

Product Liability Risk Control

Seven keys to success

By Kenneth E. Ryan

PRODUCT LIABILITY refers to the legal liability that arises out of the design, manufacture, distribution, sale and disposal of a product. If a product is defective or causes harm or injury to a person or his/her property while it is being used for its intended purpose—or in a reasonably foreseeable manner—the manufacturer, seller or both may be liable. One or both of these parties may have to pay damages to the person who was injured or suffered a loss.

Until the mid 1800s, manufacturers, wholesalers and retailers were relatively protected from product liability under the prevailing legal rule of “caveat emptor.” Loosely translated, this means “let the buyer beware.” If injured by a defective product, it was unlikely that a buyer could successfully sue and recover damages. Society and the courts generally held that customers had to look out for themselves. Most goods were agricultural products or uncomplicated manufactured goods, and it was widely believed that the buyer could, or should, easily discover defects.

The prevailing legal doctrine known as “privity of contract” provided another protection against product liability suits. Under this doctrine, persons injured by a defective product could only bring suit against the one who actually sold the product. If an injured customer purchased a defective product from a retailer, s/he would have no “privity of contract” with either the manufacturer or wholesaler and no legal basis to sue. If the person injured was anyone but the buyer, s/he would have no legal basis to sue the manufacturer, wholesaler or retailer.

Today, the pendulum has swung almost entirely in the opposite direction. The prevailing legal climate is more that of “caveat venditor”—“let the seller

beware”—and the doctrine of privity of contract in product liability suits is largely irrelevant under current law. Under the “implied warranty of merchantability” theory, a general condition of a sale is that the goods come with an implied

warranty that they are reasonably safe for the ordinary purposes for which such products are used.

Under the strict liability theory, injured parties need not prove negligence; they need only show that a product was in a “defective condition unreasonably dangerous” to the user, that injury or damage resulted from the defect and that the defect existed while the product was under the manufacturer’s control. The party seeking damages can be the buyer, bystander or any foreseeable user. Thus, not only is the manufacturer at risk, but also any commercial supplier—anyone in the business of selling goods versus the casual seller (such as the person who sells a jar of jam to a neighbor). Strict liability applies to a manufacturer (including a component part manufacturer), or anyone else in the distribution chain including wholesalers and retailers.

Manufacturers, Wholesalers & Retailers All Have Duties

Manufacturers have a duty to produce products that are “defect free” and safe for both their intended use and any reasonably foreseeable misuse. Being defect free means that the design is not defective, that no manufacturing defect exists and that adequate warnings are provided when needed.

Knowing who might be regarded as a manufacturer in any product injury situation is not always clear. Although some business owners might not consider themselves “manufacturers,” they might learn they have assumed some of the duties and accompanying liabilities of one if they:

- assemble various parts and components produced by others into a unit with their brand name or company name on it;

- sell a product under their company name, brand name or label, although functions such as actual design, manufacture, assembly and fabrication are performed by someone as a subcontractor or by the firm from which the product is purchased;

- are a retailer or wholesaler that assembles products made by others, such as bikes and barbecues;

- rebuild, retrofit or recondition used products that were originally manufactured by others in order to resell them;

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- modify or repackage new products originally manufactured by others, and sell them;
- sell products directly imported from a foreign country.

This list is not exhaustive. It is intended to point out that even if a company did not originally design and manufacture a product, it may assume the duties and liabilities of the manufacturer without being fully aware of it.

In addition to the duties and liabilities that wholesalers and retailers might assume by such actions, other duties they may have as a matter of law can include:

- **The duty to inspect and test.** Although retailers generally have no duty to inspect or test products they sell, businesses such as car dealers have been found to have a duty to inspect and test. In addition, retailers generally need to inspect and test if they recondition a product and/or warranty it as safe.

- **The duty to warn.** If an inherent danger is involved with product use, and the retailer is aware of it, yet the danger is not obvious or common knowledge, there may be a duty to warn. The user's age or mental capability will be considered when determining the extent of this duty. A retailer which purports to have expertise in a given field and knows that a product being purchased is not suitable for its intended purpose may have a duty to warn the customer.

