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Post-sale Duty to Warn: A Critical Cause of Action

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I. INTRODUCTION

Merely manufacturing, designing and selling safe products may not satisfy a product manufacturer's legal duties. A few courts, starting many years ago, held that manufacturers have a duty to warn product users when they learn of risks in their product after ...
sale, even if the product was not defective when sold. Likewise, a number of courts held that there was no such duty.

The American Law Institute recently considered the status of product liability law in the United States. This culminated in the publishing of the new Restatement (Third) of Torts: Products Liability (hereinafter Restatement (Third)). The Institute had to decide whether there was enough precedence to include the post-sale duty to warn in this new enunciation of product liability law.

The law professors (hereinafter Reporters), who served as the drafters of the Restatement (Third), studied all of the cases and felt, while there was some split of authority, enough cases were in support and common sense dictated that this duty should be included. This proposed inclusion resulted in widespread debate. The plaintiff-oriented members of the Institute wanted this section included while some of the defense-oriented members wanted it omitted or severely limited.

Post-sale duty to warn was ultimately included in the final Restatement (Third). The Restatement (Third) and case law require, in certain instances, manufacturers or product suppliers to provide post-sale warnings, or possibly to recall or repair products in a variety of circumstances. In analyzing possible post-sale liability, it is important that manufacturers and product suppliers be aware of the factors that may trigger a post-sale duty. Armed with this knowledge, they can establish procedures to identify the existence of the duty and to implement appropriate post-sale remedial measures to prevent or limit exposure based on post-sale conduct.

5. Id.
7. Id. §§ 10-11, 13.
This article provides an overview of the Restatement (Third)'s post-sale duty sections. In addition, the article highlights key issues for manufacturers and focuses upon case law that illustrates the Restatement (Third)'s sections. Finally, suggestions are provided which will help manufacturers comply with post-sale requirements.

II. RESTATMENT THIRD SECTIONS 10, 11, AND 13

The Restatement (Second) of Torts: Products Liability (hereinafter Second Restatement), which created product liability in 1965 by adopting Section 402A, did not contain post-sale duty provisions. Warnings were required only if a risk associated with a product was known or should have been known at the time of sale. The post-sale duty section in Restatement (Third) is truly new, not merely a revision of Section 388. It provides as follows:

§ 10. Liability of Commercial Product Seller or Distributor for Harm Caused by Post-Sale Failure to Warn
(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.
(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. 10

9. Id. § 388.
Section 10 does not include a duty to do anything other than warn. However, since there was case law holding that, in certain narrow instances, a manufacturer may have a duty to recall or retrofit a product, the Institute dealt with this precedent. Given the great burden of any post-sale activities, especially recall, the Institute included a section severely limiting the duty to recall a product. Section 11 of the Restatement (Third) provides as follows:

§11. Liability of Commercial Product Seller or Distributor for Harm Caused by Post-Sale Failure to Recall Product

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 (a) (1) a governmental directive issued pursuant to a statute or other governmental 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.

Section 11 basically provides that the seller or distributor is not liable for a failure to recall the product unless the recall is required by statute or regulation or the seller or distributor voluntarily undertakes to recall the product and does so negligently. The main reason for including Section 11 was to make it clear that Section 10 does not include a duty to recall the product. However, Section 11 also included the so-called "Good Samaritan" doctrine where liability can attach for a negligent recall, even if it is voluntary.

The last section pertaining to the post-sale duty to warn is Section 13. This section, which concerns a successor's liability for a failure to issue a post-sale warning, states in part:

§13. Liability of Successor for Harm Caused by Successor's Own Post-Sale Failure to Warn

11. Id.
14. Id.
15. Id.
16. Id. § 11(a)(2), (b) cmt. c (1998).
17. Id. § 13.
A successor corporation or other business entity that acquires assets of a predecessor corporation or other business entity, whether or not liable under the rule stated in §12, is subject to liability for harm to persons or property caused by the successor's failure to warn of a risk created by a product sold by the predecessor if:

the successor undertakes or agrees to provide services for maintenance or repair of the product or enters into a similar relationship with purchasers of the predecessor's products giving rise to actual or potential economic advantage to the successor, and a reasonable person in the position of the successor would provide a warning.

