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Risk assessment and hazard analysis: making products defendable

By **Kevin G. Owens**

Product manufacturers face ever-increasing challenges in the international marketplace. Among them is product liability litigation that can challenge every decision made by a manufacturer from the design through sale and for an undefined period thereafter. A manufacturer's potential liability for older or prior equipment models, discontinued lines or product lines inherited through corporate acquisition presents an even greater challenge. The old design and engineering processes, as well as old product warnings may be criticized later by jurors in light of newer technology and knowledge that may have been unavailable at the time of manufacture or sale.

Product liability lawsuits in the United States generally claim a design or manufacturing defect, or a failure to warn of dangers inherent in the product under theories of (1) strict product liability, (2) negligence, or (3) breach of warranty. The American manufacturer must also be cognizant of the changes in the Restatement (Third) of Torts: Product Liability regarding issues of post-sale duty to warn and recall of products that seek to expand the manufacturer's liability beyond the date of sale and the state of the art then-prevailing.

Manufacturers operating in an international market must be prepared to defend their products in any venue. Risk assessment and hazard analysis is a "prepackaged" tool the manufacturer can use in defending product liability lawsuits; it shows how the manufacturer considered and accounted for risk at every stage of the design process. The manufacturer who embraces this tool will be able to demonstrate to jurors and courts that their conduct was reasonable at the time the product was designed, manufactured, and sold. In short, the manufacturer that employs these practices will make its products not just safer, but more defendable in the event of a product liability lawsuit.

The Manufacturer's Duty

In the context of product liability litigation involving the design and manufacture of current and "legacy" products, among the questions presented are defining the manufacturer's duty when:

- it is sued in product liability related to a current product design;
- it learns of advancements in safety that may apply to old equipment still functioning in the field;
- it performs maintenance on its legacy equipment at customer locations;
- it discovers a defect in a design in a current line where equipment has already been shipped;
- it purchases a product line from another manufacturer and the other manufacturer is defunct, or;
- the other manufacturer remains a going concern.

Some manufacturers voluntarily issue warnings or instructions post-sale. This is often done to protect the customer and end user where the manufacturer discovers a flaw in design or instructions after the product is sold or where the manufacturer increases the safety in a later model. Reasons for doing this even when not required by law include avoiding injuries and property damage, reducing liability exposure, and protecting company brand and image.

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State-by-State Differences

In addition, a manufacturer's post-sale duty to warn or retrofit older equipment still operating in the field differs from state to state, as is apparent below. However, risk assessment and hazard analysis can help make the manufacturer defensible in any of these situations.

The Pennsylvania Supreme Court held in *DeSantis v. Frick Co.*, 745 A.2d 624 (Pa. Superior 2000), that an industrial freezer manufacturer had no duty to warn the owner of an older freezer model of a device that prevented "hydraulic shock" that was developed after the freezer was sold, which would have prevented the injury to the plaintiff. The court, however, went on to state that if the product was defective when sold due to a manufacturing or design defect, then the manufacturer has a "continuing duty to warn" of the defect after the sale by notifying distributors, sellers and owners of the defect. *DeSantis*, 745 A.2d at 631.

In Indiana, there is no defined duty to warn or retrofit past the date when the product is sold to the initial user or consumer. I.C. 34-20-5-1; *Tober v. Graco Children's Products,* 431 F.3d 572, 579 (7th Cir. 2005) (applying Indiana law). *Dague v. Piper Aircraft Corp.*, 418 N.E.2d 407 (Ind. 1981), however, at least leaves open the possible existence of a post-sale duty to warn. Any such claim would be subject to Indiana's 10-year statute of repose. *Id*.

In Texas, manufacturers generally have no post-sale duty to warn unless the manufacturer gains some significant control of the product, the product is deemed defective during that period of control, and the consumer is later injured as a result of the defect. *See Bell Helicopter Co. v. Bradshaw*, 594 S.W. 2d 519 (Texas Civ. App. – Corpus Christi 1979). In Washington, neither a manufacturer nor seller can be liable for harm under the Washington Products Liability Act (WPLA) if the harm has occurred after the product's "useful safe life" has expired (presumed to be 12 years). Wash. Rev. Code §7.72.060(1) and (2). Georgia affirmatively imposes a post-sale duty to warn against dangers discovered after a product is sold under negligence theory at common law. *DeLoach v. Rovema Corp.,* 241 Ga. App. 802, 527 S.E.2d 882 (Ga. Ct. App. 2000). Other states that apply some version of a post-sale duty to warn include Michigan, Colorado, Minnesota, North Carolina, Kansas, New Jersey, North Dakota, Maryland, New York, Iowa, Massachusetts, New Mexico, and Maine.