- **The duty of care** (i.e., to take reasonable and prudent precautions). If a retailer sells a product that is more dangerous than the one ordered, it will likely be found liable for injuries attributed to product use. In addition, a retailer will generally be found liable if a product-related injury arises from a sale in violation of a statute, such as injury arising from sale of firearms to a minor, or sale of food not fit for human consumption. Furthermore, a wholesaler or retailer that stores or ships products has a duty to be sure the conditions under which the product is stored or shipped will not render the product defective (e.g., temperature extremes, shock, sunlight, contaminants).

Again, this list is not exhaustive. It is intended to show that responsibility for product safety does not reside solely with manufacturers. To avoid product liability minefields, a wholesaler or retailer must take care to be sure the products it sells are produced by reputable manufacturers which employ reasonable measures to ensure that the products are fit for their intended use and reasonably foreseeable misuse, and that they are not unreasonably dangerous.

Commitment to providing safe and reliable products and services is becoming more critical to long-term success in today's quality-conscious marketplace. In fact, product safety is now commonly featured in national sales campaigns. The following seven risk control measures can help a company minimize its product liability loss potential.

Seven Keys to Product Liability Risk Control

Attention to seven performance areas can help business owners ensure product safety and minimize product liability loss potential. They are:

- 1) management leadership and support;
- 2) safe design;
- 3) legal review and counsel;
- 4) quality assurance and control;
- 5) product labels, packaging and warnings;
- 6) marketing and customer service;
- 7) product recall planning and implementation.

Management Leadership & Support

Product liability risk control measures will likely fail unless all involved believe that the measures have top management's support. Top management must lead by example. This means that these executives must:

- Allocate time and money to develop and implement solutions.

- Foster a culture in which all employees understand that production and sale of safe, reliable products is critical to continued business success.

- Promote open communication channels among all organizational levels, as well as with suppliers, subcontractors, distributors and other external "partners."

- Establish accountability for achieving total quality management objectives that integrate product safety and product liability prevention considerations.

- Document and update policy, procedures, goals, accountability and all product safety activities.

In addition, management must understand current legal concepts associated with product liability, use this knowledge to shape effective policy and effectively communicate this policy to employees.

Safe Design

The allegation that a product is defective in design is the most common allegation asserted in a product liability action. In its 1998 legal treatise, "Restatement of the Law Third, Torts: Products Liability," the American Law Institute (ALI) states, "A product . . . is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe. . . ." While ALI's restatement is a secondary authority (that is, it does not have binding legal authority), it reflects the law in general and how it is changing; furthermore, these documents traditionally influence and offer guidance to the courts in shaping the law.

A significant change between the Restatement Second and Restatement Third, in the products liability area, is the elimination of the "consumer expectations test" as an independent governing standard in determining whether a product is defectively designed. The "consumer expectations test" essentially allows a jury to hold a product manufacturer liable for a defective product design based on a determination that the product in question did not perform as an ordinary consumer would expect when used in an intended and reasonably foreseeable manner. The Restatement Third reduces this

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expectations test to being merely one of many factors to be considered by the jury in conducting a risk-utility balancing analysis.

To successfully protect against a lawsuit based on alleged design defect, several key factors must be considered when making design decisions. These include:

- mandatory and voluntary, codes, standards and regulations;
- reasonably foreseeable product use and misuse;
- physical or mental limitations of foreseeable users, particularly children;
- cultural/language differences for likely users;
- ease of service, maintenance and repair;
- environmental conditions in which a product may be used;
- anticipated product lifecycle;
- special disposal or storage requirements;
- interface with other products or use with non-compatible chemicals;
- advances in state-of-the-art technology;
- conducting a compressive risk assessment and design review;
- following the "safety hierarchy" that entails

1) eliminating a hazard; 2) implementing engineering controls; 3) providing warnings, training and PPE;

- adequacy of warnings, instructions and labels.

If a hazard cannot be eliminated or adequately safeguarded against via design, or adequately controlled via warnings and safe operating procedures, it may be best to keep the product off the market.

Legal Review & Counsel

Being prepared in the product liability arena requires consulting with qualified legal counsel well before a product is brought to market. This individual or firm must have considerable experience in product liability law in order to help a client avoid the many legal pitfalls that confront those in today's product distribution chain. If first contact with legal counsel involves the insurance company's attorney after suit has been filed, the battle may already have been lost.

