Avoiding Future Problems

The Increased Duty to Take Post-Sale Remedial Action

by Kenneth Ross

Manufacturers have been and will be subjected to increased post-sale responsibilities in the United States and elsewhere as a result of changes in the common and regulatory law. These changes have occurred because governmental agencies feel that manufacturers that sell defective and dangerous products need more rigorous requirements to report problems to governmental agencies, and the government agencies need more resources to monitor product safety and stronger regulations to force manufacturers to recall hazardous products. The increased responsibilities can either enhance the safety of products in the field or, if neglected, increase the possibility that the manufacturer will suffer irreparable harm to its brand name, as well as be subjected to fines, lawsuits, and the possibility of punitive damages.

Common Law and the Restatement

The American Law Institute recently considered the status of product liability law in the United States, culminating in the publishing of the new *Restatement (Third) of Torts: Products Liability* in 1998. 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 adopted requirements that manufacturers issue post-sale warnings of hazards to product users. The ALI ultimately decided that a sufficient body of law now exists to justify including the post-sale duty to warn in the Third Restatement. It requires, in certain instances, manufacturers or product suppliers to provide post-sale warnings, or possibly to recall or repair products. The post-sale duty section in the Third Restatement is truly new, and not a mere recitation of prior case law. Section 10 provides as follows:

> Liability of Commercial Product Seller or Distributor for Harm Caused by Post-Sale Failure to Warn
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> (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.
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> (b) A reasonable person in the seller's position would provide a warning after the time of sale when:
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> (1) the seller knows or reasonably should know that the product poses a substantial risk of harm to persons or property; and
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> (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
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> (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.

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

> 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:
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> (a) (1) a statute or other governmental regulation specifically requires the seller or distributor to recall the product; or;
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> (2) the seller or distributor, in the absence of a recall requirement under subsection (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 in the Restatement was to make it clear that Section 10 does not include a duty to recall the product. However, it also included the so-called "Good Samaritan" doctrine, where liability can attach for a negligent recall, even if it is voluntary.

While it is clear that over 30 states have adopted some type of post-sale duty to warn, the common law concerning the duty to recall

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and retrofit a product remains very limited. This is not true for U.S. regulatory law.

United States Regulatory Law

Despite the limited requirement to recall or retrofit products under the common law, U.S. regulatory law, for decades, has required manufacturers and sellers of various products to report safety problems to governmental agencies and undertake some sort of remedial actions, depending on the severity of the problem and the ability to find the purchasers of the product. These regulations are now being expanded, in part to deal with the concern that global safety issues, such as those experienced in the Ford-Bridgestone situation, are not being considered by manufacturers in making decisions concerning products in the United States.

Several federal agencies may become involved with recalls and have proposed or enacted new requirements.

Consumer Product Safety Commission

The CPSC has always required a manufacturer or product seller to monitor its products that are in consumers' hands and report defects that could create a substantial risk of injury to the public or may create an unreasonable risk of serious injury or death. Such reports usually result in some type of corrective action program or recall that includes repair, replacement, or refund of the purchase price.

In November 2001, the CPSC finalized revisions to its interpretative rule concerning reporting regulations to make it clear that manufacturers and product sellers must consider information generated from sources outside the U.S. when deciding whether to report. It has previously taken this position, but the Ford-Bridgestone tire recall focused attention on the relevance of such information and demonstrated that manufacturers may not consider it relevant.

The CPSC clarified its position that information a manufacturer must evaluate to determine if a reporting responsibility has arisen includes information that a firm obtains, or reasonably should have obtained, about product use, experience, performance, design, or manufacture outside the United States that is relevant to products sold or distributed in the United States. This applies to manufacturers that sell products outside the United States, and importers, distributors, and retailers that obtain or should have obtained information in a foreign country.

