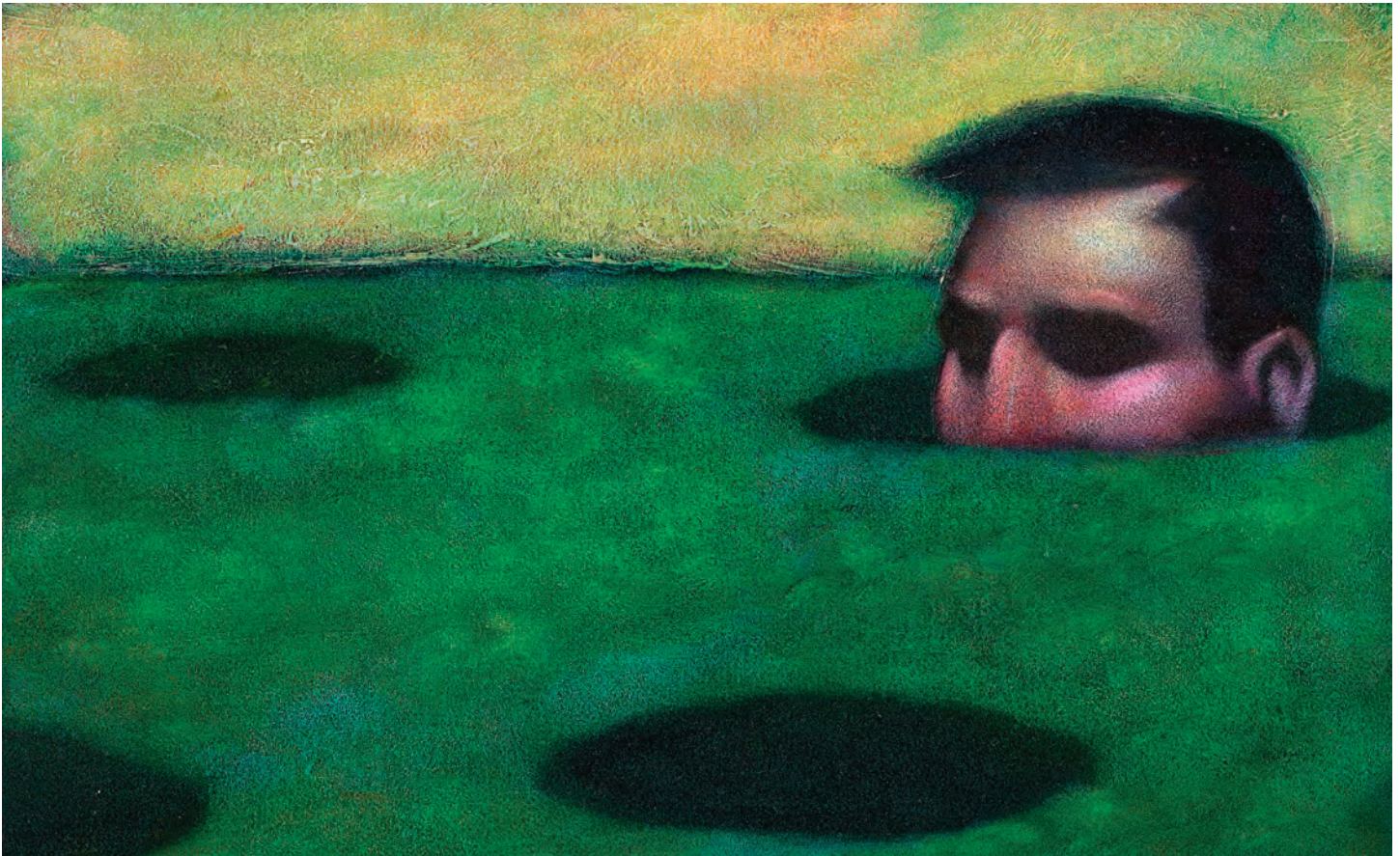


Post-Sale Duties

A Minefield for Manufacturers

By Kenneth Ross and George W. Soule



Manufacturers are being subjected more often to increased post-sale responsibilities in the United States and elsewhere as a result of changes in the common and regulatory law. Neglecting these responsibilities can fail to enhance the safety of products in the field, and increase the possibility that the manufacturer

will suffer irreparable harm to its brand name, as well as be subjected to fines, more lawsuits in the U.S. and elsewhere, a higher probability of plaintiffs' verdicts and even punitive damages.

