988). Research indicates that one-third of consumers who have read a recall notice still continue to use the unsafe product in question. Therefore, the new Regulation includes extensive new recall obligations for manufacturers of consumer products. The impact of these new measures could be significant."7

The new regulation includes several measures described below to improve recall effectiveness:

- Providers of online marketplaces that collect their customers' personal data shall make use of that information for recalls and safety warnings.
- Product registration by consumers for direct notifications regarding recalls and safety warnings shall be encouraged. This includes integrating direct contact mechanisms into customer loyalty programs and product registration systems.
- The Commission shall be empowered to adopt implementing acts in order to specify that for some specific products or categories of products, consumers should always have the possibility to

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register a product they have purchased in order to be directly notified about a recall or a safety warning related to that product.

- Recall notices should not minimize the risk at stake or be drafted in a complex way. Recall notices should be clear and transparent, and describe risks clearly. The recall notice must avoid any elements that may decrease consumers' perception of risk, for example by using terms and expressions such as "voluntary," "precautionary," "discretionary," "in rare situations" or "in specific situations" or by indicating that there have been no reported accidents.
- Economic operators must offer consumers at least two options between repair, replacement, or adequate refund of the recalled product unless the second remedy would be impossible or impose disproportionate costs on the recalling party.

On the issue of recall effectiveness, Oldenhuis has also stated:

"Effectiveness in product recall management introduces an intriguing paradox. The more successful and efficient a recall is in reaching and persuading consumers to return or stop using the recalled products, the greater the costs incurred, and consequently, the more significant the financial and reputational damage inflicted upon the manufacturer. One might assume that manufacturers would therefore opt for recall insurance. However, in practice, this is mostly not the case. Companies often seem to rely on the belief that a recall won't affect them." 8

Many of the requirements in these new regulations are based on a 2021 behavioral study done by the EU on strategies to improve the effectiveness of recalls. In addition, the UK Office for Product Safety and Standards issued a report in 2020 based on research it performed in 2017. The research tested behaviourally-informed product recall messages with a consumer panel. Responses were measured in terms of perception, sense of urgency, emotional response and likely action. 10

CONCLUSION

It is exceedingly difficult to defend cases where a recall has occurred unless you can show that the consumer read the recall notice and decided not to return the product to the manufacturer. Therefore, manufacturers should spend sufficient time to carefully prepare before sale and after sale for the possibility of a recall. This includes carefully designing a program that will be defensible if there is a class-action suit alleging an inadequate remedy or a lawsuit for injury, damage, or economic loss brought by an individual consumer or to satisfy or exceed the requirements or desires of the applicable government authority. \P

ENDNOTES

- Erazo v. Shimano, et al, USDC, Central District of California, filed October 3, 2023.
- 2. https://incompliancemag.com/article/preparing-for-and-implementing-product-recalls-in-2022
- 3. See "Recall Effectiveness Research: A Review and Summary of the Literature on Consumer Motivation and Behavior." https://www.cpsc.gov/s3fs-public/RecallEffectiveness.pdf
- 4. https://www.cpsc.gov/Recall-Effectiveness
- 5. https://www.gao.gov/products/gao-21-56
- 6. https://www.youtube.com/watch?v=a0Y-drY4qa4 (starting at the 12-minute mark)
- 7. From Rutger Oldenhuis, RecallDesk, https://www.recalldesk.com, in an email to the author dated November 27, 2023.
- 8. From Rutger Oldenhuis, RecallDesk, https://www.recalldesk.com, in an email to the author dated November 26, 2023.
- 9. https://op.europa.eu/en/publication-detail/-/publication/1a695500-9e31-11ed-b508-01aa75ed71a1/language-en
- 10. https://www.gov.uk/government/publications/insights-into-product-recall-effectiveness