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## **The Effect of Safety Regulations on Product Defect Claims**

This article addresses some considerations for counsel in offering or defending against evidence of safety regulations.

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Federal and state statutes and regulations have a significant impact on product liability litigation. Safety regulations carry the imprimatur of considered judgment by a governmental agency.

Parties often battle over whether the manufacturer has complied with those regulations, and courts have wrestled with the effect of regulations in product liability cases. In recent years, state legislatures have also adopted legal standards for dealing with these issues. This article addresses some considerations for counsel in offering or defending against evidence of safety regulations.

### **The Admissibility of Statutes to Prove or Defend Claims**

In virtually every jurisdiction, safety regulations imposed on a manufacturer are admissible on claims of negligence or product defect. Plaintiffs may contend that the manufacturer has not complied with the regulation, or that regulations establish only a minimum standard and additional measures were needed to make the product reasonably safe. Manufacturers may claim that compliance shows a product is not defective.

Courts have held that regulations are relevant in determining whether a product was safe or the manufacturer acted with reasonable care in its design. *See, e.g., Soproni v. Polygon Apt. Partners*, 971 P.2d 500, 505-06 (Wash. 1999). State legislatures have also adopted rules making regulations admissible. *See, e.g., Rev. Code Wash. § 7.72.050 (1)*.

Even if a regulation is not admissible on the issue of product defect, it may be relevant to a claim for punitive damages. *See, e.g., Malcolm v. Evenflo Co.*, 217 P.3d 514, 532 (Mont. 2009) (compliance with Federal Motor Vehicle Safety Standard not relevant to strict liability claim, but is relevant to the "mental state requisite for punitive damages").

### **The Effect of Compliance with Regulations**

There are several ways in which compliance with regulations may affect a case, and the legal impact of compliance may be different in different jurisdictions.

### ***In Some Jurisdictions, Compliance May Be Considered, But Is Not Conclusive***

In most instances, the courts and legislatures have concluded that a manufacturer's compliance with regulations is admissible as proof the product is not defective, but such evidence is not conclusive. *See, e.g., Estep v. Mike Ferrell Ford Lincoln-Mercury, Inc.*, 672 S.E.2d 345, 356-57 (W. Va. 2008); *Doyle v. Volkswagenwerk Aktiengesellschaft*, 481 S.E.2d 518, 521 (Ga. 1997) ("instead of acting as an impenetrable shield from liability, compliance, more appropriately, is to be a piece of the evidentiary puzzle"); N.C. Gen. Stat. § 99B-6 (b)(3).

This view is embodied in Restatement (Third) of Torts: Products Liability, § 4(b). The Comment to the Restatement explains that this section "reflects the traditional view that the standards set by most product safety statutes or regulations generally are only minimum standards. Thus, most product safety statutes or regulations establish a floor of safety below which product sellers fall only at their peril, but they leave open the question of whether a higher standard of product safety should be applied."

In some cases, it may be difficult for plaintiffs to persuade the factfinder that safety regulations permit or endorse an unreasonably dangerous condition. In other cases, plaintiffs may offer proof that industry unduly influenced and diluted a safety regulation, that the manufacturer withheld data from the safety agency, or that the regulation is outdated.

### ***Some Jurisdictions Hold that Compliance Creates a Rebuttable Presumption that the Product Is Not Defective***

Several states have gone one step further to create a rebuttable presumption that the product is not defective when the manufacturer proves compliance with regulations. *See, e.g.,* Colo. Rev. Stat. § 13-21-403 (1)(b); Utah Code Ann. § 78B-6-703 (2). Wisconsin's presumption applies to strict liability, but not to negligence or breach of warranty. Wis. Stat. § 895.047 (3)(b), (6).

### ***Compliance May Bar a Claim Completely***

In rare instances, courts agree with regulations adopted by legislatures or regulators, and impose the same standard on manufacturers. In these cases, courts have barred claims against manufacturers whose products comply with these regulations. *See Marchand v. Jem Sportwear, Inc.*, 147 P.3d 90 (Idaho 2006) (compliance with federal regulation on flammability of clothing bars claim); *Price v. Thomas Built Buses, Inc.*, 260 S.W.3d 300, 307 (Ark. 2007) (when state legislature "affirmatively decided not to require passenger seat belts in school buses," common law tort claim based on lack of seat belts is preempted); *Ramirez v. Plough, Inc.*, 863 P.2d 167 (Cal. 1993) (when FDA regulations and state statute require nonprescription drug labeling only in English, manufacturer has no legal duty to include warnings in Spanish).