Depending on a company's size and the complexity of its product line, legal services may be needed only on a part-time or retainer basis. However, in this era of consumer activism, new laws and regulations have a significant impact on product liability and product safety requirements. Court decisions or laws that can have important ramifications for a company occur regularly. One wrong word or misrepresentation in advertisements, sales presentations or other product literature can create an express warranty that although unintended, may create liability.

Acquisition or merger with another company likely brings with it potential liability for harm or injury arising from any defective product the other company has sold. Areas of concern that require legal review and counsel include:

- preparation of contracts, hold harmless agreements, warranties, guarantees and disclaimers;
- staying informed regarding laws, regulations and court decisions;

- evaluating product liability implications arising from acquisitions or mergers;

- reviewing advertising and sales literature for statements of "puffery" (statements that may unintentionally create express warranties);

- evaluating product labels and warnings for adequacy and compliance with codes and regulations;

- reviewing records for usefulness in defending lawsuits;

- planning product recall strategy.

Although not all-inclusive, this list certainly illustrates that much legal groundwork needs to be done, particularly by manufacturers, and that these are not "do it yourself" activities; they require the services of qualified legal counsel.

Quality Assurance & Control

Manufacturing and quality control are focal points for ensuring that products are manufactured in conformance with design criteria and specifications. People, equipment, material and the work environment must function effectively as a system so that nothing degrades product integrity and safety during the production process.

Controls are required to prevent unauthorized modification in design and to ensure that only prescribed materials are used. Care must be taken so that the product is not damaged by overstressing, temperature extremes, falling impacts or adverse storage conditions. Coding or polarizing may be necessary to prevent misassembly, particularly when differences between component parts are not easy to discern visually. Procedures are needed to ensure that a product cannot escape a quality control checkpoint.

A company should develop a written quality assurance program that is revised periodically and, at a minimum, provides for:

- testing and inspection of raw materials, component parts and finished product;
- inspection of packaging, manuals, labels and customer service work;
- engineering drawing and change control procedures;
- a system for controlling, inspecting and evaluating procedures;
- detailed records of quality assurance activities;
- validation of quality standards and size of test samples;
- control of nonconforming materials and rejects;
- calibration of testing and measuring equipment;
- periodic review and updating of the quality assurance program;
- audits of both company quality control effectiveness and that of product/components produced by subcontractors;
- general adherence to nationally recognized quality system standards such as ISO 9000.

ISO 9000 is a set of three standards for quality management systems that is recognized worldwide. First published in 1987, by the International Organization for Standardization, Geneva, Switzerland, the standards have been adopted by compa-

nies in more than 90 countries, including the U.S., Canada, Japan and the European Union.

ISO 9000:2000, "Quality Management Systems: Fundamentals and Vocabulary," establishes a starting point for understanding the standards and defines the fundamental terms and definitions used in the ISO 9000 family. ISO 9001:2000, "Quality Management Systems: Requirements," is the requirement standard used to assess a company's ability to meet customer and applicable regulatory requirements. It is now the only standard in the ISO 9000 family against which third-party certification can be carried. ISO 9004:2000, "Quality Management Systems: Guidelines for Performance Improvements," provides guidance for continual improvement of the quality management system based on eight quality management principles: 1) customer focus; 2) leadership; 3) involvement of people; 4) process approach; 5) system approach to management; 6) continual improvement; 7) factual approach to decision making; and 8) mutually beneficial supplier relationships.

It is important to recognize that these standards address guidelines and procedures for establishing quality management systems and are not substitutes for distinct technical product requirements. They are also voluntary. However, U.S. courts can—and do—use voluntary standards for establishing a manufacturer's "duty of care." As procedures necessary to produce safe products are codified and, given the ever-increasing recognition of ISO 9000 standards as "global quality assurance standards," manufacturers are in a tenuous situation if their quality assurance programs do not measure up.

Product Labels, Packaging & Warnings

When deciding whether a product is defective—that is, has been negligently manufactured or designed—or lives up to a warranty, the courts will generally apply a broad definition to the word "product." They will examine not only the functional product (what the customer uses or consumes), but also product labels, packaging, warnings, advertising, manuals, and instructions for use and maintenance. Essentially, the courts will review anything that affects user expectations about the functional product itself. Virtually anything that affects the ability to safely use or dispose of a product in a reasonably foreseeable manner is also fair game.

