

To Warn or Not to Warn— Obligations, Risks and Considerations in Product Improvements

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I. Introduction

Innovation is a key driver for any manufacturer. Developing better products, however, can reveal the weaknesses, failings, and even, possibly, the hazards of existing products. What does a manufacturer do when it becomes clear that its existing products are potentially unsafe, or could become safer in light of further research and development?

A manufacturer has a clear duty to ensure that a product it produces and sells is reasonably safe for its intended purpose. Once a product is sold, however, it leaves the manufacturer's control. Products are sold and then resold, possibly over and over again over a span of decades. The growth of global markets and the internet, which has expanded the resale market and makes the resale of products easier and more common, present challenges for manufacturers, the least of which is determining and communicating with the ultimate consumer. Manufacturers' post-sale common law duties are distinct from time-of-sale duties, and are in addition to manufacturers' duties under consumer protection regulation.

This paper will give an overview of the post-sale duty to warn and the post-sale duty to recall or retrofit existing product when innovation helps improve the safety of existing products. In particular, this paper will raise the general post-sale considerations in-house counsel may need to address when implementing product improvements, such as advising consumers of new advancements and undertaking voluntary product recalls.

II. Part I: Overview of Post-sale Duties

Product liability law is a matter of state jurisdiction. Prior to 1998, and the passage of the American Law Institute's ("ALI") *Restatement of Torts (Third): Products Liability* ("*Restatement (Third)*"), a manufacturer's duty to warn was widely recognized, but the cases were often contradictory and difficult to reconcile. While the *Restatement (Third)* is influential and has helped clarify the law on post-sale duties, some states have explicitly rejected the duties espoused in the *Restatement (Third)*. Therefore, while we attempt to draw generalizations, in-house counsel should always be aware of the need to obtain the advice of experienced preventive counsel when faced with a potential duty to warn or voluntary recall.

A. Post-sale Duty to Warn

A point-of-sale duty to warn is distinct from a manufacturer's duty to take reasonable care in manufacturing a product. A point-of-sale duty to warn involves notifying consumers of risks associated with its normal use at the time the product is sold. The manufacturer has control of the product and can easily give this warning to consumers with minimal additional expense. A *post-sale* duty to warn is, however, a more onerous obligation: the product is no longer in the manufacturer's control and it may not even be possible for the manufacturer to identify the consumers to whom a warning should be directed. A manufacturer cannot rely on a post-sale duty to warn consumers as a means to avoid liability if a product is defective when it was sold. They are separate duties.

Section 10 of the *Restatement (Third)* sets out a general post-sale duty to warn by both manufacturers as well as sellers and distributors of products, and provides:

- (a) One engaged in the business of selling or otherwise distributing products is subject to liability for harm to persons or property caused by the seller's failure to provide a warning after the

time of sale or distribution of a product if a reasonable person in the seller's position would provide such a warning.

The duty to warn is based in negligence. Any seller or distributor (which would include the manufacturer) is required to warn consumers of *newly* discovered dangers associated with the use of a product if a "reasonable person in the seller's position would provide such a warning." The determination of whether this objective standard was met by the manufacturer will be highly contextual and fact specific.

The *Restatement (Third)* lists the following factors to aid the court in determining whether a reasonable person would warn consumers:

- (b) A reasonable person in the seller's position would provide a warning after the time of sale if:
 - (1) the seller knows or reasonably should know that the product poses a substantial risk of harm to persons or property; and
 - (2) those to whom a warning might be provided can be identified and can reasonably be assumed to be unaware of the risk of harm; and
 - (3) a warning can be effectively communicated to and acted on by those to whom a warning might be provided; and
 - (4) the risk of harm is sufficiently great to justify the burden of providing a warning.

The commentary to §10 recognizes that a balance needs to be struck between protecting consumers from significant harm and the burdens imposed on sellers to identify and warn customers. The language of "substantial risk of harm" limits the scope of the duty: product-related accidents that occur infrequently and which are unlikely to cause substantial harm do not trigger a duty to warn. The *Restatement (Third)*, however, does not provide specific guidance on what constitutes a "substantial risk of harm." It should be noted that it is the *risk* which must be substantial: this refers both to the likelihood of the risk materializing as well as the magnitude of the likely harm. Clearly, a real risk of death or serious bodily injury triggers a post-sale duty to warn. However, the risk of lesser personal injury or property damage may also be sufficient to require a warning, if the risk is likely to materialize.

