USING THE REGULATORY COMPLIANCE DEFENSE IN PRODUCTS LIABILITY CASES IN VIRGINIA

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All manufacturers must follow governmental regulations and industry safety standards, or run the risk that a court will make a finding of negligence per se against them in a products liability case. Such a finding is usually fatal to a manufacturer's defense. It has long been the case that a manufacturer's strict compliance with applicable product safety statutes and regulations acted as a shield only to a negligence per se finding. Compliance does not itself preclude a finding of product defect.

However, recent Virginia case law suggests that a manufacturer may be able to use its strict compliance not only as a shield against a negligence per se finding, but also as a sword against a plaintiff to establish that its product is not unreasonably dangerous. Compliance can become a potential defense. The regulatory compliance defense asserts that if a manufacturer complies with the controlling governmental regulations or industry safety standards, then its product is not unreasonably dangerous, plaintiff's products liability claim, under Virginia law, should fail.

One argument in support of this defense is that if experts in the manufacturer's field determine that certain steps and measures are required to make a product safe, and those measures are followed by a manufacturer, they should not be second-guessed by nonexpert juries.¹ It is a simple, yet powerful argu-

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¹ See Grundberg v. Upjohn Co., 813 P.2d 89, 98 (Utah, 1991) ("[W]e do not believe that a trial court in the context of a products liability action is the proper forum to determine whether, as a whole, a particular prescription drug's benefits outweighed its risks at the time of distribution. In a case-by-case analysis, one court or jury's determination that a particular drug is or is not 'defectively designed' has no bearing on any future case. As a result, differences of opinion among courts in differing jurisdictions leaves unsettled a drug manufacturer's liability for any given drug. Although the FDA may have internal differences of opinion regarding whether a particular new drug application should be approved, the individuals making the ultimate judgment will have the benefit of years of experience in reviewing such products, scientific expertise in the area, and access to the volumes of data they can compel manufacturers to produce. Nor is the FDA subject to the inherent limitations of the trial process, such as the rules of evidence, restrictions on expert testimony, and scheduling demands.").

ment and one that should not be ignored by defense counsel.² This is but one of many policy arguments in favor of a regulatory compliance defense.³

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The regulatory compliance defense can be a very useful tool and one that is receiving greater recognition in Virginia, especially in the federal courts. What follows is a review of the standard for product liability in Virginia, recent decisions demonstrating a move toward greater acceptance of the regulatory compliance defense, and practice pointers to set the stage for effectively using the defense.

I. THE STANDARD FOR PRODUCT LIABILITY IN VIRGINIA

The standard of safety of goods imposed on the manufacturer of a product is essentially the same whether the theory of liability is labeled breach of warranty or negligence. The product must be fit for the ordinary purposes for which it is to be used.⁴ In order to recover under either of these theories against the manufacturer of a product, "a plaintiff must show (1) that the [product was] unreasonably dangerous either for the use to which [it] would ordinarily be put or for some other reasonably foreseeable purpose, and (2) that the unreasonably dangerous condition existed when the goods left the manufacturer's hands."⁵ A plaintiff must also establish that the defect actually caused his injury.⁶

A product is unreasonably dangerous if it is defective in assembly or manufacture, unreasonably dangerous in design, or unaccompanied by adequate warnings concerning its hazardous properties.⁷ Whether a product is unreasonably dangerous is a question of fact.⁸

² Paul Dueffert, Note, *The Role of Regulatory Compliance in Tort Actions*, 26 HARV. J. ON LEGIS. 175, 217-18 (1989). ("Against such complex regulatory schemes, the rule that regulatory compliance cannot shield a defendant from liability seems archaic.").

³ "Critics urging a stronger regulatory compliance defense constitute part of a larger group of critics that in recent years has attacked the entire products liability system as too costly and erratic, as well as responsible for making insurance less affordable and less available for many products, dramatically increasing prices for some products, deterring innovation, slowing the development and marketing of products, unduly burdening interstate commerce, and reducing American competitiveness in the global marketplace. While these claims have been sharply disputed and the evidence to support them contested, critics of the current system have pressed, often successfully, for tort and products liability reforms to address their concerns. Proposed reforms have included an array of measures to limit damage awards and to establish legal standards that make claims more difficult to bring or to win. These proposed reforms often include a strengthened regulatory compliance defense as part of their package of reforms." Teresa Moran Schwartz, Regulatory Standards and Products Liability: Striking the Right Balance between the Two, 30 U. Mich. J.L. Ref. 431, 436-38 (1997) (citations omitted).

⁴ Jeld-Wen, Inc. v. Gamble by Gamble, 256 Va. 144 (1998); Logan v. Montgomery Ward, 216 Va. 425, 428, 219 S.E.2d 685, 687 (1975).