As a result, product labels and product packaging must be considered part of the product or even viewed as products themselves. Therefore, manufacturers or others who repackage, assemble, rebuild or sell under their own label must be familiar with applicable mandatory and voluntary codes, regulations and standards regarding labels and packaging.

Improper disposal of some packages or containers can result in pollution or serious physical injury (e.g., hazardous chemicals and exploding aerosol cans); inadequate design can lead to damage during shipment or storage that in turn, can result in serious physical damage or personal injury (e.g., leakage of flammable liquids, gases). Product labels, instructions

and warnings should help ensure that this does not occur. Inadequate warnings on labels or instructions for use can also lead to inappropriate use or misuse, with serious consequences to the user. Keep in mind that neither warnings nor instructions are a satisfactory substitute for proper design.

Several important product labeling, packaging and warning risk control factors must be considered.

- Labels must be clear, concise, accurate and easy to understand.

- Warnings must be conspicuous and designate the degree of hazard (e.g., CAUTION, WARNING or DANGER).

- Warnings and instructions should be repeated in the various languages of primary users.

- Warnings must convey the consequences of failure to heed (e.g., causes burns, dizziness, blurred vision, may be fatal if ingested).

- Labels should describe proper method of disposal, particularly if the contents are toxic, corrosive, caustic or flammable.

- Labels must be firmly attached so they remain in place and are legible for the life of the product.

- Warnings, labels, instructions and MSDS must be congruent.

- Packaging should have its own labels and warnings as appropriate.

- Packaging should be designed to minimize harm to contents or handlers during shipment, handling and storage.

- Packaging must meet standard requirements of relevant regulatory agencies such as DOT and the U.S. Postal Service.

A duty to warn arises when 1) product safety will be improved by informing users of a product hazard/danger and instructing them how to avoid it; or 2) the product cannot be made more safe but its utility is great (i.e., its benefit significantly exceeds the risk) and the user must be alerted to the hazard/danger and given the opportunity to make an informed decision to either avoid or assume the risks associated with using the product (Campbell and Edwards).

Marketing & Customer Service

Under current law, any promise or representation of fact made about a product in advertising, on labels, during sales presentations or otherwise normally constitutes an express warranty. This holds true whether or not there is intent to make such a warranty and whether or not the word "warranty" or "guarantee" is used. The statement can be made by a sales clerk, service representative or anyone affiliated with or representing a company.

Case Study: Inadequate Warning

In *Products Liability in a Nutshell*, Jerry Phillips discusses how, in *Boyl v.*

California Chemical Co., the manufacturer's warning about the toxic qualities of its product did not go far enough because it did not address a safe means of disposal. Its product, Triox, a weed killer, was prominently labeled as a strong poison. The user was also warned to thoroughly wash and destroy the container once it was empty.

The plaintiff used a spray tank to apply the Triox. Afterward, she thoroughly rinsed the tank and poured the rinse water on the grass in her backyard. Five days later, while sunbathing in the area where she had poured the rinse water, she was badly burned by the Triox residue that remained. The court held that the defendant either knew, or should have known, of the stable quality and long-lasting contamination properties of the sodium arsenate contained in the product. Accordingly, the company could be held to a duty to give "some reasonable notice or warning concerning a safe disposal of the rinse residue" (Phillips).

Case Study: Defective Design

While baling alfalfa with his closed-throat baler, Tim Kinser, a Kansas farmer, became entangled up to his waist in the compression rollers of the baler's feed intake unit. A farmhand and a fellow farmer used bumper jacks and an acetylene torch to free him. An ambulance transported him to the county hospital, where he was pronounced dead within 30 minutes. Suit was brought in the U.S. District Court, District of Kansas, against Gehl Co., the baler manufacturer, by the decedent's wife on behalf of herself and the decedent's estate. The suit alleged that the baler was defective in design and unreasonably dangerous. Other bases for suit included negligent manufacture and breach of warranty. Following a seven-day trial, the jury found the manufacturer 55 percent at fault and the farmer 45 percent at fault and assessed \$3,849,181 in damages. The verdict, as well as the court's denial of a motion for a new trial, were appealed to the U.S. 10th Circuit Court of Appeals, where the lower court ruling was affirmed (*Kinser v. Gehl Co.*).