Outside the specific areas of automotive, aviation, pharmaceuticals and medical devices, manufacturers may not have mandated post-sale duty to conduct surveillance of product safety. They are, however, under a continuing duty to warn consumers of known hazards posed by their products, or hazards that, acting reasonably, they should have known about. However, in practical terms, manufacturer warranty programs and consumers reporting of defects and injury provide manufacturers with information about the safety records of their products. Once a manufacturer is aware of a safety issue, in-house counsel should turn his or her mind to the factors outlined in §10(b) to determine whether it has a duty to warn, including:

- The nature of the product and its users: are the users of the products vulnerable, *i.e.* children or the elderly?
- Is the product widely used and mass-marketed, or is it a specialized item with a narrow and distinct market?
- How serious is the harm or danger posed by the product in its ordinary use or likely misuse? Is the potential harm likely to cause serious injury or death?
- The number of incidents reported to it or through its distributor network. How frequent are these incidents in light of the number of units in the market?
- How long is the product life? Is it possible to determine at what point in the product life-cycle that the injuries or risk is arising?

- Is it possible to reach the ultimate consumers? Are products frequently serviced or otherwise brought back within the manufacturer's control or distribution network?
- What kind of action do consumers need to take in light of the harm posed? Do consumers need to stop using the product immediately?
- Is it possible to retrofit or modify the product to eliminate the hazard? Does the manufacturer need to do the retrofit or could the consumer do the retrofit properly?
- What is the cost and effectiveness associated with giving this warning? How does the manufacturer monitor compliance?

We note that the s.10 of the *Restatement (Third)* is not reflected in all states' law, but it does represent best practices. Readers should note that the precise content of the duty to warn may vary slightly from state to state. For example, in some states, the post-sale duty to warn may be limited to latent defects at the time of manufacture. Michigan is such a state (*Gregory v. Cincinnati, Inc.* 538 N.W.2d 325 (1995)). In other states, the post-sale duty to warn may be broader and require warnings of any significant risks which become known to the manufacturer after sale.

The decision to provide a warning to consumers may be a difficult one. There are potentially significant legal consequences for a manufacturer that fails to warn consumers of newly discovered defects or safety issues with products they manufacture. And there could be serious consequences by warning of defects or hazards. The decision is not one that should be left to sales or business units.

B. Post-sale Duty to Recall

Once consumers are warned of a significant risk posed by an existing product in the market, the question may then become whether the manufacturer is required to do anything to remedy the safety issue. Prior to the *Restatement (Third)*, there were contradictory views on whether a common law duty to recall or retrofit products existed that would require a manufacturer to offer a remedy where none is required by a relevant regulator.

A duty to recall products when new dangers are discovered is primarily a matter in the control of product safety regulators, such as the Consumer Product Safety Commission, the Food and Drug Administration (or Health Canada) the National Highway Traffic Safety Administration, the National Transportation Safety Board and the Federal Aviation Administration (or Transport Canada). Regulations enforced by these agencies impose various duties on manufacturers to follow the safety of their products and report safety issues and may issue directives requiring a recall or remedial action.

The *Restatement (Third)* recognizes the primacy of regulatory oversight. Liability for a negligent recall based on *newly* discovered defects in §11 of the *Restatement (Third)* arises only when a governmental directive requiring a recall is issued or the seller conducts a voluntary recall. A manufacturer, however, is not otherwise under a duty to offer consumers a remedy to a newly discovered defect.

Section 11 provides:

One engaged in the business of selling or otherwise distributing products is subject to liability for harm to persons or property caused by the seller's failure to recall a product after the time of sale or distribution if:

- (a) (1) a governmental directive issued pursuant to a statute or administrative regulation specifically requires the seller or distributor to recall the product; or

(2) the seller or distributor, in the absence of a recall requirement under Subsection (a)(1), undertakes to recall the product; and

(b) the seller or distributor fails to act as a reasonable person in recalling the product.

If a seller complies with its regulatory obligations to report newly discovered defects to the relevant regulatory agency, and the regulator does not conduct an investigation or does not issue a directive to recall the product, the manufacturer does not have a further independent duty to recall the product (although there may still be a duty to warn consumers). A manufacturer, however, may have many other reasons, such as consumer retention and the protection of its brand and associated goodwill, which will lead it to offer consumers a remedy to newly discovered dangers posed by their products. If a manufacturer nevertheless voluntarily undertakes to recall a product, it must act as a reasonable person in the product recall. In reality, a manufacturer may be ready to launch a remedy or recall but must wait for the relevant regulatory authority to approve and authorize the remedy or recall program. This puts the manufacturer in a difficult position in the case of a voluntary recall.