A few states bar a claim for punitive damages when the product complies with safety regulations. *See* Ohio Rev. Code Ann. § 2307.80 (C), (D); Tenn. Code Ann. § 29-39-104 (d), (e); *Contra Gryc v. Dayton-Hudson Corp.*, 297 N.W.2d 727, 733-35 (Minn. 1980) (compliance with federal test for flammability does not preclude punitive damages).

## **Noncompliance with Regulations**

Noncompliance with regulations is also treated differently in different jurisdictions.

### ***In Some Locales, Noncompliance May Be Considered, But Is Not Conclusive***

Just as evidence of compliance may be considered by the factfinder, so may evidence of noncompliance. *See, e.g., Aleo v. SLB Toys USA, Inc.*, 995 N.E.2d 740, 750-51 (Mass. 2013) (“violation of statute, ordinance, or regulation, although not conclusive, is evidence of negligence on the part of the violator”); Rev. Code Wash. § 7.72.050 (2).

### ***Noncompliance May Create a Rebuttable Presumption That the Product Is Defective***

Some of the same statutes that create a presumption of no defect if the product complies with regulations also create a presumption that the product is defective if it fails to comply. *See* Colo. Rev. Stat. § 13-21-403 (1)(b), (2) (“noncompliance with a government code, standard, or regulation ... which contributed to the claim or injury shall create a rebuttable presumption that the product was defective or negligently manufactured”).

On the other hand, some of the statutes that create a presumption for compliance do not recognize a presumption for noncompliance. *See* Tex. Civ. Prac. & Rem. Code § 82.008; Mich. Comp. Laws Serv. § 600.2946 (4) (“noncompliance with regulations or standards relevant to the event causing the death or injury promulgated by, a federal or state agency does not raise a presumption of negligence on the part of a manufacturer or seller”). Presumably, in these states with one-sided presumptions, evidence of noncompliance is still admissible.

### ***Negligence Per Se***

The Restatement (Third) of Torts: Products Liability, § 4(a) provides: “a product’s noncompliance with an applicable product safety statute or administrative regulation renders the product defective with respect to the risks sought to be reduced by the statute or regulation.” The Restatement Note observes that this rule “finds its origin in a common-law rule holding that the unexcused omission of a statutory safety requirement is negligence *per se*.” The Restatement cites *Harned v. Dura Corp.*, 665 P.2d 5, 12 (Ala. 1983), which held that the trial court should have instructed the jury that an air tank manufacturer’s violation of an industry standard adopted by state law constituted negligence *per se*.

There are few recent cases reflecting the Restatement/*Harned* conclusion that noncompliant products are defective as a matter of law. As discussed above, some states have established a rebuttable presumption for noncompliance.

## **Other Issues in the Application of Regulations**

### ***Effective Date of Regulation***

Compliance or noncompliance is typically measured at the time of manufacture (Kan. Stat. Ann. § 60-3304), or at time of sale (Colo. Rev. Stat. § 13-21-403). Regulations adopted after the sale of the product may be inadmissible to prove the product was defective. *See Cover v. Cohen*, 461 N.E.2d 864 (N.Y. 1984).

### ***Form of Evidence of Regulation***

In most instances, evidence of safety regulations and a manufacturer's compliance or noncompliance is offered by the parties' experts. Regulations, however, are more than evidence; they are the law. Thus, it may be appropriate for the court to instruct the jury as to applicable regulations. *See Hagan v. Gemstate Mfg., Inc.*, 982 P.2d 1108, 1117 (Oregon 1999).

### ***Effect of Presumption***

Legal presumptions vary in their effect. Some "burst" — or go away — when evidence to the contrary is offered; others may stay and shift the burden of persuasion. Presumptions also vary as to what type, or quantum, of evidence is required to rebut them. State statutes creating presumptions for compliance or noncompliance often are silent on how to address the presumptions in trial.

Indiana's high court, in *Schultz v. Ford Motor Co.*, 857 N.E.2d 977, 986-87 (Ind. 2006), held that the trial court did not err by instructing the jury on the statutory presumption based on compliance even though the plaintiff had offered evidence to the contrary. *See also Egbert v. Nissan N. Am., Inc.*, 167 P.3d 1058, 1061 (Utah 2007).

In Texas, the claimant may rebut the presumption created by compliance by proving that the regulations "were inadequate to protect the public from unreasonable risks of injury or damage" or that the manufacturer "withheld or misrepresented information or material relevant to the ... agency's determination of adequacy of the safety standards or regulations." Tex. Civ. Prac. & Rem. Code § 82.008(b).