This article will discuss U.S. and foreign law, how a manufacturer can try to adequately meet its post-sale responsibilities, and how to defend a product liability



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ity case when the product in question has been recalled.

U.S. Common Law

Over 30 states have adopted some type of post-sale duty, most notably a post-sale duty to warn. In addition, the American Law Institute (“ALI”) recently considered the status of product liability law in the United States, culminating in 1998 in the publishing of the *Restatement (Third) of Torts: Products Liability* (“Third Restatement”). The Second Restatement did not include any mention of post-sale responsibilities. However, beginning in 1959 and continuing over the years, a number of courts have created rules describing when manufacturers should issue post-sale warnings of hazards to product users.

The ALI ultimately decided that a sufficient body of law existed to justify including a post-sale duty to warn in the Third Restatement. Section 10 requires, in certain instances, that manufacturers or product suppliers should provide post-sale warnings.

Section 10 does not include a duty to do anything other than warn. However, because a few courts have held that, in certain narrow instances, a manufacturer may have a duty to recall or retrofit a product, the ALI included a section (Section 11) in the Third Restatement that severely limits the duty to recall a product.

Section 11 provides that the seller or distributor is not liable for a failure to recall a 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 in the Restatement was to make it clear that Section 10 does not include a duty to recall. However, it also included the so-called “Good Samaritan” doctrine, where liability can attach for a negligent recall, even if it is voluntary.

Portions of this article have been adapted from the following articles written by Kenneth Ross: *Adequate and Reasonable Product Recalls*, For The Defense, DRI, October 2003, and *Avoiding Future Problems: The Increased Duty to Take Post-Sale Remedial Action*, For The Defense, DRI, April 2002.

§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 when 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 when:
 - (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 may 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.

While not all states have adopted a post-sale duty to warn, manufacturers who sell nationwide must assume that they have such a duty since they can expect that a claim could arise in any state.

U.S. Regulatory Law

Even though the common law limits the manufacturer’s post-sale duties, U.S. regulatory law for decades has required manufacturers and sellers of various products to report safety problems to government agencies and undertake some sort of remedial action, depending on the severity of the problem and the ability to find the purchasers of the product.

The U.S. Consumer Product Safety Commission (“CPSC”) is the most important federal safety agency since it has jurisdiction over all consumer products. The Consumer Product Safety Act (“CPSA”), Section 15(b), independently requires manufacturers, importers, distributors and retailers to notify the Commission immediately if they obtain information that reasonably supports the conclusion that a product distributed in commerce: 1) fails to meet a consumer product safety standard or banning regulation; 2) contains a defect that could create a substantial product hazard to consumers; 3) creates an unreasonable risk of serious injury or death; or 4) fails to comply

with a voluntary standard upon which the Commission has relied under the CPSA.

The most important provision concerning reporting to the Commission is Section 15(b)(2), which requires both a defect and the possibility of a substantial product hazard to trigger the reporting obligation. 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.

There is an additional reporting responsibility that applies even if there is no defect. Section 15(b)(3) requires a report if there is an unreasonable risk of serious injury or death, even if the product does not have a defect.

These regulations were recently expanded in part to deal with global safety issues. In November 2001, the CPSC clarified its position by saying that a manufacturer must, in part, evaluate product use, experience, performance, design, or manufacture *outside the United States* to determine if a reporting responsibility has arisen.

Fines for failure to report or for late reporting have become more frequent and more expensive in recent years. In the last

Number of Cases Where CPSC Has Sought Civil Penalties

Fiscal Year	# of Manufacturers or Retailers That Were Fined	Fine Range
2002–03	5	\$ 30,000–\$ 885,000
2003–04	10	\$100,000–\$1,000,000
2004–05	8	\$300,000–\$4,000,000

two fiscal years, the CPSC has significantly increased the number of cases where civil penalties were sought. In the 2002–03 fiscal year, there were five manufacturers or retailers that were fined; fines ranged from \$30,000 to \$885,000. In the 2003–04 fiscal year, 10 manufacturers or retailers were fined, ranging from \$100,000 to \$1,000,000. And, in the 2004–05 fiscal year, eight manufacturers or retailers were fined with fines ranging from \$300,000 to \$4,000,000. The higher fines during the 2004–05 fiscal year are an aberration because they involved multiple violations (*e.g.*, late reporting or no reporting for different products over different periods of time). And, lastly, in the 2005–06 fiscal year to date, four manufacturers paid fines ranging from \$100,000 to \$700,000.