The section further states that a reasonable person in the successor's position would provide such a warning if the four above conditions in Section 10 are met.

Case law supports the inclusion of Section 13 into the Restatement (Third)'s post-sale duty sections and emphasizes the same important factors for finding successor liability.

III. DISTINGUISHING POST-SALE DUTY FROM PRE-SALE DUTY

In examining the prior case law, it became apparent to the Reporters that there was great confusion by juries, judges and scholars. Many of the cases were unclear as to whether the jury or judge believed that the product was defective when sold or was not defective when sold but thereafter became defective.

If it was defective when sold, then it was judged under Section 402A (or now Section 2 of the Restatement (Third)). Since the Second Restatement did not have a post-sale duty section, courts that discussed this new theory of liability simply assumed that the defect became known after sale without considering whether it was defec-

18. Id. § 12. Section 12 provides for liability for a successor manufacturer even if a predecessor manufacturer sold the product in a defective condition. Id. 19. Id. 20. Id. 21. Sherlock v. Quality Control Equip. Co., 79 F.3d 731, 734 (8th Cir. 1996) (holding that the critical element is a continuing relationship between the successor and the predecessor's customers for the successor's benefit); Patton v. TIC United Corp., 77 F.3d 1235, 1240 (10th Cir. 1996) (holding that a successor entity may incur a duty to warn if it has knowledge of the defective condition and has a more than causal relationship with the predecessor's customers). 22. Henderson & Twerski, supra note 4, at 669. 23. Restatement (Second) of Torts § 402A (1965), Restatement (Third) of Torts: Products Liability § 2 (1998).
tive when sold.\(^{24}\)

The *Restatement (Third)* makes it clear that this post-sale duty is independent of a time-of-sale defect and therefore selling a defective product can result in claims of time-of-sale defect and also post-sale failure to warn.\(^{25}\) In addition, the *Restatement (Third)* makes it clear that if the product was defective when sold, the manufacturer cannot be absolved of liability by issuing a post-sale warning.\(^{26}\)

While the *Restatement (Third)* is generally viewed as favorable to manufacturers and product sellers, this section clearly establishes a cause of action that creates opportunities for plaintiffs to argue for more discovery of post-sale actions, more admissibility of post-sale accidents, and more allegations of punitive damages.\(^{27}\) In addition, by stating that a manufacturer cannot cut off liability no matter how good the post-sale warning program, this section almost creates absolute liability if someone is injured by a product defect that was known after sale and the manufacturer undertakes a less than reasonable post-sale warning program.\(^{28}\) Plaintiff will argue that a program that was not successful in warning them was not reasonable.

**IV. A CAUSE OF ACTION BASED ON POST-SALE DUTY SOUNDS IN NEGLIGENCE**

While synthesizing years of judicial consideration of post-sale issues, Section 10 still raises many questions that surely will be litigated for years. However, one aspect of Section 10 is clear. A cause of action based on post-sale duties must sound in negligence, since the reasonableness of a product supplier's conduct is the focus of the post-sale inquiry.\(^{29}\)

According to Section 10(b), a seller can only be subject to post-sale duties if a "reasonable" person would have supplied such a warning.\(^{30}\) The four factors are fact-based, making the reasonableness of supplying a post-sale warning the key to establishing a post-

26. *Id.*
27. Researchers analyzing punitive damage cases have found almost 75% of such awards to be based on the failure of a manufacturer to take appropriate post-sale actions. Thomas Koenig, *The Law Arises Out Of Fact, Even For A "Poet Laureate"*, 28 *Suffolk U. L. Rev.* 1021, 1026 (Winter 1994).
29. *Id.* § 10 cmt. b (1998).
30. *Id.* § 10(a).
sale duty. 31

Judging post-sale conduct through the lens of negligence is consistent with previous case law. Actual or constructive knowledge of a post-sale risk is necessary to impose a post-sale duty. 32 Also, negligence is the correct legal theory when a manufacturer's conduct is at issue 33 and, as such, application of a post-sale duty depends on the reasonableness of the manufacturer's conduct. 34 Consequently, a product supplier cannot be strictly liable for post-sale conduct under Section 10.