Again, as with the case of the post-sale duty to warn, certain states have rejected the §11 duty in the *Restatement (Third)*. Advice of local counsel may be required to determine the extent it may be liable for damages to consumers (in addition to administrative or regulatory sanctions) if it fails to recall a product or fails to act reasonably in a voluntary recall.

III. Part II: The Problem of Innovation

Manufacturers often improve upon their product design on a regular basis. As technology improves, manufacturers are able to use superior materials, improved manufacturing processes, and better product design. However, if the improved product solves a previous defect, does a post-sale duty arise? Are manufacturers obliged to notify their consumers of every product improvement or when it is possible to modify a product to eliminate a known risk? Innovation, therefore, is a double-edged sword.

A. Advancement of the State of the Art

Additional research and development of a product may result in the discovery of a previously unknown defect. Once a manufacturer learns of a defect which poses a substantial risk of harm, there is likely a post-sale duty to warn. As noted in Part I above, the *Restatement (Third)* distinguishes between the manufacturer's duty to warn of the risks associated with the normal use of its products at the time of sale and a more onerous post-sale duty to warn of newly discovered risks or dangers.

Courts, too, recognize that innovation would be stifled if manufacturers faced liability for products they have sold every time they made safer products. The desire to encourage innovation and the development of safer products is a widely-acknowledged policy choice that underlies many decisions in which courts have rejected a post-sale duty to warn, or, where such a duty exists, a duty to recall or retrofit.

It is important to note that there is a distinction between discovering a previously unknown risk versus simply making product improvements. A manufacturer discovering that a product poses a substantial risk obviously may trigger the post-sale duty to warn in addition to regulatory reporting obligations. A product improvement, however, without more, does not trigger the post-sale duty to warn. While the fact that a manufacturer adds a safety feature to an existing product design, or enhances its safety may suggest that the existing product is defective, an existing product does not become defective simply because future products are safer. A safety improvement is not evidence that the original product was not reasonably safe for its intended

purpose. If a manufacturer learns through field reports or consumer feedback that the improvement also addresses a safety concern, there may also be a duty to warn, depending on the nature of the hazard.

Manufacturers are only required to design to the state of the art at the time the product was designed and manufactured. Innovation advances the state of the art. An automobile that was safe in 1978 is no longer safe by today's state of the art. Where technology advances such that new designs can improve safety, the new feature should be considered as an advancement in the "state of the art" and older models should not be deemed defective. However, if the safety improvement corrects a defect that existed at the time of sale (that is, a defect that the manufacturer knew about, or should have known about) the previous model may be considered defective. The discovery of an existing or original defect may expose the manufacturer not only to liability for the original defect, but also to potential post-sale duties.

Certain industries, however, operate under a heightened duty to warn. The duty to warn is based on reasonableness, the duty is heightened depending on the industry of the manufacturer. For particularly hazardous and heavily regulated products, the post-sale duty to warn may be more stringent. Pharmaceutical manufacturers, for example, are held to the standard of an expert in the field (*Proctor v. Davis*, 291 Ill.App.3d 265). As an expert, the manufacturer is obligated to keep abreast of scientific developments relating to its product, continuously warn physicians of the risks of the drugs, and to notify the medical profession of any additional side effects discovered. The Illinois Appellate Court found that a pharmaceutical manufacturer cannot wait for sufficient proof of a cause-effect relationship before alerting the medical profession of the risk. Further, a failure to warn cannot be excused merely because the potentially endangered users are few in number.

For expert manufacturers, courts have required them to warn of improvements in their product, even if the product was reasonably safe when it was sold. These manufacturers may be required to notify of new scientific knowledge gained after the product has been released to the market. This heightened duty for drug and medical device manufacturers is based in part on the presence of a learned intermediary, namely physicians, who are easily accessible to the manufacturer. Generally, drug or medical device manufacturers are not required to notify the consumer directly, and may notify the learned intermediary. This is different than a heavy machinery manufacturer, for example, which must locate its products and identify its customers, for products which may have been sold and re-sold countless of times. This is also true for juvenile product manufacturers, due to the vulnerability of the users.