⁵ Jeld-Wen, Inc., 256 Va. at 148 (quoting Morgen Indus., Inc. v. Vaughan, 252 Va. 60, 65, 471 S.E.2d 489, 492 (1996))

⁶ Logan v. Montgomery Ward, 216 Va. 425, 428, 219 S.E.2d 685, 687 (1975); Marshall v. H.K. Ferguson Co., 623 F.2d 882, 885 (4th Cir. 1980).

Austin v. Clark Equip. Co., 48 F.3d 833, 836 (4th Cir. 1995); Bly v. Otis Elevator Co., 713 F.2d 1040, 1043 (4th Cir. 1983).

⁸ Singleton v. International Harvester Co., 685 F.2d 112, 115 (4th Cir. 1981).

While a manufacturer may not be held liable for every misuse of its product, it may be held liable for a foreseeable misuse of an unreasonably dangerous product. The standard does not require a manufacturer to supply an accident-proof product. Common knowledge of a danger from the foreseeable misuse of a product does not alone give rise to a duty to safeguard against the danger of that misuse. To the contrary, the purpose of making the finding of a legal duty as a prerequisite to a finding of negligence, or breach of implied warranty, in products liability is to avoid the extension of liability for every conceivably foreseeable accident, without regard to common sense or good policy."

II. REGULATIONS AS THE STANDARD

The Second Restatement of Torts states that compliance with a legislative enactment or an administrative regulation does not prevent a finding of negligence where a reasonable man would take additional precautions. The comments to section 288 reveal that this theory is based on the assumption that regulations are the minimum requirements. The comments are the minimum requirements.

The *Third Restatement of Torts* goes further in stating that a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation.¹⁴ While the *Third Restatement* does not go so far as to say that meeting the requirements is an absolute defense, it does show how the pendulum may be swinging in favor of the regulatory-compliant manufacturer.¹⁵

Federal courts in Virginia have begun to embrace this argument. In *Alevromagiros v. Hechinger Co.*, the Fourth Circuit held that while conformity with industry custom does not absolve a manufacturer or seller of a product from liability, such compliance may be conclusive when there is no evidence to show that the product was not reasonably safe. In *Hechinger*, the court directed a verdict in favor of the manufacturer after plaintiff failed to establish the

⁹ Featherall v. Firestone Tire & Rubber Co., 219 Va. 949, 964, 252 S.E.2d 358, 367 (1979); Sloan v. General Motors Corp., 249 Va. 520, 526, 457 S.E.2d 51, 54 (1995).

¹⁰ Besser Co. v. Hansen, 243 Va. 267, 276, 415 S.E.2d 138, 144 (1992).

¹¹ Jeld-Wen, Inc. v. Gamble by Gamble, 256 Va. 144, 149 (1998).

¹² Restatement (Second) of Torts § 288.

¹³ "Where a statute, ordinance or regulation is found to define a standard of conduct for the purposes of negligence actions, as stated in §§ 285 and 286, the standard defined is normally a minimum standard, applicable to the ordinary situations contemplated by the legislation. This legislative or administrative minimum does not prevent a finding that a reasonable man would have taken additional precautions where the situation is such as to call for them." *Comments*, Restatement (Second) of Torts § 288.

 $^{^{14}}$ Restatement (Third) of Torts: Products Liability § 4.

¹⁵ Lorenz v. Celotex Corp, 896 F.2d 148, 151 (5th Cir. 1990), reh'g denied, 901 F.2d 1110 (5th Cir. 1990) (compliance with governmental safety standards is strong and substantial evidence that a product is not defective); see also Ashley W. Warren, Compliance with Governmental Regulatory Standards: Is It Enough to Immunize a Defendant from Tort Liability? 49 BAYLOR L. REV. 763 (1997).

¹⁶ 993 F.2d 417, 420-21 (4th Cir. 1993).

9:43

product violated any standard. Plaintiff's expert never performed physical tests to determine whether the product, in this case a ladder, conformed to the published industry standards. Moreover, he testified to no customs of the trade, referred to no literature in the field, and did not identify the reasonable expectations of consumers. "A plaintiff may not prevail in a products liability case by relying on the opinion of an expert unsupported by any evidence such as test data or relevant literature in the field." ¹⁷

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In *Mears v. General Motors Co.*, ¹⁸ the plaintiff sued an auto manufacturer alleging that a defect in the breaking system caused her auto accident. Plaintiff alleged that her truck was unreasonably dangerous because it used a single hydraulic brake system rather than a safer split-hydraulic system. The court granted defendant's motion for summary judgment finding that the breaking system complied with industry standards that existed at the time of manufacture. "While conformity with industry practice is not conclusive of the product's safety, because an industry could adopt a careless standard, the cases where a member of an industry will be held liable for failing to do what no one in his position has ever done before will be infrequent."¹⁹