V. ACQUISITION OF POST-SALE KNOWLEDGE

Section 10 may create an affirmative duty for product suppliers to exercise reasonable care to learn of post-sale problems with their products. Section 10(a) bases a post-sale duty, in part, on suppliers who know or reasonably should know their products pose a substantial risk of harm to persons or property. 35 In addition, comment c states that the general duty of reasonable care may require manufacturers to investigate when reasonable grounds exist for the seller to suspect that a hitherto unknown risk exists. 36

However, comment c also makes it clear that, except for prescription drugs and medical devices, "constantly monitoring product performance in the field" is usually too burdensome and will not support a post-sale duty. 37 Despite this language, Section 10 and comment c may impose a broader duty on product suppliers than recent case law to establish systems to obtain information from the field. The failure of a manufacturer to set up an information gathering system and then claim a lack of knowledge may appear unreasonable to a jury, especially when one could be set up with little effort and expense.

Many courts, however, mimic the language of the Restatement (Third), and are concerned about imposing too heavy of a burden on manufacturers to monitor field performance. In Patton v. Hutchinson Wil-Rich Manufacturing Company, the Kansas Supreme Court

31. Id. § 10(b).
36. Id. at cmt. c.
37. Id.
held that plaintiffs who allege post-sale duty claims must prove that manufacturers "acquired knowledge of a [post-sale] defect." 38 Hutchinson Wil-Rich Mfg. did not impose an affirmative duty on suppliers to take reasonable steps to learn of post-sale problems not brought to their attention. This is consistent with earlier opinions. 39

In contrast to the Restatement (Third)'s post-sale duty to warn section, the Court of Appeals for the Seventh Circuit recently stated that "the well established and generally accepted law in Illinois is that manufacturers do not have a continuing duty to warn." 40 The plaintiff in Birchler v. Gehl Company was injured while working with a hay baler manufactured by the defendant. 41 He brought suit against the defendant alleging that because the defendant knew of three other accidents similar to his accident, the defendant was under a duty to warn the plaintiff of the supposed risk of injury. 42 The court, however, did not agree. 43 The decision clearly states there is no post-sale duty. 44

On the other hand, there is a rule that requires drug manufacturers to keep informed of scientific developments and provide the medical profession with information about the risks of drugs already on the market. 45 This affirmative duty for drug manufacturers is consistent with the language in Section 10 and may also be imposed by Federal Regulations for other products.

The language in Section 10 could extend the scope of other manufacturers' and suppliers' legal duties by requiring reasonable affirmative actions to learn of post-sale product risks. Regardless of the legal duty, affirmatively trying to learn of post-sale risks is a beneficial activity for enhancing product safety and preventing ac-

39. Cover, 461 N.E.2d at 871 (post-sale duty triggered by knowledge "brought to the attention of" manufacturers and vendors); Comstock, 99 N.W.2d at 634 (duty triggered when knowledge of post-sale risk "becomes known" to manufacturers); McAlpin v. Leeds & Northrup Co., 912 F. Supp. 207, 210 (W.D. Va. 1996) (ends of justice require a manufacturer to warn if the manufacturer is made aware of the defect (citing Island Creek Coal Co. v. Lake Shore, Inc., 832 F.2d 274, 280 (4th Cir. 1987))).
40. Birchler v. Gehl Co., 88 F.3d 518, 521 (7th Cir. 1996).
41. Id.
43. Id.
44. Id.
VI. EXISTENCE OF THE DEFECT: A QUESTION OF TIMING

Section 10(a) obviously contemplates that knowledge of a risk or defect acquired by a supplier must be obtained after the sale. The section is less clear about when the defect must actually come into existence. Comment a to Section 10 explains that a post-sale duty may be imposed "...whether or not the product is defective at the time of original sale...." The Institute also acknowledges in comment a that imposing a post-sale duty, even if the product was not defective when sold, is relatively new. It is quick to point out, however, that satisfaction of Section 10's four factors should prevent "unbounded" and "onerous" post-sale burdens on product sellers.