In Illinois, *Jablonski v. Ford Motor Co.,* 398 Ill. App. 3d 222, 923 N.E.2d 347 (5th Dist. 2010) *reversed*, 955 N.E.2d 1138, 2011 Ill. LEXIS 1136, 353 Ill. Dec. 327 (2011), the Fifth District Illinois Appellate Court reversed course on Illinois precedent on post-sale duties and determined to impose a post-sale duty to warn on Ford Motor Company. The availability of a post-sale retrofit kit intended to address a design flaw in two automobile models served as the basis for imposition of a post-sale duty, which the court found to be continuous, even after sale and irrespective of later design improvements

Regardless of the availability of the retrofit kit, the Illinois Supreme Court in *Jablonski* reversed the appellate court and declined to impose a post-sale duty on Ford. The Supreme Court characterized Illinois precedent regarding a manufacturer's duty to warn in the following terms: "[W]hen a design defect is present at the time of sale, the manufacturer has a duty to take reasonable steps to warn at least the purchaser of the risk *as soon as the manufacturer learns or should have learned of the risk created by its fault*" (*see* 2011 Ill. LEXIS 1136 at p.52 (emphasis added)). This might be interpreted to imply the existence of a post-sale duty to warn, even when the manufacturer was unaware of the risk posed by the product at the time of its sale. However, the court went on to cite other cases in which the argument for imposition of a post-sale duty to warn was rejected. *See, e.g.*,*Carrizales v. Rheem Mfg. Co.*, 226 Ill. App. 3d 20, 34, 589 N.E.2d 569, 579 (1981); *Modelski v. Navistar Int'l Trans. Corp.*, 302 Ill. App. 3d 879, 890, 707 N.E.2d 239, 247 (1999); *Collins v. Hyster Co.*, 174 Ill. App. 3d 972, 977, 529 N.E.2d 303, 306 (1988). The Supreme Court did not rule out the imposition of a post-sale duty but rather found that this plaintiff had merely failed to plead and prove the requisite facts for imposition of one in this case.

These decisions … signal a possible shift to imposition of a post-sale duty on manufacturers …

These decisions and others signal a possible shift to imposition of a post-sale duty on manufacturers, which is likely prompted by the Restatement (Third) of Torts: Product Liability. The Restatement provides that one engaged in the business of selling or otherwise distributing products is subject to liability for harm to persons or property caused by the seller's failure to provide a warning after the time of sale or distribution of a product *if a reasonable person in the seller's position would provide such warning.* According to the Restatement, a reasonable person would provide a warning *after* the time of sale if (1) the seller knows or reasonably should know that the product poses a substantial risk of harm to persons or property; (2) those to whom a warning might be provided can be identified and can reasonably be assumed to be unaware of the risk of harm; (3) a warning can be effectively communicated to and acted on by those to whom a warning might be provided; (4) the risk of harm is sufficiently great to justify the burden of providing a warning. While the Restatement directly addresses only sellers and distributors, the comments to it apply the guidelines to manufacturers as well.

See **ANALYSIS** on next page

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ANALYSIS

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Risk assessment and hazard analysis

Formal programs of risk assessment and hazard analysis should be an integral part of product design and manufacturing. It is an effective means of assuring the safety of a product *and* of better defending a lawsuit. In many instances a manufacturer or seller will use a standard to demonstrate that a design or warning was "state of the art." Companies selling products in the European Union are required by its Product Liability Directives to conduct formal risk assessment before applying a *CE* mark to their products. Failure to comply with these and similar standard requirements most certainly will be emphasized to a jury or court as a failure by the manufacturer or seller to act reasonably during the design process

Risk assessment and hazard analysis is a task-based approach for the assessment of risks posed by a design and for identifying affected persons, the tasks they perform, and the hazards associated with those tasks. It is a formal, documented process of:

- analyzing a product's design;
- identifying potential hazards in the design;
- rating the likelihood and severity of harm posed by any such hazards, and;
- determining if changes to design are needed.

While risk assessments are not universal, they have been introduced in some U.S. standards. American National Standards Institute (ANSI) standards covering machine tools and packaging machinery require suppliers and users to conduct a risk assessment. The standard sets forth seven steps in the risk assessment process: (1) prepare for/set limits of the assessment; (2) identify tasks and hazards; (3) assess initial risk; (4) reduce risk; (5) assess residual risk; (6) achieve acceptable risk; and (7) document the results. Further, the risk assessment should include a listing of all items related to the assessment.