In Lemons v. Ryder Truck Rental, Inc., the court held absent proof of a violation of a governmental, industrial, or safety standard, plaintiff is required to offer evidence as to "actual industry practices, knowledge at the time of other injuries, knowledge of dangers, published literature, and . . . direct evidence of what reasonable purchasers consider defective." In Virginia, the mere fact of an accident is not enough to establish the existence of a defect. Virginia has rejected the evidentiary presumption of res ipsa loquitur in products liability cases. 22

In Wilder v. Toyota Motor Sales, U.S.A., Inc., 23 the Fourth Circuit upheld the United States District Court for the Western District of Virginia decision's granting summary judgment in favor of Toyota. In this case, plaintiff alleged he suffered injury as a result of a defective air bag in his vehicle, which he claimed deployed late. Toyota presented an affidavit from its experts that the air bag system on the Tacoma truck was well designed, well tested, consistent with industry custom, and not defective. The court found that while conformity with industry custom does not absolve a manufacturer or seller of a product from

¹⁷ Id. at 422.

¹⁸ 896 F. Supp. 548, 551-53 (E.D. Va. 1995).

¹⁹ *Id.* at 552 (quoting Sexton v. Bell Helmets, Inc., 926 F.2d 331, 337 (4th Cir.) (applying Kentucky law), *cert. denied*, 502 U.S. 820, 116 L. Ed. 2d 52, 112 S. Ct. 79 (1991) (quoting W. Prosser, *Handbook on the Law of Torts* § 33, at 167 (4th ed. 1971)).

²⁰ 906 F. Supp. 328, 332-33 (W.D. Va. 1995) (citing *Alevromagiros*, 993 F.2d at 420-21).

²¹ Logan v. Montgomery Ward, 219 S.E.2d 685, 688 (1975).

²² Id.

²³ 23 Fed. Appx. 155, 2001 U.S. App. LEXIS 26787, 2001 WL 1602043, (4th Cir. 2001).

liability, such compliance may be conclusive when there is no evidence to show that the product was not reasonably safe.²⁴

In *McAlpin v. Electric Furnace Co.*, ²⁵ the court held that in determining what constitutes an unreasonably dangerous defect, a court will consider safety standards promulgated by the relevant industry, as well as the reasonable expectations of consumers. ²⁶ In *McAlpin*, decedent was killed when a stove exploded. The decedent's representative filed suit against the manufacturer, alleging that the stove was inherently dangerous. The court granted defendant's motion for summary judgment, finding that the stove did not deviate from industry standards and that it did meet the expectations of consumers. ²⁷

These cases demonstrate that plaintiffs cannot rely simply on the subjective opinions of their experts. "We are unprepared to agree that 'it is so if an expert says it is so.'"

These decisions make clear that the bar has been raised for plaintiff to win against a regulatory-compliant manufacturer.

III. Practice Pointers

A. REMOVE THE CASE TO FEDERAL COURT

All of the above-cited cases are federal cases applying Virginia law. Federal courts in Virginia are more likely than state courts to grant summary judgment or directed verdicts. Because of this, federal courts are also more likely to grant summary judgment or directed verdicts based on the regulatory compliance defense. In products liability cases, the manufacturer is frequently located in a different state from the plaintiff's, so removing the state case to federal court based on diversity jurisdiction is an option counsel for a manufacturer should always consider.

B. KNOW THE REGULATIONS

When representing manufacturers, attorneys should become intimately familiar with the regulations and industry standards that apply to their client's product. Counsel should first consult with their client about all relevant regulations. Counsel should also conduct independent research and consult experts in the appropriate fields.

A product can be defective only if it is imperfect when measured against a standard existing at the time of sale or against reasonable consumer expecta-

²⁵ 1996 U.S. Dist. LEXIS 12618 (1996).

²⁴ Id. at 157.

²⁶ *Id.* (citing *Alevromagiros*, 993 F.2d at 420 (citing Sexton v. Bell Helmets, Inc., 926 F.2d 331, 337 (4th Cir.), *cert. denied*, 502 U.S. 820, 112 S. Ct. 79, 116 L. Ed. 2d 52 (1991))).

²⁷ Canterbury v. Mercedes-Benz of N. Am., Inc., 1991 U.S. App. LEXIS 3893 (4th Cir., 1991) (citing Lorenz v. Celotex Corp, 896 F.2d 148 (5th Cir. 1990), *reh'g denied*, 901 F.2d 1110 (5th Cir. 1990); Farrell v. Klein Tools, Inc., 866 F.2d 1294 (10th Cir. 1989)).