The position of Section 10—that it is immaterial whether the defect existed at the time of sale—contrasts with many decisions where courts have refused to impose post-sale duties when products were not defective when sold. Recently, for example, the Michigan Supreme Court refused to recognize a duty to repair or recall where a product not defective at the time of sale becomes obsolete or unreasonably dangerous due to post-sale technological advances. The Michigan court reasoned that "imposing a duty to update technology would place an unreasonable burden on manufacturers. It would discourage manufacturers from developing new designs if this could form the basis for suits or result in costly repair and recall campaigns." This holding is consistent with many other opinions.

46. Discussion *supra* Section V.
48. *Id.*
49. *Id.*
50. *Id.*
52. *Id.* at 337.
VII. PRODUCT USERS: CAN THEY BE IDENTIFIED?

Section 10(b) requires proof that people to whom a post-sale warning should be provided can be identified before a post-sale duty is triggered.54 This case-specific inquiry will depend on a number of factors including the type of product, the number of units sold, the number of potential users, the availability of records and the available means of tracing product users.55 Comment e makes it clear that when no records identifying the customers are available, a post-sale duty will not arise.56

These factors formed the basis for the Wisconsin Supreme Court's holding that the manufacturer of a sausage stuffing machine had a duty to provide users with information about a new safety by-pass valve.57 The machines were sold to a limited market where the manufacturer knew all of the product's owners.58 The Wisconsin court made it clear, however, that it was not crafting a continuing duty for all manufacturers to warn of safety improvements, since many products are mass produced and tracing users to warn of safety improvements would place an undue burden on manufacturers.59

Similarly, the North Dakota Supreme Court has held that it would be difficult to require the manufacturer of mass-produced tire rims to trace individual users if the rims were not unique or sold to a specialized group of customers.60 While recognizing the problem of providing individual notice to the original purchasers, this court nevertheless held that the defendant had a duty to warn foreseeable users about the potential dangers of using the product which were discovered after the product was sold.61

An interesting question remains as to how far a manufacturer must go to identify its customers. What would a reasonable manufacturer concerned about safety do? Establishing a "traceability" system before the product is sold is the most effective way to find

55. Id., at § 10 (Reporter's Note to comment a).
56. Id. § 10 cmt. e.
58. Id. at 923.
59. Id. at 924-25.
60. Crowston, 521 N.W.2d at 408.
61. Id. at 409; see also Hodder v. Goodyear Tire and Rubber Co., 426 N.W.2d 826, 832 (Minn. 1988) (holding tire rim manufacturer had a post-sale duty to instruct and warn, so that potential users of its product would be apprised of safety hazards which, at an earlier time, were not fully appreciated).
customers. However, such systems take planning, considerable effort, and substantial cost. The question of whether a particular defendant's actions are "reasonable" will be case-specific and decided by the jury. The Institute continually stresses in comments to Section 10 that this duty should not be "unbounded" and "onerous" and that courts need to be careful before imposing such a duty.

The federal government has jurisdiction over many products and may "raise the bar" in this area. In March 1999, the U.S. Consumer Product Safety Commission convened a meeting of manufacturers to discuss ways in which recalls can be made more effective. These discussions included ways in which manufacturers could be required to better ascertain and maintain the identities of purchasers of certain consumer products. Product registration and warranty card returns are among the methods being considered. The federal government already mandates customer tracking for products such as car seats and medical devices.

VIII. DUTY TO INFORM OF SAFETY IMPROVEMENTS

Manufacturers should always strive to improve the safety of their products. But does the manufacturer have a duty to inform prior customers of each safety improvement made in similar products manufactured after the sale of the less safe product? Some courts have found it reasonable to impose a duty to inform purchasers of safety improvements when:

1. There is a continuing relationship between the manufacturer and the purchaser;
2. The market is limited; and
3. The cost of providing notice of the safety improvement

63. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 10, cml. a, d (1998). There are also several federal guidelines as well as industry guidelines describing what might be considered a reasonable program. For a recent example of an industry produced guideline, AMERICAN SOCIETY FOR QUALITY, THE PRODUCT RECALL PLANNING GUIDE (1999).
64. CPSC Public Forum on Purchaser Identification, March 23, 1999.
66. Id. at 6052.
67. 49 C.F.R. § 588.5-6 (1999).
68. 21 U.S.C.A. § 360i(e) (West 1998).
Most courts, however, have found that there is no post-sale duty to inform customers of safety improvements when the original product has been properly designed and manufactured.  