B. Duty to Retrofit or Recall

Manufacturers may focus initially on complying with the requirements of the relevant regulatory agency when faced with a mandatory product recall. However, aside from an agency mandated recall, manufacturers should be aware of liability surrounding voluntary recalls or retrofits. Courts have attempted to draw a distinction between a recall and recall in *Bell Helicopter Co. v. Bradshaw*, 594 S.W.2d 519 (Tex.Civ.App.1979), *Dion v. Ford Motor Co.* 804 S.W.2d 302 and *Ostendorf v. Clark Equipment Co.*, 122 S.W.3d 530 (2003). The difference between a recall and a retrofit is not clearly delineated in the cases. A retrofit, in theory, is not a recall. A recall generally involves the manufacturer withdrawing a defective product from the market and replacing it with a new product. A retrofit may involve the manufacturer *replacing* a *defective* component, but not replacing the defective product with a new product. More generally, however, a retrofit may also provide consumers with the ability to take advantage of the opportunity enhance the safety of a non-defective product. In a classic recall situation, the manufacturer typically is addressing a post-sale safety issue caused by a newly discovered defect. In the case of a retrofit program, the manufacturer is upgrading existing products, whether defective or not, in order to enhance the product's safety in light of newly discovered defects or technological advances.

Innovation and technology advances that improve existing products do not require a manufacturer to retrofit or recall previous models of the product. The *Restatement (Third)* intentionally excluded a duty to retrofit or recall a product since courts have rarely imposed such a duty on manufacturers. The courts have taken an even more restrictive view with the duty to recall than with the duty to warn. Generally, a manufacturer does not need to recall or retrofit their products to incorporate post-sale state of the art designs. In some instances, courts have gone as far as holding that there is no duty to recall or retrofit products posing a life-threatening hazard, unforeseeable at the time of sale (although there may be a duty to warn). The courts have, so far, been sensitive to the concern about discouraging innovation and advancements. In *Lynch v. McStome and Lincoln Plaza Associates*, 378 Pa.Super.430., the Superior Court of Pennsylvania has found that imposing a duty to retrofit products with changes in the state of the art would inhibit manufacturers from developing improved designs. The court found such a duty to be onerous and oftentimes impossible. Courts have often reiterated that if such a duty is to be imposed, it is the legislature or government agency that is better suited to weigh the consequences and competing interests at stake.

However, this is not to suggest that a manufacturer can safely assume that it is under no obligation to provide a remedy if it discovers a post-sale danger in an existing product. Courts have in the past imposed a duty to recall in certain circumstances where the risk of harm is widespread and severe. The nature of the defect will play a large role in determining the appropriate course of action. If the discovered risk poses a serious risk of harm, a recall will likely be mandated by regulatory authorities. If a large number of products are likely to be affected, a voluntary recall may be appropriate, either at the manufacturer's own instance, or in cooperation with a regulatory agency. Similarly, a recall may be reasonable if the manufacturer is able to regain control over products in the marketplace, for example, because the market is highly specialized and users can be easily identified and contacted, or the products are frequently returned to the manufacturer or a distribution network for service.

C. Voluntary Recalls and Retrofits

In certain situations, regulatory agencies have mandated a recall, such as where the risk of harm is widespread and severe (for example with airplanes). Even if the regulator would not mandate a recall, the decision to implement a *voluntary* recall program presents additional legal obligations on the manufacturer to act reasonably in carrying out the recall. If a manufacturer voluntarily assumes a duty to recall its products, it then has a duty to act reasonably, and with the same level of conscientiousness as if it were a government-directed recall. This duty is not based on a duty to recall, but on the general duty of care to avoid foreseeable harm as well as the duties placed on anyone who undertakes to render services to another person, who then in turn relies on this undertaking. The better prepared the manufacturer and in-house legal are to handle recalls, the more likely it is that the manufacturer will discharge its duty to act reasonably in a voluntary recall. Thus, a manufacturer conducting a voluntary recall exposes itself to liability if they act unreasonably.