The heightened activity of the CPSC increases the possibility that a product will be recalled, that harmful admissions will be made in a recall press release, letter to customers, and posters in stores, and that a possible fine could be imposed for late reporting or no reporting. All of these activities could provide a challenge to any lawyer defending a case involving a report to the CPSC and a recall.

Foreign Regulatory Activity

Recalls and other post-sale remedial programs are also required under the law of many foreign nations. Recently, there has been an expansion of a manufacturer's responsibilities to monitor safety, report problems to government bodies, and possibly recall its products. Global recalls convinced the European Commission that there is an interrelationship between the safety in products sold around the world, that the current laws were inadequate, and that it was appropriate to expand a manufacturer's responsibilities.

Safety problems in one country may indicate a problem in another country. And despite the lack of U.S.-style product liability litigation, foreign governments have not been shy about demanding remedial action in appropriate situations. United States and foreign government agencies dealing with safety communicate regularly with each other to identify instances where safety problems or remedial actions in one country could signal a problem in another country.

The most significant recent European effort to address post-sale duties is implementation of the General Product Safety Directive throughout the European Union ("EU"). The Directive obligates EU member countries to impose upon consumer product manufacturers a general requirement to place only safe products on the market. The 2004 Directive substantially expands manufacturers'

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and governments' post-sale responsibilities. It attempts to strengthen each member country's powers to monitor and to improve collaboration on market surveillance and enforcement. The mechanism for this effort is a Product Safety Network that will develop procedures for a Rapid Alert System (RAPEX). RAPEX requires member countries to inform the European Commission of serious risks so that it can alert other member countries. In 2005, there were 847 notifications of safety problems to the EU; over 80 percent of them dealt with serious risks.

The objective of this new Product Safety Network will be to facilitate the exchange of information on risk assessment, dangerous products, test methods and results, and recent scientific developments. Presumably, there will be closer cooperation in tracing, withdrawal, and recall of dangerous products. The obligations and enforcement powers of the member countries have been expanded to meet these objectives. The EU has also clarified when a member country can order or organize the issuance of warnings or a recall of a dangerous product.

The 2004 General Product Safety Directive ("Directive") also 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 have a duty to immediately notify government agencies 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 requirement of the Directive.

The Directive 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. . . ." This threshold for reporting appears to be much lower than under any U.S. statute or regulation and therefore should result in more reports and presumably more recalls.

While non-compliance with foreign standards and regulations has generally not been admissible at trial in the U.S., plaintiffs' attorneys may try to introduce such non-compliance to support an argument for punitive damages.

A manufacturer that recalls a product in the United States and not in a foreign country, or in a foreign country and not in the U.S., should have a good reason for the inconsistency. The plaintiff may try to use any inconsistent approach to post-sale reporting and remedial programs to gain an advantage. The plaintiff may even try to argue that an inconsistent approach exhibits a malicious disregard for public safety, even if the public is in a foreign country.

The Directive is currently being implemented in the countries that comprise the European Union. It is unclear at this point whether there will be consistent implementation of this directive and how each country will enforce compliance.

Meeting a Manufacturer's Post-Sale Duties

The foundation of a post-sale program is establishment of an information network that will allow a company to determine how its product is performing in the United States and around the world. This information is necessary for the manufacturer to make decisions about whether any post-sale corrective action is appropriate.

The increased impact of foreign events on U.S. responsibilities makes it even more important that this network gather infor-

mation received anywhere in the world. In addition, the regulatory and common law requirements discussed above apply to information the manufacturer obtained (or should reasonably have obtained) that identifies an unsafe condition. Therefore, anything less than a “reasonable” effort at obtaining information may be considered by the jury or government agency in determining whether the manufacturer should have known about the problem.

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. Personnel should be trained to ensure that sufficient information is gathered concerning the claims and accidents so that potential problems can be identified. Lawsuits (including settlements and verdicts) will provide the same information.

Customer complaints and warranty returns provide 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. Again, personnel should be trained to identify and clarify the information so that it is accurate and substantiated. The manufacturer does not want to gather and maintain inaccurate and overstated complaints and claims that incorrectly make it appear that a problem exists.