Section 10 does not foreclose a finding of a failure to issue a post-sale warning of safety improvements but makes it clear that the four factors in Section 10 must be met. However, it says that "...in most cases it will be difficult to establish each of the four § 10 factors that are a necessary predicate for a post-sale duty to warn if the warning is merely to inform of the availability of a product-safety improvement."  

To date, a duty to inform product users about safety improvements has only been required by a few courts and only in limited factual circumstances.  

This might be a difficult area for manufacturers to make a reasonable decision. A plaintiff might argue that the original product is defective without the safety improvement and use the improvement as proof of a time-of-sale defect. Since it is sometimes difficult to decide whether a jury will accept this argument, a manufacturer must carefully consider whether it is reasonable and prudent to notify prior customers of safety improvements.  

The manufacturer should perform the kind of analysis that is done in deciding whether a duty arises in the first place using Section 10. If the manufacturer's post-sale improvement significantly improves safety and the manufacturer can easily find its customers, the manufacturer should consider informing its prior customers about the safety improvement.  

For example, if a manufacturer were to significantly improve the warning labels on its product or add labels where none initially existed, it is a good idea to provide the labels, at cost or free of charge, to purchasers of prior products. Labels are usually very inexpensive and easy to disseminate. As a result, a jury might feel that a product was defective without the improved labels or feel

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69. Kozlowski, 275 N.W.2d at 923-24.  
72. Id. § 10 (Reporter's Note to comment a).  
73. Kozlowski, 275 N.W.2d at 924 (holding a duty to inform users of machine of post-sale safety improvements where users were traceable); Bell Helicopter Co. v. Bradshaw, 594 S.W.2d 519 (Tex. Civ. App. 1979) (holding a duty to retrofit where manufacturer assumed duty to notify users of safety improvements).
that the manufacturer should have disseminated the labels to its prior customers.

On the other hand, if the manufacturer creates a safety improvement that would double the price of the original product, it would not be necessary for a manufacturer to provide the safety improvement free of charge to prior customers. The argument would be that the customer would have paid for the improvement in the original price of the product. If the safety improvement significantly improves safety, it might be advisable for the manufacturer to inform prior purchasers of the improvement and allow them to purchase it if they wish.

Decisions in this area are difficult to make and can have unfortunate consequences. If the manufacturer makes the wrong decision, it could result in significant liability.

IX. POST-SALE DUTY TO RECALL

Section 11 sets forth a limited duty to recall a defective product. Comment a makes it clear that this duty is different from the post-sale duty in Section 10. This comment also says that improvements in product safety do not trigger a duty to recall or retrofit a product. Manufacturers would be discouraged from making products safer.

This limited duty is based mostly on a governmental directive, specifically requiring the manufacturer to recall the product. The Michigan Supreme Court recently declined an invitation to impose a duty to recall or repair in a negligent design claim where a plaintiff alleges that a manufacturer knew or should have known of a defect at the time of sale. While Michigan required a warning in such circumstances, the court concluded that "the duty to repair or recall is more properly a consideration for administrative agencies

75. Id. at cmt. a (stating "[t]he duty to recall or repair should be distinguished from a post-sale duty to warn about product hazards discovered after sale").
76. Id.
77. Id.
78. Id. (stating "[m]oreover, even when a product is defective within the meaning of §2, §3, or §4, an involuntary duty to recall should be imposed on the seller only by a governmental directive issued pursuant to statute or regulation."); see also 15 U.S.C.A. § 2061(b)(1) (West 1998).
79. Gregory, 538 N.W.2d at 333-34.
and legislatures . . ."\(^{80}\)

Unfortunately, the Institute incorporated the "Good Samaritan" or "volunteer" rule that one who undertakes a rescue must act reasonably so as not to put the rescued party in worse shape than before.\(^{81}\) This rule, in the context of product liability, comes from the belief that voluntary recalls are typically undertaken in the anticipation that a governmental agency will require one anyway.\(^{82}\)

This belief, by the Institute and some courts, may be correct in a general sense. However, there are many voluntary recalls, retrofits, or even post-sale warning programs that are done to enhance safety and would not constitute a post-sale duty under Section 10. With this doctrine incorporated into the *Restatement (Third)*, some manufacturers may not undertake what they truly believe are voluntary programs unless they are prepared to do so in a way that would not be considered negligent. This determination is difficult and case-specific.