Similarly, there is no duty to offer consumer post-sale upgrades to meet the evolving state of the art. However, consumers are often offered upgrades to extend or enhance the performance of products. Automobile manufacturers send service bulletins regularly to their dealer network. Mobile phone manufacturers and software companies offer continual upgrades. If a voluntary retrofit is offered, manufacturers have a duty to act reasonably in completing that undertaking. There may be business reasons why a manufacturer would want to give consumers the option to retrofit or upgrade existing products. Where the retrofit program is offered as a courtesy or suggestion to consumers, and the product in itself is not defective, courts will be extremely hesitant to find that the manufacturer voluntarily exposed itself to liability. For example, in situations where the manufacturer issues bulletins to its dealers strongly urging them to encourage their customers

to purchase additional safety devices for previous models of the product, it has been found that this does not establish an assumed duty to retrofit or recall (*Ray v. Rheem Textile Systems, Inc.*, 2002 WL 433157).

Even if there was a voluntary retrofit, liability does not necessarily arise. Liability for harm arises if the failure to exercise reasonable care increases the risk of harm or the harm is suffered because of the other's reliance upon the undertaking. This is based upon the Restatement (Second) of Torts §323 which applies to any negligent performance of an undertaking to render services. Voluntary retrofits are thus akin to any voluntary undertaking.

There is little guidance in the case law regarding when a voluntary retrofit becomes a voluntary recall and thus triggering the application of §11 of the *Restatement (Third)*. Courts speak to retrofits and recalls very generally and interchangeably. Furthermore, states have adopted the *Restatement (Third)* differently. The distinction between a recall and retrofit is not necessarily what triggers legal implications. The bottom-line is when a retrofit or recall is conducted on a voluntary basis, the manufacturer must do so reasonably. Particularly when there is a risk of harm or death, it is prudent to seek external counsel's advice as to the parameters of a reasonable voluntary recall or retrofit.

In addition, manufacturers should be clear on the purpose of the retrofit. Using a retrofit program to implement what is effectively a recall (a "silent recall") potentially exposes a manufacturer not only to liability for negligently implementing the recall (for example, by failing to adequately give notice to all affected consumers) but possibly to punitive damages in addition to the inevitable negative publicity and harm to the reputation of the brand and the manufacturer's goodwill.

Faced with the decision to voluntarily implement a recall, or to undertake a retrofit, the following factors may be relevant:

- Is there evidence that the product was defective at the time of sale, either because the defect should have been known, or there was an inadequate warning of a known defect, triggering a duty to warn?
- Is there evidence that a post-sale defect poses a substantial risk of harm to consumers triggering a duty to warn?
- What is the nature or severity of the hazard posed by the product? Does it arise in ordinary use? What kind of warning or other remedy will reasonably address the risk in light of the severity and frequency of the hazard posed?
- Is the product a specialized product? Are the intended users vulnerable, *i.e.* children or the elderly? Are the consumers or users of the product particularly knowledgeable or skilled in their own right?
- Does the manufacturer have a degree of control over the product through post-sale service or other customer contact?
- Can an effective recall program be implemented and at what cost? For example, can the affected products be identified and traced to consumers? Is there a workable solution to remedy the hazard?

IV. Conclusion

Innovation is vital and necessary to the development of safer consumer products. However, existing products that were safe and met the state of the art at the time of sale inevitably become unsafe, or less safe, in comparison to newer products. Where innovation reveals that an existing product is less safe, a manufac-

turer will need to determine whether the existing product was always unsafe, or whether it has simply been eclipsed. The post-sale duty to warn hinges on reasonableness. It is an objective assessment of what a reasonable person would do in the circumstances. The more severe the risk and the greater the number of people it affects, the more likely that liability will be imposed for a failure to warn. If innovation reveals that a product is in fact unsafe, in-house counsel must take the lead in determining whether the manufacturer is under a duty to warn, or even a duty to recall existing products.

Once consumers have learned that a manufacturer has improved the safety of a product, the manufacturer faces additional potential issues. Safety innovations may be used by plaintiffs as evidence that existing products were in fact defective, making ongoing litigation more difficult to defend. A recall may encourage opportunistic new class action litigation. Competitors may use a recall as an opportunity to gain a competitive advantage. Safety innovations may even (but are less likely) to attract the attention of a regulatory safety agency, leading to an investigation and ultimately an order to recall existing products. Formal recalls can also be very damaging to a company's reputation, are expensive and are usually only partially effective. Then again, so is the decision not to recall a defective product. Many agencies, however, will allow manufacturers to voluntarily recall products. In such cases, manufacturers voluntarily assume a duty to conduct the recall to the same standards as a formal recall. This should not be undertaken lightly.