Post-Sale Duties: How to Decide When the Duty Arises
By Kenneth Ross*

One of the most important issues facing any manufacturer is how to determine whether they have a post-sale responsibility to report to a government agency in the U.S. and elsewhere and whether they have to undertake a post-sale corrective action such as issuing a safety bulletin or undertaking a recall or retrofit. A failure in either of these areas can result in big fines assessed by a government and possible punitive damages for failure to fix a known safety problem.

This article will examine the common law and regulatory law and guidance on these two issues and describe a new draft guidance coming out of the European Union (EU) which could be helpful in performing this analysis.

Basic U.S. Post-Sale Law

Let's start with the U.S. where courts first enunciated a manufacturer's post-sale duty in 1959. *Comstock v. General Motors Corp*., 99 N.W.2d 826 (Mich.1959). Since that time, courts and commentators have generally concluded that there is some post-sale responsibility, but have differed greatly on when that duty arises and how far it goes.

The courts who considered post-sale issues clearly utilized a negligence balancing test to decide whether a post-sale duty arose. The higher the risk of injury with the current product in the hands of consumers and the lower the difficulty in getting a message to those consumers, the greater the duty to at least warn them. This test is very similar to the negligence formulation of Judge Learned Hand in *U.S. v. Carroll Towing*, 159 F.2d 169 (2nd Cir.1947).

Judge Hand set forth three criteria for determining whether a person's conduct was negligent: (1) the probability that injury would result from the actor's conduct; (2) the gravity of the harm that could be expected to result should injury occur; and (3) the burden of taking adequate precautions to avoid or minimize injury. Judge Hand went on to express this test in the form of an algebraic equation: "If the probability be called P; the injury L [loss]; and the burden B [*i.e.*,

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the burden of precaution to avoid the risk of loss]; liability depends upon whether B is less than L multiplied by P; *i.e.*, whether B is less than PL." 159 F.2d at 173.

This negligence formulation goes to the core of how to analyze whether the manufacturer is negligent in selling a product that causes injury. It can also be used, as shown below, when analyzing post-sale responsibilities.

When considering these post-sale issues, juries and judges got confused about whether the product had to be defective when it left the control of the manufacturer. However, the N.Y. Court of Appeals, in 1984, clearly stated their view on this issue in an influential opinion by stating:

> "[a]lthough a product [may] be reasonably safe when manufactured and sold and involve no then known risks of which warning need be given, risks thereinafter revealed by user operation and brought to the attention of the manufacturer or vendor may impose upon one or both a duty to warn." *Cover v. Cohen*, 461 N.E.2d 864, 871 (N.Y. App. Div. 1984).

Since the 1980s, more and more courts considered post-sale responsibilities and the vast majority stated there was some duty. However, there were virtually no clear pronouncements of when it arose. It was considered an issue to be decided by the jury.

In the early 1990s, the American Law Institute undertook to restate the law of product liability. The Reporters were expanding on one section (section 402A) of the Restatement of Torts, 2d into a full blown stand alone Restatement which was finished in 1998 and eventually encompassed 21 sections and 382 pages. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY (1998) ("Restatement").

One of the most difficult issues that the Reporters addressed dealt with post-sale duties. They read all of the cases and concluded that the juries and courts were unclear about what triggered the duty and what had to be done when it did arise. However, they did their best to draft a section of the Restatement that was a synthesis of what they believed to be the best reasoned portions of the case law and analysis by legal commentators.

The key section is §10 which states:

§ 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.

The Reporters "attempted to limit this 'monster' duty somewhat by requiring that a plaintiff establish each of the four factors set forth in §10." See Henderson and Twerski, *Teacher's Manual for Product Liability: Problems and Process*, at 199 (4th ed. 2000). Despite these limits, in the end, the Reporters concluded that this duty was "probably the most expansive area in the law of products liability" and a "timeless duty to warn." *Id*.

A great many lawsuits have been filed alleging a violation of post-sale duties. This allegation which deals with activities after sale of the product makes discovery of post-sale incidents more relevant and based on an analysis of punitive damage verdicts, increases the chances for a punitive damage award. Rustad, *In Defense of Punitive Damages in Products Liability: Testing Anecdotes with Empirical Data*, 78 Iowa L. Rev. 1, 65-66 (1992) (three out of every four punitive

damage awards in products liability actions from 1965-1990 were for failure to warn of known dangers and post-marketing failures to remedy known dangers).

This monster duty has not been tamed and every manufacturer must understand when the duty arises. However, the balancing test enunciated in Section 10 is very subjective, open to significant interpretation, and can result in widely different conclusions from manufacturers.