If a manufacturer conducts a proper Risk assessment and hazard analysis of its product at the design stage, by the time the product goes into production, the manufacturer will have a file containing documentation of each of the steps outlined in the ANSI standard. In the event of a product liability lawsuit, that file will serve as a cornerstone of the defense of that design, showing careful consideration of the safety aspects considered at each stage of the design process, how safety and revisions were addressed in the design, and the scientific justification for each safety-related design decision. The manufacturer who can present that file to its defense lawyer in a later product liability lawsuit will have made that design defensible before a jury.

In the event of a product liability lawsuit, that [assessment and analysis] file will serve as a cornerstone of the defense of … design …

Risk assessment and hazard analysis is not a magic bullet that makes a design unassailable, but the benefits of performing it are clear: avoidance of injuries and property damage, reduction of liability exposure, satisfaction of legal obligations and duties to end users, and protection of the company's assets, reputation, and brand image.

The manufacturer that performs a proper risk assessment and hazard analysis will have preserved all pertinent records of the design process and will have proof of careful consideration of all reasonably foreseeable risks and how they were accounted for in the design process. This will enable the defendant manufacturer's witnesses and experts to competently explain and defend design decisions to a jury. It is particularly beneficial in defending a legacy product in circumstances where those who designed it are retired from the manufacturer or are otherwise unavailable.

Risk assessment and hazard analysis can also be used to attack an opposing expert who criticizes the manufacturer's product design because opposing experts rarely conduct their own formal risk assessment and hazard analysis of the product they are criticizing — or of their own proposed alternative designs — making the assessment and analysis an effective tool for cross-examining an opposing expert.

Ultimately, the manufacturer that conducts a formal risk assessment and hazard analysis will be in the best position to demonstrate that it indeed has satisfied its duty to design and manufacture a product that is reasonably safe for its intended uses and users.•

■ **Kevin G. Owens** *is an equity shareholder in the Chicago and Indiana law firm of Johnson & Bell, Ltd., where he serves as co-chair of the firm's Product Liability Practice Group. Opinions expressed are those of the author.*

DTCI Award Recipients Named

The DTCI is honored to announce the 2020 outstanding defense lawyers of the year.

Defense Lawyer of the Year

Michael Tolbert has been named the 2020 **DTCI Defense Lawyer of the Year**. He is a partner in the Gary firm of Tolbert & Tolbert and the recently installed president of the Indiana State Bar Association. The Defense Lawyer of the Year award is presented to a licensed lawyer who, in the opinion of the Awards Committee, as approved by the Board of Directors, has promoted the interests of the Indiana defense bar, since the last annual meeting of the DTCI, in a most significant way in the fields of litigation, legislation, publication or participation in local, state or national defense organizations.

Diplomats of the Indiana Defense Trial Counsel

The DTCI has installed as a **Diplomat of the Indiana Defense Trial Counsel** a member of the Indiana bar who, in the judgment of the officers and directors of the Defense Trial Counsel of Indiana, has distinguished himself throughout his career by outstanding contributions to the representation of clients in the defense of litigation matters. The 2020 recipient is **John McCrum**, a partner in Eichhorn & Eichhorn in its Hammond office.

Outstanding Young Lawyer

The DTCI **Outstanding Young Lawyer** award is presented to a member of the Defense Trial Counsel of Indiana, less than 35 years old, who has shown leadership qualities in service to the Indiana defense bar, the national defense bar, or the community. The 2020 recipient is **Barath Raman,** an associate with Lewis Wagner and chair of the DTCI Construction Law Section.•

2020 CALENDAR

The final day of section breakouts has been approved for 2.0 CLE hours total.

General Session Nov. 19-20 CLE pending.

To register for remaining events,
Log in at www.dtci.org
Select "Events," then "Conferences"
Choose your events and "Submit"
Confirmatory email will be sent & Zoom Links sent the day before each event

Nov. 12
Virtual Section Sessions
Employment Law 2:30-3:30 p.m.
Trial Tactics 3:30-4:30 p.m.

Nov 19-20
Virtual 27th Annual Conference & Annual Meeting of Membership

Nov. 19
"Facing Change: Social Justice & Racial Equity"
followed by BOSMA Philanthropy Project

Nov. 20
Mediation Amid COVID-19, Legislative Update, & Ethics for Trial Counsel

For details about any of these events ***or information about possible cancellations due to COVID-19****, please e-mail* ***lmortier@dtci.org****. For the latest changes, notices, and additions, check the events calendar on the DTCI homepage at* ***www.dtci.org***

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