Hopefully, more manufacturers will "do the right thing" and try to improve the safety of their products and try to anticipate what might be considered reasonable. Unfortunately, the fact that an accident happened means, by definition, that the post-sale remedial program was arguably ineffective for the injured party.

**X. LEGAL COMPLIANCE AND GOOD BUSINESS PRACTICES**

**A. Management Of A Post Sale Program**


A manufacturer should be guided in its implementation of a post-sale program by a formal product safety policy. The policy serves as a guidepost for overall product safety. In addition to this general statement of product safety, a manufacturer should consider having a post-sale action plan. This document establishes procedures for analyzing the need for post-sale action and for implementing whatever action is determined to be appropriate.

Both of these documents are part of good business practices and could be helpful in defending any litigation that might arise. It is important to point to a document, endorsed by the Board of

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81. *See supra* note 15.
Directors, the Chief Executive Officer, the President, or General Manager which confirms a manufacturer's desire to market safe products and to identify and remedy any post-sale problems that come to their attention.

2. Information Network

The foundation of a post-sale program is established in an information network that will allow a company to determine how its product is performing in the marketplace. This information is necessary for the manufacturer to ultimately make decisions about what, if any, post-sale action might be necessary.

A manufacturer has a number of readily available sources of information. For example, notices of claims or accidents might provide information on the types of products that are failing, the mode of failure, and possible misuse of the product. Lawsuits will provide the same information, as well as reports from plaintiffs' experts that may provide further insight into how the product could be made safer. Customer complaints and warranty returns are fertile sources of information. A pattern of complaints and returns may indicate that a product is failing in a particular mode on a regular basis.

An inordinate number of sales of a particular component part may indicate that a part is failing prematurely. Of course, observations by sales personnel and by service personnel who are actually out in the field talking to customers are also invaluable sources of information. Post-sale information can also come from competitors at trade shows or as part of membership in a trade association. Lastly, post-sale information, albeit some of it unsubstantiated or even incorrect, is now on the Internet. Some companies monitor the Internet, especially sites where customers might visit, to see what is being said about their products.

3. Analyzing The Information

Once a manufacturer has obtained all relevant information, it must determine whether post-sale action is necessary. Good business practices and good litigation planning require that someone be in charge of the post-sale program. Juries want to know that some person or specific group has the responsibility of managing this problem.

Generally, some form of product safety committee should ana-
lyze the information. This committee should be made up of representatives from various areas of the company, including engineering, service, sales, marketing, and legal. It is also very important that the lawyer who is advising the committee be experienced in product liability and regulatory law.

The committee analyzing the post-sale information should hold regular meetings. This is important, both to make certain that information is being reviewed on a timely basis, and to show a jury that the company is acting reasonably in how it handles its post-sale analysis. The number of persons who are allowed to attend should be limited and those who take notes at these meetings should write them carefully.

Determining whether post-sale action is necessary under the common law requires applying the factors identified in case law and Section 10 above to the facts learned through the information gathering network. If there are a number of injuries involving the same product, with the same basic failure mode, it most likely will be necessary to take some type of post-sale remedial action.

If the network reveals one incident involving property damage out of many products in the field, it may be important to take note of the incident, but no post-sale action may be necessary. A manufacturer must simply apply the factors to the information gathered, keeping in mind that the primary objective is to make safe products, prevent accidents, and, if necessary, present itself as a responsible company to the jury.