During the trial, expert witnesses for the plaintiff suggested design improvements that, in their opinion, could have reduced the severity of injury. These included installation of an automatic shutoff mechanism (in the form of a lanyard or cable) on the front of the baler; movement of the pick-up tines further back along the bottom of the baler; movement of the hay hold down bar and/or elongation of the power take off (PTO) tongue to minimize an operator's potential proximity to the feed intake area; and construction of a guard in front of the pick-up tines. They supported their opinion regarding the feasibility of the guarding proposal by noting that John Deere had adopted similar modifications to its closed-throat baler.

Because no one witnessed the accident, it is unclear exactly how the decedent became entangled in the baler's pick-up assembly area. It was speculated that he was either attempting to unplug the baler or fix the automatic tying mechanism. Plaintiff's expert theorized that either action would have put the decedent within inches of the pick-up tines, and he likely lost his footing and was pulled into the machine. Because of the many moving parts in the baler's feed intake and assembly areas, the manufacturer had issued warnings in its operator's manual and posted a series of warning decals on the machine itself detailing the proper handling of the baler. These warnings direct users to follow a "mandatory safety shutdown procedure" before unclogging, cleaning, adjusting, lubricating or servicing the unit. Under this procedure, users must 1) disengage the PTO; 2) shut off the tractor engine and remove the starter key; 3) wait for all movement to stop; and 4) remove all power connections, including the PTO device, from the tractor.

An expert for the manufacturer testified that the machine was not dangerous beyond the expectations of farmers who use it. The defense suggested Kinser's failure to recognize an open and obvious danger was the cause of his injuries. In essence, they suggested that had the decedent heeded product warnings and followed the proper shutdown procedure, he would not have been injured. Plaintiff's attorney did not dispute this.

However, several farmers testified that it is common practice to exit the tractor with the PTO engaged in order to assess feeding problems and mechanical malfunctions in the feed intake unit and adjust the twine in the automatic tying mechanism. Despite the mandatory shutdown procedure, these farmers said the nature of their work makes it impracticable to abide by the instructions. Farmers frequently work alone and often have only a small window of time in which to harvest crops at ideal climatic conditions.

In addition, plaintiff's expert witness insisted that a prudent manufacturer would know that farmers frequently step off their tractors and approach attached balers without first disengaging the PTO. They advised that while farmers recognize the potential for injury inherent in this procedure, they do not fully appreciate the magnitude of the risk involved. They further observed the mere posting of warnings is ordinarily insufficient to make a product safe. They also noted that under a proper "design hierarchy," warnings constitute an adequate response to a hazard only if the manufacturer is unable to either eliminate that hazard altogether or erect a guard to shield against it. This jury apparently agreed that the product design was defective and that warnings cannot compensate for a defective design.

While an expression of an opinion or belief (e.g., this is the best of its kind) is not normally considered an express warranty, it may be construed as such in cases involving serious personal injury and/or sympathetic plaintiffs (e.g., children). Therefore, it is best to avoid exaggerations about product features or qualities. Anyone in an organization who has contact with customers should be well-versed in product application and limitations, as well as the consequences that can result from overstatements or misinformation they provide. Any statements made in advertisements, sales literature, oral sales presentations and similar mediums must be factual. The company must always be able to substantiate them with documented test results and other data; the same holds true for actual or intended warranties or guarantees.

Customers must be informed about the proper use and maintenance of products so they will be safe for use throughout the anticipated lifecycle. Any time or scope limitations of a warranty or guarantee must be communicated. Customers must also be advised of service and proper use requirements that must be met for the warranty or guarantee to remain in effect.

From an insurance coverage perspective, service or repair functions are actually in the realm of "completed operations" exposure rather than product liability. However, from a liability perspective, this distinction effectively makes little difference to the company that performs such functions. The use of improper or inadequate replacement parts or materials, modifications that increase a hazard or reduce safety, poor workmanship, inadequate training, incomplete records and making statements not supported by data, can do the same harm here as they can toward product liability exposure. Consequently, this area requires the same integrated approach to safety.