In Kansas, the presumptions created by compliance or noncompliance may be rebutted by a preponderance of the evidence. Kan. Stat. Ann. § 60-3304 (a), (b). *See Egbert*, 167 P.3d at 1062 ("preponderance of the evidence is sufficient to overcome the presumption of nondefectiveness").

### ***Admissibility of General Safety Regulations on Product Defect Claims***

Sometimes the regulation offered to prove a product defective or reasonably safe does not apply directly to the manufacturer or its product, and the court must determine whether the regulation is admissible on product defect. The most prominent example of this type of evidence is Occupational Safety and Health Administration (OSHA) regulations, which apply to employers and not directly to manufacturers.

The courts have split in deciding whether OSHA regulations are admissible on the issue of product defect. Some courts have denied admission of OSHA regulations simply because they do not apply to manufacturers. *See Byrne v. Liquid Asphalt Sys.*, 238 F.Supp.2d 491 (E.D.N.Y. 2002); *Minichello v. U.S. Industries, Inc.*, 756 F.2d 26, 29 (6th Cir. 1985) (relying on OSHA provision 29 U.S.C. § 653(b)(4) that "Nothing in this chapter shall be construed ... to enlarge or diminish or affect in any other manner the common law or statutory rights, duties or liabilities of employers and employees under any law with respect to injuries, diseases or death of employees arising out of, or in the course of, employment").

Other courts have concluded that OSHA regulations are not relevant because of substantive aspects of their product liability laws. Thus, when the standard of care is not relevant to a strict liability claim that focuses on the product, OSHA regulations may not be relevant. *See Nesbitt v. Sears, Roebuck & Co.*, 415 F.Supp.2d 530, 534 (E.D. Pa. 2005); *Lutz v. National Crane Corp.*, 884 P.2d 455, 465 (Mont. 1994).

When the issue is whether the manufacturer complied with the standard of care in designing the product, some courts have admitted OSHA regulations. *See Hansen v. Abrasive Eng'g & Mfg.*, 856 P.2d 625, 629 (Or. 1993) (regulations “are relevant, even though not binding on defendant, for exactly the same reasons that the ANSI [American National Standards Institute] standards are relevant, *i.e.*, because they pertain to the issue of whether defendant met the standard of care.”). The Utah Supreme Court has held that OSHA regulations are admissible evidence of industry standards and that compliance therewith triggers the state’s statutory presumption of non-defectiveness. *Slisze v. Stanley-Bostitch*, 979 P.2d 317, 321 (Utah 1999).

### **Preemption of State Law Tort Claims By Federal Statutes and Regulations**

Federal statutes or regulations may be intended by Congress to regulate certain products on an exclusive basis, barring any application of state statutes or regulations, or recoveries on tort claims. In these circumstances, the U.S. Constitution’s Supremacy Clause applies, so that federal law governs singularly and precludes state regulation or claims.

Preemption may be express, when Congress explicitly precludes state law in regulation of a product. *See, e.g., Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (preemption clause in Medical Device Amendments bars claims challenging safety and effectiveness of medical device given FDA premarket approval); *Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011) (National Childhood Vaccine Injury Act preempts design defect claims against vaccine manufacturers for tort recoveries based on vaccine side effects).

On the other hand, preemption may be implied, as when federal regulation is so pervasive it occupies the field, or when state law (including potential tort recoveries) conflicts with federal provisions. *See David G. Owen, Federal Preemption of Products Liability Claims*, 55 *S.C.L. Rev.* 411 (2003). For example, in *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000), the U.S. Supreme Court held that tort claims based on the fact that a vehicle was not equipped with a driver’s-side airbag conflicted with the Federal Motor Vehicle Safety Standard and were preempted. Contrast *Williamson v. Mazda Motor of Am., Inc.*, 562 U.S. 323 (2011) (claim that manufacturer should have installed a lap and shoulder belt in rear center seat did not conflict with standard); *see also Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002) (Federal Boat Safety Act and Coast Guard decision not to require propeller guards on motorboats do not preempt state law claims based on failure to guard propellers).

### **Conclusion**

The admissibility and effect of compliance or noncompliance with safety regulations to prove or defend product defect claims will depend on a variety of federal and state laws, and will vary by state. Safety regulations are likely to play an important role in the factfinder’s resolution of product defect claims, so counsel should prepare an effective strategy to use or mitigate the impact of this evidence.

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