Determining whether post-sale action is necessary also involves an analysis of any applicable government laws or regulations that provide criteria for making this decision. The U.S. Consumer Product Safety Commission [hereinafter CPSC] provides criteria for determining the existence of a substantial product hazard. The criteria to be considered are the pattern of defect, the number of defective products distributed in commerce, and the severity of risk to consumers. Using these criteria will provide guidance to the manufacturer about what information to gather and how to analyze the information. The CPSC provides little further guidance on this threshold question and expects the manufacturer to report a substantial product hazard or any suspicion that the product contains such a hazard to the CPSC. In that event, the staff of

84. Id. at 116 C.F.R. § 1115.12.
85. Id.
the CPSC will help the manufacturer analyze the information and decide what, if any, appropriate post-sale remedial measures are necessary.

4. Determining The Appropriate Post-Sale Action

Once the manufacturer has identified a post-sale hazard that should be remedied, it must decide what post-sale action to take. There are a number of available options. The most appropriate action will depend upon the previously used factors such as the severity of the harm and the likelihood of personal injury or property damage. For example, the problem may be corrected by simply sending a safety notice to distributors/retailers. If there is concern about the notice reaching the ultimate user/purchaser of the product, the safety notice should be sent directly to the users/purchasers. Of course, a manufacturer's ability to do this will depend on its ability to locate its purchasers and product users.

If the severity of the harm and the likelihood of the injury are significant and a warning is insufficient, a manufacturer might go to the field and retrofit the allegedly defective product.\(^6\) Depending upon the ease with which the product can be returned to the manufacturer, a retrofit in the plant might be appropriate. If retrofitting the product does not result in the elimination of the hazard, or if a retrofit is simply not feasible for the product, it may be necessary to recall the product.

As previously discussed, the manufacturer needs to consider the available post-sale options under the common law and also identify any government laws or regulations that apply. Many federal government agencies, once they learn of a problem, will classify the level of risk. Once the level is classified, the manufacturer can identify regulations that define the extent of the post-sale activities.

For example, the CPSC has established a hazard priority system defining hazards as Class A, Class B or Class C.\(^7\) A Class A hazard exists when a risk of death or grievous injury or illness is likely or very likely, or serious injury or illness is very likely.\(^8\) Class A hazards warrant the highest level of company and CPSC action and

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\(^6\) While this is not required under the common law, it still may be appropriate when considering safety and may be required by some government agency.

\(^7\) U.S. CONSUMER PRODUCT SAFETY COMMISSION, CORRECTIVE ACTION HANDBOOK (October 1988).

\(^8\) Id.
immediate, comprehensive and imaginative corrective action measures are required.99 Class B and Class C hazards are lesser hazards and less immediate and comprehensive corrective action measures are necessary.90

The Food and Drug Administration assigns a classification to a recall to indicate the degree of health hazard presented by the product. These are listed as Class I, Class II and Class III.91 Class I is defined as a situation in which there is a strong likelihood that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.92 Class II and Class III are lesser levels of severity and require less comprehensive post-sale programs.93

Under the CPSC guidelines, the kinds of corrective measures to be considered include joint news releases; sending out safety notices with bills; purchasing advertisements in national and/or regional newspapers and magazines; installation of a toll-free telephone line to receive calls from consumers; using incentives to encourage users to return the product; distributing point-of-purchase posters to alert consumers to a recall; using warranty cards to identify users of the product; and notifying trade associations and other groups for whom the recall may have particular concern.94

5. Adequacy Of Post-Sale Remedial Measures

Whether a manufacturer decides to warn, retrofit, or recall, it is very important that the initial notice of the post-sale action be properly written and contain the appropriate message. Any communication made by a manufacturer to a dealer or customer will be judged according to the same adequacy standards as warnings are generally judged. This means that a letter notifying a dealer or customer of a product problem must describe the hazard, the consequences of the hazard, and how to avoid the hazard.95 The best in-

89. Id.
90. Id.
91. FOOD AND DRUG ADMINISTRATION REGULATORY PROCEDURES MANUAL, PART 5, CH. 5-00, RECALL PROCEDURES (May 1988).
92. Id.
93. Id.
95. Burch v. Amsterdam Corp., 366 A.2d 1079, 1086 (D.C. 1976) (holding that "[t]he seller or manufacturer of a product whose use could result in foresee-
formation gathering network in the world and the best safety committee is useless if the communication that is ultimately sent is inadequate to promote any action.