An unusual number of sales of safety-critical component parts may indicate that a part is failing prematurely. Of course, observations by sales and service personnel who are actually out in the field talking to customers are invaluable sources of information. Post-sale information can also come from competitors at trade shows or as part of membership in a trade association.

Post-sale information, albeit some of it unsubstantiated or even incorrect, is now posted by consumers on the Internet. Some companies monitor the Internet, especially sites customers might visit, to read comments about their products. Each manufacturer will need to determine whether a follow-up investigation of safety issues raised by customers or product owners who post such information is warranted. Ignoring such information can be perilous, but following up on all alleged safety issues could be time-consuming and fruitless.

Some statutes and regulations set forth post-sale monitoring requirements. These need to be considered in establishing a post-sale program. Monitoring requirements include the kinds of information that should be considered and the kinds of documentation that need to be maintained.

Once a manufacturer has obtained all relevant information, it must determine whether post-sale action is necessary. This includes reporting to the relevant governmental agency and undertaking some form of remedial plan.

Ideally, a corporate or divisional product safety committee will analyze the information. This committee should be made up of representatives from various areas of the company, including engineering, service, sales, marketing and legal. The lawyer advising the committee should be experienced in product liability and regulatory law in the countries where the affected product was sold.

Analyzing the information and deciding what it means is the most critical phase of this process. Many manufacturers use or should use risk assessment prior to selling their products. This process identifies the risk, probability of the risk occurring, consequences if it occurs, and methods to minimize the risk. Before sale, the manufacturer should make a projection on the probability of the risk occurring. It is, of course, difficult to estimate the probability of an event occurring when it has never happened before.

After sale, the manufacturer is, in effect, plugging new numbers into its risk assessment. Post-sale incidents may indicate risks or consequences that were never imagined, or increase the estimated probability calculated before sale. Redoing the pre-sale risk assessment is a good way to formally recalculate the numbers and assumptions. Unfortunately, that does not really answer the question of whether remedial action is necessary and what form it should take.

Because the manufacturer’s products have presumably been sold in all 50 states, it is necessary to assume that a post-sale duty to warn exists. And, because the law in the states differs, the best approach is to examine the Third Restatement to gain a general sense of the national law on post-sale duty to warn. Therefore, determining whether post-sale action is necessary under

the common law requires applying the factors in the Third Restatement to the facts learned through the information-gathering network and the results of the revised risk assessment.

For regulated products, the manufacturer needs to identify the threshold for taking action as required by the appropriate government agency. Using the criteria established by the applicable agency will provide guidance to the manufacturer about what post-sale information to gather and how to analyze it.

It is beyond the scope of this article to describe the various ways in which a manufacturer can recall its products. For more information, see Kenneth Ross, “Adequate and Reasonable” Product Recalls, For The Defense, October 2003, at 18, and Jason L. Hertzberg, *Consumer Product Recalls*, For The Defense, December 2005, at 59.

Recalls can be extremely difficult and very ineffective, despite the best of efforts. There are no clear guidelines in the common law or even with government agencies about how effective a recall has to be. Recalls or retrofit programs with an effective rate of less than 10 percent have been deemed acceptable by the CPSC. And, the CPSC has said that the average response rate from consumers for most recalls is between four percent and 18 percent.

Virtually no recalls have 100 percent compliance. As a result, the manufacturer will have many products in the field that it has admitted or intimated are defective or at least pose a risk of injury. After an injury occurs and a lawsuit filed, how will the manufacturer defend its product?

Defending a Product after a Recall

Even the most airtight recall campaign may not result in a finding of no liability. See *Third Restatement, section 10, comment j*. If the accident occurs after the recall, the manufacturer may need to defend the integrity of the recall process. If so, the manufacturer will need to prove that it acted reasonably, reaching out as best it could to product users to inform them of the recall. Contacts with registered owners, distributors, and retailers through letters, posters, press releases and ads in trade and consumer publications are the most common recall notification vehicles. If the recall information did not reach the par-

ticular consumer involved in the accident, the manufacturer may need to explain why it did not. If the consumer did receive the recall information and did not act upon it, the manufacturer may have a comparative fault defense against the claim.