Food and Drug Administration

The FDA regulates foods, drugs, cosmetics, medical devices, biologics, radiation-emitting products, and feed and drugs for pets and farm animals. It has various regulations requiring manufacturers of these products to report safety problems or hazards. However, the FDA has no authority under the law to order a recall. Usually, the manufacturer will voluntarily undertake a recall, or the FDA will request that a recall be undertaken. If the company does not recall its products after being requested to do so, the FDA can seek a court order authorizing the federal government to seize the product.

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United States Department of Agriculture

The Food and Inspection Service (FSIS) of the USDA is responsible for ensuring that meat and poultry products are safe, wholesome, and accurately labeled, and also inspects pasteurized egg products. The FDA regulates all other foods.

When the FSIS learns about adulterated or mislabeled meat or poultry, it will request the company to recall the product if such a recall has not yet been instituted. While no company has yet refused, if one did, the FSIS has the authority to detain and/or seize meat and poultry products that may be hazardous.

National Highway Traffic Safety Administration

The NHTSA regulates motor vehicles and motor vehicle equipment. A manufacturer of the vehicle or the equipment, which determines that a safety-related defect or noncompliance with a NHTSA regulation exists in its product, must report to NHTSA within five working days. The manufacturer's proposed remedial program is to be included with the report. This remedy will always include a recall of the affected products from the customers' control if the product has made it into the market.

The Ford-Bridgestone tire recall directly led to the enactment of new legislation governing recalls of motor vehicles and motor vehicle equipment. On November 1, 2000, Congress passed the aptly named Transportation Recall Enhancement, Accountability, and Documentation Act (TREAD) in response to disclosures of non-reporting of tire problems in foreign countries.

TREAD adds a number of sections to Title 49 of the United States Code concerning increased reporting responsibilities. See, in particular, 49 U.S.C. §30166. Section 3(a) of TREAD discusses reports to NHTSA of defects in motor vehicles and motor vehicle equipment that occur in foreign countries. Manufacturers have five working days to report after determining that they will conduct a safety recall or other safety campaign in a foreign country on a vehicle or equipment that is identical or substantially similar to one they offer in the United States. Section 3(a) also requires a report when a foreign government requires a recall on an identical or substantially similar vehicle or equipment. Section 3(b) requests the Department of Transportation to create a rule concerning early warning reporting requirements. These requirements concern warranty and claims data received by the manufacturer from foreign or domestic sources claiming serious injuries or property damage from alleged defects.

On December 21, 2001, NHTSA issued a proposed regulation to implement these early warning requirements; per TREAD, NHTSA is required to issue a final regulation by June 30, 2002. The proposed regulation will require manufacturers to regularly provide data to NHTSA. Manufacturers will no longer be allowed to determine for themselves whether a safety-related defect or noncompliance exists. NHTSA will analyze the data and presumably encourage the manufacturer to report and undertake a recall.

The early warning provisions would require large volume manufacturers of motor vehicles to report all incidents alleged or proven to have been caused by a possible vehicle or equipment

defect in the United States and in foreign countries. Manufacturers would not need to provide data concerning internal investigations and design changes in parts and components. This was originally proposed but strenuously opposed by the manufacturers as burdensome and unclear as to when an internal investigation begins. In addition, manufacturers would have to provide to NHTSA, in part, reports of consumer complaints and warranty claims related to problems with components and systems.

The new TREAD requirements will seriously increase the post-sale monitoring of product safety and reporting to this government agency.

Foreign Regulatory Activity

Recalls and other post-sale remedial programs are required under the law of many foreign nations. Again, it was foreign recalls by Ford-Bridgestone that were not also undertaken in the United States that focused attention on the interrelationship of safety in products sold around the world. This attention has caused expansion of a manufacturer's responsibilities to monitor safety, report problems to governmental bodies, and possibly recall its products.

Safety problems in one country may indicate a problem in another country. And, despite the lack of the vigorous sort of product liability litigation we know in the U.S., foreign nations are not shy to demand remedial action in appropriate situations. United States and foreign governmental agencies dealing with safety are regularly communicating with each other to identify instances where safety problems or remedial action in one country could signal a problem in another country.