Letters to dealers or customers notifying them of potential post-sale problems should be written very clearly and be very explicit. This means that if a manufacturer has experienced prior accidents or prior injuries, it should probably say so in the letter, describing the general nature of the problem and the types of injuries. A manufacturer should be careful not to understate the problem.

The letter should be written keeping in mind that it will be read by potential future plaintiffs who will challenge its adequacy in future litigation if they are injured. This should not preclude a manufacturer from writing the letter, but should encourage them to write it in a way that will be helpful in defending any litigation that might arise. The manufacturer may even want to perform a small focus group survey to confirm that the reader understands the communication and is inclined to follow its instructions.

Under the common law and Sections 10 and 13 of the Restatement (Third), there is little guidance on how to adequately communicate a post-sale program. The cases also are not particularly helpful in determining whether a post-sale program has been performed adequately. Government guidelines do provide some guidance, and they should be considered, even if the manufacturer's product does not fall under the jurisdiction of these agencies.\footnote{U.S. CONSUMER PRODUCT SAFETY COMMISSION, CORRECTIVE ACTION HANDBOOK (October 1988); 16 C.F.R. § 1115.20.}

For example, the CPSC provides clear guidelines for implementing product safety recalls.\footnote{Id.} Certainly, if the manufacturer's product is a consumer product, these guidelines should be followed. However, even if the products are not consumer products, and do not fall under another agency's jurisdiction, the guidelines should still be considered.

The CPSC guidelines provide specific suggestions for commu-
communicating recall messages. They suggest that on notices to consumers, distributors and retailers, the words "Important Safety Notice" or a heading such as "Recall Notice" appear in the lower left-hand corner of the envelope and at the beginning of each letter.\(^{98}\) If there are press releases, the CPSC says that the release must contain information such as a description of the products and its intended use, a description of the specific product hazard, and directions as to how consumers may obtain refunds, replacement or repair of the product.\(^{99}\) The press release should contain a glossy black and white photograph or line drawing of the product and the defect.\(^{100}\)

Guidelines are also provided by other federal government agencies, and they might be considered in identifying the best post-sale remedial program for a particular manufacturer.\(^{101}\)

In determining the adequacy of the program, the manufacturer must consider what percentage of success is adequate. Anything less than a 100% success rate leaves the possibility that a hazardous product is still in the hands of consumers or users and that such a defect could cause injury and result in a lawsuit. In many situations, particularly involving the mass distribution of consumer products, the manufacturer would never expect to or achieve anything close to a 100% success rate. In the consumer product area, product safety experts consider a 25% response rate for a recall program to be excellent.

For a recall of medical devices, the Food and Drug Administration has established effectiveness levels ranging from 100% of the customers who received the recall notice down to 2% of these customers.\(^{102}\) The levels correspond to the severity of the product hazard.

It is possible for a jury to believe that the manufacturer engaged in an adequate post-sale program and find the manufacturer not liable for an injury suffered by a user of the defective product. Juries expect manufacturers to engage in comprehensive post-sale programs, but do not expect a 100% success rate. Unfortunately, while a jury might feel that the manufacturer's post-sale program

\(^{98}\) \textit{Id.}
\(^{99}\) \textit{Id.}
\(^{100}\) \textit{Id.}
\(^{101}\) \textit{Food and Drug Administration Regulatory Procedures Manual, Part 5, Ch. 5-00, Recall Procedures (May 1988).}
\(^{102}\) \textit{Id.}
was reasonable and adequate, it would still be possible for them to hold the manufacturer liable for selling a defective product in the first place. In other words, initial liability for selling a defective product cannot be cut off by undertaking a post-sale remedial program that is not 100% effective.103

XI. CONCLUSION

Post-sale duties have been expanding in the United States by court decision and legislative action. The Restatement (Third) affirms this expansion and, in some respects, broadens the post-sale responsibilities of manufacturers. Manufacturers must act now to put into place an appropriate information gathering network and establish appropriate committees or trained personnel who can analyze the gathered information to determine whether post-sale actions might be appropriate. A failure to take timely and adequate remedial actions could result in huge liability, including punitive damages, that could eventually result in large numbers of injured people and lead to the demise of the manufacturer.