Product Recall Planning & Implementation

To paraphrase Robert Burns, the famous Scottish poet, man's best laid plans often go wrong. Despite the best product design, quality controls, manufacturing practices, legal counsel and planning, and contingency plans are needed to deal with the possibility that a defective product may cause harm or injury to a user or innocent bystander.

Objectives of a Recall

According to Consumer Product Safety Commission (CPSC), a product recall is designed to:

- 1) locate defective products as quickly as possible;
- 2) remove defective products from the distribution chain and from the possession of consumers;
- 3) communicate accurate and understandable information in a timely manner to the public about the product defect, the hazard and the corrective action; companies should design all informational material to motivate retailers and media to get the word out and consumers to act on the recall (CPSC).

Hammer suggests five principal reasons for instituting product recalls:

- 1) Analysis indicates the presence of a potential hazard that could lead to an accident.
- 2) Users, consumers or other persons have report-

ed various unsafe conditions, characteristics or occurrences.

3) An accident or accidents reveal an unforeseen deficiency.

4) A government act, standard, regulation or other mandatory requirement is violated.

5) Product characteristics are incompatible with advertised claims for safety.

Essential elements of a product recall and retrofit plan include top management involvement, support and leadership. These are demonstrated by:

- a policy statement that describes purpose, objectives and functional accountabilities;

- a recall procedure manual with written procedures for each operating unit, including criteria and procedures for deciding whether and how a recall will be initiated;

- a strategy and criteria for communicating with the media;

- a procedure for communicating and working with government agencies that may either mandate recalls or require notification of voluntary recalls;

- a procedure for notifying all customers, other users and other potentially affected parties in the manufacturing/distribution chain;

- a method for funding recalls and allocating recall expenses;

- a policy to include legal counsel in all aspects of recall planning.

Another essential element is a provision for product traceability and recordkeeping. This entails:

- determining recall potential and product liability loss potential of all products sold;

- determining how products will be located and removed from the stream of commerce or modified in the field;

- establishing a procedure for tracking products that are resold and/or have a plan to notify such users through media and/or trade publications;

- estimating the cost of traceability;

- identifying critical parts and components and establishing records and procedures to be able to track them from suppliers throughout the distribution chain;

- maintaining comprehensive and detailed records of all design, quality assurance/manufacturing data, testing, shipping and distribution;

- maintaining backup records at a second location should primary records be lost due to fire, flood or other perils;

- establishing a records-retention policy, typically based on anticipated life of the product, plus 30 years for critical records;

- periodic review of records to verify that the current system meets company needs.

This process also requires that management establish decision-making criteria for voluntary recalls. These include:

- moral and ethical considerations that are critical for avoiding or minimizing risk of adverse publicity, loss of reputation, product litigation, and risk of government intervention and regulation;

- legal, statutory and regulatory requirements such as recalls mandated by agencies such as CPSC, Dept. of Transportation and the Food and Drug Administration;

- limiting use of financial considerations for situations when the product defect does not affect safety and the decision is one of weighing a recall against potential loss of customer goodwill.

Management must also establish and implement performance audit criteria. These criteria must provide for:

- periodic review, evaluation and updating of the product recall and retrofit plan;

- review and update of the plan when new products are added to product line;

- use of outside auditors.

To be most effective, the recall management program must also ensure:

- periodic review of internal documents bearing on possible recalls;

- periodic examination of record retention policies to determine whether there is a sound, realistic business reason for maintaining a particular record;

- the involvement of experienced legal counsel throughout the process (Ream).

Failure to have a product recall plan can produce severe consequences that can threaten business survival. Product recall insurance may be an option, but few insurers are likely to cover those who need the coverage most, particularly if they do not have or are not ready to implement a comprehensive plan to recall and remove defective products from the market or to retrofit those products with needed safety improvements.

Conclusion

Mitigating product liability loss potential requires genuine commitment by senior management and the active involvement of all segments of an organization. Manufacturers, wholesalers and retailers all have duties and may be liable if a defective or unreasonably dangerous product causes harm when it is being used as intended or even during reasonably foreseeable misuse. ■

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