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, *Downing v. Overhead Door Corp.*, 707 P.2d 1027, 1033 (Colo. Ct. App. 1985); *Braniff Airways, Inc. v. Curtiss-Wright Corp.*, 411 F.2d 451 (2d Cir. 1969), the Reporters dealt with this precedent.

Given the great burden of any post-sale activities, especially recall, the Reporters included a section severely limiting the duty to recall a product. Section 11 of the Restatement provides as follows:

> §11. Liability of Commercial Product Seller or Distributor for Harm Caused by Post-Sale Failure to Recall Product
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> 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 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 case law concerning the duty to recall or undertake some other corrective action is still very slim. It provides little guidance in any specific situation and is very much based on the facts of each situation. Therefore, each manufacturer must be prepared to use some rational analytical process to determine how far the post-sale duty goes and how to defend itself against a negligence claim if an accident occurs. See Ross, *"Adequate and Reasonable Product Recalls,"* For the Defense, Defense Research Institute, Inc., October 2003.

U.S. Regulatory Law

Let's see if U.S. regulatory law is helpful in giving guidance as to when a post-sale arises. The U.S. Consumer Product Safety Commission is governed by the Consumer Product Safety Act. Section 15(b) of the Act requires, in part, that a manufacturer report to the CPSC if the product has a defect which creates the possibility of a substantial product hazard.

The regulations to the CPSA provide some guidance on how to analyze the need to report. The first question is whether there is a defect. Under this section, a product without a defect is not subject to the reporting requirements even if injuries occur. Many products are reasonably safe and not defective and people still get hurt.

However, if there is a defect, the next question to be answered is whether this defect could create a "substantial product hazard." The Commission starts this analysis by saying:

> Generally, a product could create a substantial hazard when consumers are exposed to a significant number of units or if the possible injury is serious or is likely to occur. However, because a company ordinarily does not know the extent of public exposure or the likelihood or severity of potential injury when a product defect first comes to its attention, the company should report to the Commission even if it [sic] in doubt as to whether a substantial product hazard exists. *CPSC Recall Handbook.*

Then the regulations provide factors a manufacturer must consider in determining if there is a substantial product hazard: pattern of defect, number of defective products in commerce, severity of risk, and likelihood of injury.

All of these factors are similar to the risk part of the Learned Hand formula for negligence. However, the CPSC does not include in the regulations mandating a report, the burden on the manufacturer to find its consumers and to reduce the risk, factors which are considered in the case law and the Restatement. Therefore, the CPSC provides a much lower threshold for reporting and undertaking post-sale actions.

The Food and Drug Administration and the National Highway Traffic and Safety Administration similarly have thresholds for reporting which are much lower than the common law.

This is all understandable. The federal agencies do not always demand that you recall your product. There are many reports to the government that do not result in any post-sale corrective action. Therefore, the government wants manufacturers to report even if doubt about whether they meet the threshold to report, so they can work with the manufacturer to determine if a corrective action is necessary.

Except for products that do not fall under any regulatory regime such as machinery and equipment used in a workplace, the manufacturer will first need to analyze its post-sale duties based on the regulatory law of the governing agency before they consider the common law or the Restatement.

Foreign Post-Sale Regulatory Law

The 2004 General Product Safety Directive ("GPSD") that is now being implemented in all EU countries increases responsibilities for manufacturers and distributors. Distributors will have to monitor the safety of products placed on the market, especially by passing on information on product risks, keeping and providing documentation necessary for tracing the origin of products, and cooperating in actions taken by manufacturers and government agencies to avoid the risks.

Both manufacturers and distributors now will have a duty to immediately notify the relevant government authorities when they know or ought to know that a product they have placed on the market poses risks to the consumer that are

incompatible with the general safety requirements of the Directive. This means that a manufacturer has sold a product that is not "safe."

GPSD defines a "safe product" as one that "does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons…" Suffice it to say that this threshold for reporting appears to be much lower than under any U.S. statute or regulation which usually requires that a defect and substantial risk be present and under U.S. common law which requires that there be a substantial risk of harm before a post-sale duty to warn arises. However, this low threshold is somewhat tempered by the adoption of risk assessment principles which will assist a manufacturer selling into the EU in quantifying the level of risk involving products in consumers hands. See the discussion below on risk assessment.

Practitioners in the EU predict that implementation of the GPSD will result in more recalls, more publicity within the EU and elsewhere, more effects on product liability litigation (either by making litigation more likely or making the risk of an adverse result more likely), more criminal prosecutions, and more disputes between companies in the chain of production and distribution.

Most countries in Asia-Pacific have also adopted laws which require manufacturers to report safety problems to the government and to take appropriate remedial actions. For example, in October 2004, China implemented new recall procedures for defective vehicles. The government agency in charge of administering this program is trying to position itself as an international recall center. And China expects to use these recall procedures as a blueprint for implementing recall procedures for other products.