However, many recall-related cases involve accidents that occurred *before* the recall was commenced. The mere fact of a product recall is often a magnet for lawsuits, regardless of the true cause of the accident. Defending against a recall is challenging, given that most recall letters admit that the product is defective and such evidence leaves a lasting impression on juries.

Whether the accident occurred before or after the recall started, manufacturers can position themselves to make their best defense in court with these practical strategies.

Act decisively and expeditiously in conducting the recall

Manufacturers are best positioned to defend their products if they can demonstrate that they acted swiftly and affirmatively in proceeding with the recall. It is more difficult to defend products where accidents occurred during the decision-making period. Juries will not take kindly to manufacturers who appear as if they stalled or tried to blame someone else. Manufacturers should also assume that documents involved with the recall process will be admissible in court and therefore should be drafted with care.

Draft the recall message with care

The way the recall message is drafted may determine its admissibility in court. For example, manufacturers may choose to characterize the measure as a “product improvement” rather than admit that the product is defective. The manufacturer may explain that the product change is offered to protect against misuse of the product. Even the term “recall” can carry a negative connotation and some manufacturers choose to substitute the phrase “product safety bulletin” in their consumer and distributor alerts. It is important to emphasize in the communication that the safety issue requiring the recall may not exist in every product. Also, the communication should create an incentive for the user to fix the product to reduce the number of products in the field containing the recall condition.

Pick the “losers” and “winners” and settle the losers

Prompt evaluation of claims and lawsuits is key. Usually, settlement is the best option when it is determined that the accident at issue was caused by the recall condition. Early evaluation and settlement in these cases will save on costs and attorney fees. On the other hand, manufacturers may

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take a stand and defend their product when they determine that the accident was not caused by the recall condition. Recognize that, whenever a recall is involved, even a “winner” of a case can be difficult to defend as evidence of a recall can be very prejudicial, leaving juries with the impression that a product is defective and caused the injury even when it did not.

Weigh the pros and cons of excluding the recall

Sometimes the admission of product recall evidence at trial may be beneficial and a manufacturer should consider that before immediately moving to exclude. For example, manufacturers may want to admit evidence of a recall to defend against a punitive damages claim. Such evidence would prove the manufacturer’s commitment to safety and the well being of its consumers. On the other hand, a recall notice can be prejudicial to manufacturers because it can create an assumption that the manufacturer had prior knowledge of a problem and has admitted to a product defect.

Courts are split as to whether product recall evidence is admissible in products liability litigation, but there are several approaches for manufacturers who choose to try to keep the recall from being introduced into evidence. For example, treat the recall as a subsequent remedial measure that occurred after the accident. Under

Rule 407 of the Federal Rules of Evidence, subsequent remedial measures are inadmissible to prove negligence or a defect in a product, although such evidence may be offered for other purposes such as proving ownership, control or for impeachment.

Manufacturers should also be prepared when plaintiffs argue that recall evidence is admissible as an admission that a product is defective. *Barry v. Manglass*, 55 A.D.2d 1, 389 N.Y.S.2d 870 (1976), and its progeny can be used to counter that argument. The *Barry* court ruled that a recall letter issued after an accident is not to be construed as an admission that the product is defective and that it was reversible error to instruct a jury that it is. *Tober v. Graco Children’s Products, Inc.*, 431 F.3d 572 (7th Cir. 2005), provides ammunition for the exclusion of CPSC correspondence notifying a manufacturer that a product is hazardous. In *Tober*, the Seventh Circuit affirmed the Indiana District Court’s decision to bar evidence of the CPSC’s preliminary determination that a manufacturer’s child swings presented a substantial risk of injury to children. The court rejected plaintiff’s appeal that the CPSC’s notice to the manufacturer was admissible as an adoptive admission by a party-opponent.

Defense counsel may also attempt to exclude product recall evidence on the basis of relevancy, arguing that the evidence is not related to the same product or defect as the component and alleged defect involved in the accident. *See Jordan v. General Motors Corp.*, 624 F.Supp. 72, 77 (E.D.La. 1985); *Verzywvelt v. St. Paul Fire & Marine Insurance Co.*, 175 F.Supp.2d 881, 888 (W.D.La. 2001). A Rule 403 objection is also appropriate if such evidence would be unfairly prejudicial or would mislead or confuse the jury. *See Muniga v. General Motors Corp.*, 102 Mich. App. 755, 302 N.W.2d 565, 568–69 (1980); *Vockie v. General Motors Corp., Chevrolet Division*, 66 F.R.D. 57 (E.D.Pa. 1975).