European Union

The EU's Machinery Safety Directive sets forth essential health and safety requirements relating to design and construction of industrial machinery and safety components. It creates a post-sale duty to update instructions by requiring manufacturers to draw the user's attention "to ways—which experience has shown might occur—in which the machinery should not be used." While the scope of the industrial machinery post-sale duty remains largely undefined, manufacturers should monitor their products' field experience and consider incorporating revisions into their warnings and instructions.

The most significant European Union action to address post-sale duties is the General Product Safety Directive. It obligates EU member countries to impose upon producers a general requirement to place only safe products on the market. The original 1994 Directive contains a requirement that imposes on manufacturers a post-sale duty to monitor their products. This presumably means manufacturers must update warnings and instructions in accordance with the information gathered from the monitoring program. National authorities, which also are required to monitor product performance, can request that manufacturers issue new warnings based on their post-sale monitoring.

The General Product Safety Directive has been criticized for lack of clarity and other weaknesses, especially in the area of post-sale monitoring and withdrawals and recalls. For example, some officials were upset that their government received notification of a safety problem in Europe from a U.S. agency that received a report from the European manufacturer.

On December 3, 2001, the European Parliament voted to repeal the 1994 Directive as of January 15, 2004, to be replaced with a new General Product Safety Directive. European Union members are required to adopt the 2004 Directive as their national law (although they may retain provisions in their own law that are more restrictive than the Directive).

The 2004 Directive substantially expands manufacturers' and government's 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 will be a Product Safety Network that will develop Rapid Alert System (RAPEX) procedures. RAPEX requires member countries to inform the Commission of serious risks so that it can alert other member countries.

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. In addition, joint surveillance and testing projects, the exchange of expertise and best practices, and cooperation in training activities will be established and executed. Presumably, there will be close 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. This includes clarification of 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 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 2004 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…" Suffice it to say that this threshold for reporting appears to be much lower than under any U.S. statute or regulation.

Outside the European Union

Many other nations have requirements to report to government agencies when a recall is undertaken or when a problem arises and before the recall is commenced. These include Canada, Japan, Australia, and many countries in Asia-Pacific.

All of these countries have adopted some type of product liability law, and it can be expected that the government has or will adopt some type of consumer protection legislation. Enforcement will vary from country to country and possibly product to product. Any diligent, responsible manufacturer will need to determine its reporting responsibilities in all countries in which its products are being distributed. This will be no easy task.

The effect on U.S. litigation

While non-compliance with foreign standards and regulations has generally been deemed not to be admissible evidence at trial, such non-compliance has been, and can be expected to continue to be, used frequently by plaintiffs in their arguments to support punitive damages. For example, a manufacturer that recalls a product in the United States and not in a foreign country should have a good reason for

the inconsistency. The plaintiff will try to argue that this exhibits a malicious disregard for the public safety. Is the fact that the public is foreign any excuse? Public opinion arising out of the Ford-Bridgestone recall shows that the public certainly doesn't understand how a manufacturer can recall a product in a foreign country and not in the U.S. The plaintiff will try to use any inconsistent approach to post-sale reporting and remedial programs to its advantage, regardless of the country where it occurred.

Post-Sale Remedial Programs

Learning about a manufacturer's reporting responsibilities is hard enough, especially if it sells products around the world. Determining just how to *meet* its post-sale responsibilities can be a much more daunting task. Many official governmental regulations and guidance in the United States and elsewhere, as well as many unofficial suggestions, contain information the manufacturer needs in meeting post-sale responsibilities. So, where to begin? The following is a synthesis of best practices obtained from a variety of U.S. and foreign sources.

Product safety policy and post-manufacture action plan

A manufacturer should be guided by a formal product safety policy. The policy serves as a benchmark for overall product safety. In addition to a general statement of product safety, there should be an additional 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 in the United States and anywhere else the product is being sold.