In Japan, an amendment to the Consumer Products Safety Law was promulgated on December 6, 2006. The Amendment requires that every manufacturer and importer of a consumer product report to METI within 10 days if they obtain information concerning a serious product accident caused by a consumer product.

The Amendment requires manufacturers and importers to report to METI if they obtain information that a "serious product accident" was caused by one of their consumer products. A "serious product accident" is defined as: (1) an accident that caused danger to a consumer's life or body, namely, (i) death, (ii) injury or sickness, treatment of which lasts at least 30 days or which will have a

permanent consequence, or (iii) carbon monoxide poisoning; or (2) an accident that caused a fire.

This reporting responsibility in Japan does not depend on the existence of any defect or on a belief that the product could cause a serious injury in the future. If it caused a serious product accident, even if it was someone else's fault, the manufacturer must report.

And the Liberal Democratic Party of Japan just released a report proposing the establishment of a new government agency charged with sole responsibility for devising and implementing consumer-related policies. This new agency would have the power to conduct inspections at companies whose products are found responsible for accidents involving consumers and to confiscate profits obtained by firms through unlawful methods.

The result of these differing laws and regulations is that a manufacturer may have a duty to report to some government authority somewhere in the world, but not to all governments where they sell their product. In that case, they must decide which government to report to and whether they need to tell the other governments about the report and why they aren't reporting to all of them.

Risk Assessment and its Use in Post-Sale Analysis

Originally developed in the 1950s, risk assessment and related engineering evaluations have, since that time, been a part of the design and manufacturing process. Recently, however, risk assessment has become a topic of discussion in legal and manufacturing circles. Industries and standards groups in the United States and Europe have turned their attention to risk assessment and developed specific methodology for their industries or specific products.

Negligence, as described by Judge Hand above, served as a core concept in the development of product liability in the 1960s and 1970s. It is also consistent with the risk assessment process and resulting design and manufacturing decisions.

Risk assessment is a tool for manufacturers to identify possible hazards and provide a basis for considering alternative designs to mitigate or control risks. A risk assessment offers the opportunity to identify hazards associated with intended uses and reasonably foreseeable misuses and to take steps to eliminate or control them before an injury occurs. This process can be a key factor in successfully reducing risks to an acceptable level.

In 2004, when it issued its General Product Safety Directive, the EU included typical risk assessment principles to be used by manufacturers in helping to determine when a reporting responsibility arose. These guidelines were meant to supplement the definition of "safe product" and provide a consistent framework for analyzing post-sale problems. However, these principles were significantly criticized because they were very subjective thereby leading to unpredictable and inconsistent reporting, and they tended to quantify some remote risks so as to make reporting a necessity if the principles were followed. See *Lovells Product Safety Newsflash*, December 17, 2007.

As a result, this risk assessment process was recently revised and a new draft has been issued by the EU for comment in 2008. This new draft provides some good analytical tools that can be used by manufacturers in deciding whether to report to a government agency and whether to undertake a corrective action. See http://ec.europa.eu/consumers/safety/committees/index_en.htm

In the guidelines, they define risk as "the combination of the severity of the possible damage and the probability that this damage occurs." They then detail three steps to determine risk: (1) identify the seriousness of the hazard that is intrinsic to the product; (2) determine the probability to which the consumer is in practice injured by the intrinsic product hazard; (3) combine the hazard (in terms of the severity of injury) with the probability (in terms of fraction numbers) to obtain the risk.

There is more guidance on how to take these three steps, including a number of examples showing how to use the methodology, and a table which allows the manufacturer to chart the level of risk and determine if the level is "serious", "moderate", "low" or "acceptable." This determination will help with the decision about whether to report and how to report.

This risk assessment process is an organized way for a manufacturer to analyze post-sale risk. It could be used by manufacturers to decide whether to report to a government agency, and even if a report is necessary, whether to undertake a corrective action. Predicting future risk is the key to deciding whether a recall or some other corrective action is necessary.

Using this risk assessment methodology could be helpful, even if done for selling products into the U.S., in that the manufacturer would appear to be a diligent company who utilized the "best practices" represented by this EU draft in

analyzing post-sale risk. The use of this methodology might also be helpful in justifying the company's decision about whether a corrective action is necessary and also in defending a future product liability case against allegations that the post-sale analysis was inadequate and the decision to not recall the product was wrong.

Conclusion

Manufacturers must be aware of the best practices and methodologies available or required to design a reasonably safe product, monitor post-sale activities, and undertake legally required or appropriate post-sale activities. Failure to do so could subject the manufacturer to significant legal liability, either as established by a government or a jury or court.