Even when the recall evidence is admitted, defendants may argue for a jury instruction limiting the weight of the evidence pursuant to Rule 105 of the Federal Rules of Evidence. For more information and authority on evidentiary issues, see Pamela W. Carter, *Defending Against Product Recall Evidence at Trial*, For The Defense, April 2002, at 43.

Defense counsel must also assess whether it is likely that the recall will remain excluded throughout the trial. If the evidence is admitted in the middle of the trial, the defense may find its credibility impaired. It may be better to deal with the recall up front, then explain why the recall condition did not exist or did not cause the accident.

Police the claims made against the manufacturer

Generally, there is no common law duty to recall a product, but, once a recall is undertaken, the manufacturer must act reasonably in implementing the recall. *See Third Restatement §11*. At trial, manufacturers should be careful to police plaintiff's arguments that are not supported by legal duties. For example, a claim that the recall should have been conducted earlier is simply a variation on the impermissible argument that the manufacturer had a duty to recall the product.

Manufacturers should also police claims that they should have reported incidents to the CPSC or NHTSA. There is no private cause of action for violating CPSC or NHTSA reporting requirements. *Ayres v. General Motors Corp.*, 234 F.3d 514, 523 (11th Cir. 2000); *Drake v. Honeywell, Inc.*, 797 F.2d 603, 609 (8th Cir. 1986). Manufacturers should use motions *in limine* to exclude recall-related evidence and claims not supported by legal duties.

Put the risk of injury into perspective

If the recall letter pertains to a safety condition, manufacturers should provide some context for the jury. Contrast the number of accidents and injuries involving a particular safety condition with the total use of the product to demonstrate the minimal risk involved. Use such factors as the number of products produced each year, the num-

ber of years the product has been in use, and the total miles or hours of product use per year. In the case of a motorcycle, for example, juries will find an isolated number of accidents and injuries more reasonable when they find that consumers have used thousands of that particular motorcycle over millions of miles.

Tell the due care story

Manufacturers should explain to the jury how they are careful, prudent and concerned with product safety. Tell the jury about the numerous government regulations and industry standards that the product meets and surpasses and the continual in-house product testing and risk evaluation the product undergoes. Jurors also should be informed about the many warnings and instructions displayed in product literature, owner's manuals, on-product warnings, and hang tags. This evidence is needed for the jury to understand why the recall condition was not discovered in the product's design process and why the product was not defective when it was sold.

Prove that the recall condition did not cause the accident

A manufacturer's best bet for winning a case involving a recall is by proving that the recall condition does not exist in the particular product or by proving that the recall condition did not cause the accident. If the recall involves a stuck throttle, prove that the throttle was not stuck and the accident was caused by operator error. If the recall involves a defective seat belt, prove that plaintiff was not wearing the seat belt at the time of the accident. Given the prejudicial impact of the recall, the defense will bear the practical burden of persuasion in proving the true cause of the accident.

Prove that another factor was the cause of the accident

The manufacturer's recall becomes irrelevant when other factors or conduct are to blame for the accident. Point to any after-market modifications to the product and any risk-taking use of the product by the plaintiff. Also point to any misuse or inadequate maintenance of the product. The case for defendant is stronger when plaintiff's conduct violates explicit guidelines in the owner's manual or in product warnings.

Try the comparative fault case against others

Even if the plaintiff can make a case that the product is defective, a manufacturer can alleviate its share of the liability by persuading the jury to allocate fault to the plaintiff or third parties. For example, argue that the plaintiff is at fault for failing to respond to the recall letter or that a third-party user is at fault for ignoring on-product warnings.

Conclusion

Manufacturers need to be prepared to recall their products even if they have never had to do so in the past. Once a product safety issue arises, it is too late to develop a plan. Preparing for a recall before it occurs can significantly increase its effectiveness and lessen the costs and disruption. Of course, the manufacturer also needs to employ pro-active pre-sale product liability prevention techniques so that a recall is not necessary in the first place or if one is necessary, that the manufacturer has the best defense possible under the circumstances. And, if an accident occurs and suit is filed, the manufacturer should retain defense counsel who are experienced with defending cases involving recalled products. 