Both of these documents represent good business practices and could be helpful in defending any litigation that might arise. It is important to be able to point to a document, endorsed by the board of directors, the CEO, the president, or the general manager, that confirms a manufacturer's desire to market safe products and to identify and remedy any post-sale problems that come to its attention, regardless of where the product is sold.

Pre-sale advance planning

A manufacturer's most important post-sale responsibility is to establish post-sale procedures *before* the product is sold so the manufacturer can easily and efficiently obtain information, analyze it, make decisions about appropriate post-sale remedial programs, and implement the programs. These procedures cannot be implemented after sale of the product—it will be too late. Below are some of the measures a manufacturer should consider implementing.

1) Products should be designed and tested with the possibility of post-sale problems in mind. For example, the product should be designed in modules so that components that prove to be defective can be replaced without needing to replace the entire product.
2) Products should be manufactured using traceability and marking procedures that are used before manufacture, during manufacture, and during distribution. A continuous log of all batches, materials, processes, materials, components, and design changes of safety-critical parts should be maintained. Products or components should be marked or coded so that anyone, including customers, can identify the product to be returned.
3) The manufacturer should develop a post-sale exposure audit where the manufacturer summarizes worst-case scenarios and develops initial strategic action plans for each scenario. This would include a determination of safety-critical parts and what can occur if they fail.
4) The manufacturer must develop an information-gathering network before sale so that appropriate information is identified and analyzed. This procedure is so important that it is discussed in more detail below.
5) The manufacturer's lawyers should analyze and make agreements with upstream and downstream entities that anticipate and deal with post-sale issues such as information that must be supplied, who has the responsibility or authority to report to a governmental agency, which approvals are necessary to undertake a remedial program, who pays for the remedial program, etc. Insurance and indemnity provisions must also be in the agreement.
6) The manufacturer, in cooperation with all entities in the distribution chain, should design and maintain an effective product and customer database so that different levels of customers in the chain of distribution can be identified quickly. These databases must be updated periodically.
7) Press releases, customer alerts, distributor bulletins, Web site postings, and questions and answers to be used by management should be drafted before sale or, at least, not too long after sale. Processes to communicate this information quickly and efficiently to the appropriate people or entities should be developed at this time. For example, a manufacturer should be able to almost instantly send (by broadcast fax or e-mail) a message to its distributors requesting that the distributors and their customers embargo sales of a particular product. This will prevent sales of unsafe products and minimize the number of products to be recalled.
8) The manufacturer must develop criteria on the types of remedial programs that may need to be implemented and develop procedures and processes to implement each of these programs. Recall is not always necessary. And, different levels of recall may be appropriate, depending on the level of risk and difficulty of locating the products.
9) The manufacturer should consider record creation and retention procedures so that sufficient documents are created to demonstrate the due diligence used by the manufacturer in identifying the problem and addressing it. This will include determining the record keeping requirements of all relevant governmental agencies or applicable standards or directives, including ISO 9000 if the manufacturer is so certified.
10) The manufacturer should even consider creating procedures to reintroduce the product to the market. This involves an analysis of the worst-case scenarios, how to test and modify the product quickly, and how to design communications to

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restore and strengthen the product's reputation among the distributors, retailers, and customers.

11) Lastly, the manufacturer should consider recall training, drills, and full-scale mock exercises. When a crisis occurs, it will be time and money well spent.

A manufacturer needs to be careful that this pre-sale planning does not appear to be an admission that the company expects safety problems with this product and is just planning for the inevitable recall. The planning needs to be routine and consistent with the product safety policy. It can also be justified as necessary to comply with U.S. and foreign regulations that require a manufacturer to be better prepared to recall its product.

Information-gathering network

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 world marketplaces. This information is necessary for the manufacturer to ultimately make decisions about which, if any, post-sale action might be necessary.