²⁸ Alevromagiros, 993 F.2d at 421 (quoting Viterbo v. Dow Chem. Co., 826 F.2d 420, 421 (5th Cir. 1987)).

JOURNAL OF CIVIL LITIGATION, VOL. XVII, NO. 3 (FALL 2005)

tions held at the time of sale.²⁹ Because of this, counsel should be familiar with the regulations, and in addition, learn the "consumer expectations held at the time of sale." The level of consumer expectations can be established through evidence of actual industry practices, published literature, and from direct evidence of what reasonable purchasers considered defective. *Id.* Counsel should obtain literature that sets forth the standards at the time of the sale and not today's standards.

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C. LAY THE FOUNDATION FOR SUMMARY JUDGMENT MOTION THROUGH DISCOVERY

Defense counsel should establish the regulatory compliance defense early in the litigation through discovery. Defense counsel should prepare interrogatories, document requests, and possibly requests for admissions concerning governmental regulations or industry standards that plaintiff alleges the manufacturer violated.

Counsel should also be prepared to question plaintiff's expert on compliance issues. The goal for counsel is to obtain testimony from plaintiff's expert that regulations and industry standards were not violated.

Another category of questions that counsel should include in his questions for plaintiff's expert is consumer expectations. Information regarding consumer expectations at the time of sale is often hard to obtain. It is equally hard for plaintiff to obtain. Therefore, defense counsel should cover in detail all evidence relied upon by plaintiff's expert to establish this.

These steps are designed to establish a summary judgment argument on the regulatory compliance defense.

D. GET A FAVORABLE JURY INSTRUCTION

In an asbestos case in Texas, defense counsel for the manufacturer was able to secure a very favorable jury instruction.³⁰ At the close of the evidence, the district court, upon Celotex's request, instructed the jury that: "Compliance with government safety standards constitutes strong and substantial evidence that a product is not defective."³¹

Celotex did two things that allowed for such a favorable ruling. First, it set forth the applicable standard. Second, it demonstrated that it had met the standard. Celotex presented evidence that until the end of the 1960s, exposure to asbestos dust counts below five million particles per cubic foot was generally considered safe. Celotex then presented evidence that use of Celotex's products produced dust counts below the threshold limit. Celotex introduced the results of several studies of asbestos exposure among insulation workers. In each case,

²⁹ Mears v. General Motors Corp., 896 F. Supp. 548 (1995).

³⁰ Lorenz v. Celotex Corp., 896 F.2d 148 (5th Cir., 1990), reh'g denied, 901 F.2d 1110 (5th Cir. 1990).

³¹ The language of this instruction comes directly from *Gideon v. Johns-Manville Sales Corp.* 761 F.2d 1129, 1144 (5th Cir. 1985). "Compliance with such government safety standards constitutes strong and substantial evidence that a product is not defective." *Id.*

the study concluded that exposure levels were below the five million particles per cubic foot threshold.

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While no Texas state decision set forth the proposition that "compliance with government safety standards constitutes strong and substantial evidence that a product is not defective," none contradicted this statement, either.³² Because the instruction was substantively correct and was supported by the evidence, the trial court did not err in giving it.

It is well settled that the jury should be instructed on a legal theory if the evidence adduced at trial is sufficient to justify such an instruction.³³ Defense counsel first must establish through evidence the relevant standard and establish that standard has been met. After this has been done, counsel should then craft and submit a *Lorenz*-like jury instruction applicable to their case using relevant Virginia case law.

IV. Conclusion

Regulatory compliance should no longer be viewed by defense counsel as simply a minimum requirement their client needs to satisfy to avoid a negligence per se finding against them. Current regulations are becoming so sophisticated that manufacturers' compliance with them should no longer be a starting point for the court to evaluate whether a product is unreasonably dangerous. Rather, defense counsel should use their clients' compliance with the relevant governmental regulations or industry safety standards as a weapon against plaintiff's products liability claim. The crafting and use of that weapon should begin early in the discovery phase of litigation, and should continue through dispositive motions and certainly in jury instructions. While Virginia does not currently allow compliance alone to preclude, as a matter of law, a finding of product defect, there is some movement in that direction. Defense counsel in products liability litigation should become aware of the relevant case law and the policy arguments behind the decisions, and use these arguments to their clients' advantage.

³² See Gideon v. Johns-Manville Sales Corp., 761 F.2d 1129 (5th Cir. 1985), and Dartez v. Fibreboard Corp., 765 F.2d 456 (5th Cir. 1985). Both Gideon and Dartez were diversity cases applying Texas law, and in both cases the court determined that compliance with governmental safety standards is strong and substantial evidence that a product is not defective.

³³ Lorenz v. Celotex Corp., 896 F.2d 148, 151-52, reh'g denied, 901 F.2d 1110 (5th Cir. 1990).