The enhanced impact of foreign events on U.S. responsibilities makes it even more important that this network encompass information received anywhere in the world. In addition, the regulatory and common law requirements 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 governmental agency in determining whether you 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, 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 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 on the Internet. This will include customer complaints against a manufacturer's products or its competitors' products. 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. However, following up on all alleged safety problems could be very time-consuming and fruitless.

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

Analyzing the information and taking action

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. It is also very important that the lawyer advising the committee is 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 best guess 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 doesn't really answer the question of which action is necessary.

Determining whether post-sale action is necessary under United States common law requires applying the factors identified in the case law and Section 10 of the Third Restatement of Torts to the facts learned through the information-gathering network and the results of the revised risk assessment. 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 Section 10 to gain a general sense of the national law on post-sale duty to warn.

For products regulated by a government agency, the manufacturer needs to identify the threshold for taking action. For example, the 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 which information to gather and how to analyze the information. However, the CPSC provides little further guidance on this basic question and expects the manufacturer to report a substantial product hazard, or any suspicion that the product contains such a hazard, to the CPSC.

After the manufacturer reports to a government agency, the agency will most likely, if

not always, strongly encourage some type of remedial program. So, the manufacturer must be prepared, if it can as part of its report, to describe the remedial program that it believes will solve the problem.

If the information 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. If a number of injuries involving the same product occur, with the same basic failure mode, some type of reporting and post-sale remedial action will always be necessary.

Implementing a Post-Sale Program

If adequate pre-sale planning has occurred, implementing the program will be less difficult and more organized than if no planning occurred. Everyone will know what to do and when to do it. Because so many variations of programs exist that are dependent on the distribution chain, the product type, the risk, and the governmental agency involved, it is too much to discuss in detail here.

Many sources of information exist that will help a company plan an effective post-sale program. These include government agencies, lawyers, crisis management companies, management experts, and companies that specialize in recall management. Below is a listing of some of these entities and Internet sites, as well as useful articles and books where more information can be found.

- CPSC *Recall Handbook*. http://www.cpsc.gov/businfo/8002.html
- U.K. Department of Trade and Industry, *Consumer Product Recall—A Good Practice Guide*. http://www.dti.gov.uk/CACP/ca/advice/productrecall/pdf/consumer.pdf
- CPSC *Recall Checklist*. http://www.cpsc.gov/businfo/recallcheck.pdf
- NTHSA *Safety Recall Compendium*. http://www.nhtsa.gov/cars/rules/standards/recompendium.pdf
- *Product Recall in Australia* (Clayton Utz). http://www.claytonutz.com.au/prl/Product_Recall_0501.pdf
- Returns Online (a company with an excellent recall management program). http://www.returnsonline.com/
- Example of an excellent web site for a voluntary replacement program. http://www.sprinklerreplacement.com/VRP/enterVRP.php3
- *The Corrective Action Handbook*. Available for purchase at http://www.patonpress.com/
- "A Strategic Approach to Managing Product Recalls," Harvard Business Review, September-October 1996, Reprint 96506
- *The Product Recall Planning Guide*, American Society for Quality

Conclusion

Post-sale duties are among the most complex and most potentially dangerous responsibilities a manufacturer and product distributor can have. Most punitive damage cases involve some evidence that the manufacturer knew or should have known about a post-sale problem and did not take adequate remedial actions to prevent accidents involving deaths, injuries, or property damage.

Most manufacturers do not like to spend significant time and resources planning for an event that they hope will never occur. They tend to wait until it happens to figure out what to do. This article explains why this duty is too complex to consider only when a problem occurs. Pre-sale planning, from a legal, regulatory, and process standpoint, is critical to ensure that the likelihood of a post-sale problem is minimized and, if it occurs, can be handled in the most efficient and effective manner.

Failing to take such actions can result in huge losses in litigation, cancelled insurance, government fines and possibly criminal penalties, and ultimately, demise of the business entity. The phrase "an ounce of prevention is worth a pound of cure" has a great deal of application and meaning in this area. FD