

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>
<b>THIS DOCUMENT RELATES TO</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>
Carolyn Lewis et al. v. Ethicon , Inc. et al. Case No. 2:12-cv-4301	

**MEMORANDUM OPINION AND ORDER  
(Amending Summary Judgment Order [Docket 194])**

**I. Background**

On January 15, 2014, I entered a memorandum opinion and order resolving the parties' motions for summary judgment. (*See* Mem. Op. & Order [Docket 194]). In that opinion, I held that the plaintiffs were not required to establish a safer alternative design as part of their strict liability design defect claim. (*See id.* at 11-12). I based that holding on Texas Civil Practice & Remedies Code § 82.005, which states in relevant part:

(a) In a products liability action in which a claimant alleges a design defect, the burden is on the claimant to prove by a preponderance of the evidence that:

(1) there was a safer alternative design; and

(2) the defect was a producing cause of the personal injury, property damage, or death for which the claimant seeks recovery.

(b) In this section, "safer alternative design" means a product design other than the one actually used that in reasonable probability:

(1) would have prevented or significantly reduced the risk of the claimant's personal injury, property damage, or death without substantially impairing the product's utility; and

(2) was economically and technologically feasible at the time the product left the control of the manufacturer or seller by the application of existing or reasonably achievable scientific knowledge.

...

(d) This section does not apply to:

(1) a cause of action based on a toxic or environmental tort as defined by Sections 33.013(c)(2) and (3); or

(2) a drug or device, as those terms are defined in the federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 321).

(e) This section is not declarative, by implication or otherwise, of the common law with respect to any product and shall not be construed to restrict the courts of this state in developing the common law with respect to any product which is not subject to this section.

The briefing schedule related to summary judgment motions did not allow the parties to file reply briefs. Research in preparation for trial of this matter persuaded me that I needed further legal argument. I therefore ordered the parties to provide thorough briefing on this topic, which they have done. I now realize my earlier ruling was a mistake. I therefore **REVERSE** that ruling and **FIND** that the plaintiffs are required to establish the existence of a safer alternative as part of their strict liability defective design claim. To be clear, this finding does not change my denial of the defendant's summary judgment motion on the strict liability defective design claim because the plaintiffs have proffered evidence of alternative designs. (*See* Mem. Op. & Order [Docket 194], at 12 n.1).

## II. Analysis

Subsection (d) of the statute states that "this section does not apply to . . . a drug or device, as those terms are defined in the federal Food, Drug, and Cosmetic Act (21 U.S.C.

Section 321).” As I previously found, the TVT is a “device” as defined by the Food, Drug, and Cosmetic Act. (*See* Mem. Op. & Order [Docket 194], at 11-12). The parties do not dispute this. Therefore, by the literal terms of the statute, it does not apply to the TVT. I essentially must ignore the statute in my analysis of whether the plaintiffs must establish a safer alternative design.

Section 82.005 states that it “is not declarative, by implication or otherwise, of the common law with respect to any product . . . .” Therefore, the statute does not change or supplant the common law, but merely adds an additional requirement for plaintiffs in product liability actions. The Texas Supreme Court held as much when it stated that section 82.005 “does not attempt to state all the elements of a product liability action for design defect.” *Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 256 (Tex. 1999). The *Hernandez* court further wrote that

[w]hether a defective-design action can be maintained . . . does not, therefore, depend entirely on section 82.005. A claimant must not only meet the proof requirements of the statute but must show, under the common law, that the product was defectively designed so as to be unreasonably dangerous, taking into consideration the utility of the product and the risk involved in its use. . . . [W]e must consider not only the requirements of section 82.005 but those of the common law as well.

*Id.* at 257.

Therefore, section 82.005 is merely one part of a design defect claim. But because I ignore section 82.005, I turn to the common law as it existed before the 1993 enactment of section 82.005. The plaintiffs point to several cases where the existence of a safer alternative design was apparently not required as a matter of law. *See, e.g., Boatland of Houston, Inc. v. Bailey*, 609 S.W.2d 743, 745-48 (Tex. 1980); *Turner v. Gen. Motors Corp.*, 584 S.W.2d 844, 850-51 (Tex. 1979); *Temple EasTex, Inc. v. Old Orchard Creek Partners, Ltd.*, 848 S.W.2d 724, 732 (Tex. App. 1992).

Regardless of the plaintiffs' assertions that these cases did not require proof of a safer alternative design, the Texas Supreme Court's holding in *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379 (Tex. 1995), is dispositive here. *Caterpillar* was decided in 1995, but the plaintiff's cause of action accrued in 1988 and the court applied the common law as it existed prior to the enactment of section 82.005. *See Caterpillar, Inc. v. Shears*, 881 S.W.2d 923, 926 (Tex. App. 1994) *rev'd*, 911 S.W.2d 379 (Tex. 1995); *Hernandez*, 2 S.W.3d at 255 ("section 82.005(a) and (b) of the Texas Civil Practice and Remedies Code [is] applicable to cases . . . that accrued on or after September 1, 1993"). The court in *Caterpillar* held that "if there are no safer alternatives, a product is not unreasonably dangerous as a matter of law." *Caterpillar*, 911 S.W.2d at 384.

Since *Caterpillar*, the Texas Supreme Court has reaffirmed that, under the common law, plaintiffs must establish the existence of a safer alternative design. *See Hernandez*, 2 S.W.3d at 258 ("A safer alternative . . . is a prerequisite to liability under section 82.005(b), as it has come to be under the common law."); *Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 335 n.4 (Tex. 1998) (applying the common law and stating "we made clear in *Caterpillar* that a safer alternative is a prerequisite to a finding of design defect"); *Am. Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 433 (Tex. 1997) (applying the common law and citing *Caterpillar* for the proposition that "if there is no safer alternative to the cigarette manufactured by American, then its cigarettes are not unreasonably dangerous as a matter of law").

Other courts applying Texas product liability law to medical devices and drugs have reached the same conclusion—that plaintiffs must establish a safer alternative design. *See, e.g., Rojas v. Teva Pharm. USA, Inc.*, 920 F. Supp. 2d 772, 779 (S.D. Tex. 2013) (prescription metoclopramide); *Dyer v. Danek Med.*, 115 F. Supp. 2d 732, 738 (N.D. Tex. 2000) (pedicle screws); *Brockert v. Wyeth Pharm., Inc.*, 287 S.W.3d 760, 769 (Tex. App. 2009) (hormone-

replacement therapy drugs); *Merck & Co., Inc. v. Garza*, 277 S.W.3d 430, 440 (Tex. App. 2008) (Vioxx drug), *rev'd on other grounds*, 347 S.W.3d 256 (Tex. 2011).

The plaintiffs argue that I should give little weight to this authority because the Texas Practice Guide and a Houston Law Review article support their position.<sup>1</sup> But I simply cannot ignore the Texas Supreme Court's pronouncements on Texas law. *See Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938); 19 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 4507 (2d ed.) (“[T]he federal court must determine issues of state law as it believes the highest court of the state would determine them.”).

I now **FIND** that the plaintiffs must establish a safer alternative design in order to succeed on their strict liability defective design claim. This finding does not change my denial of the defendant's summary judgment motion on the strict liability defective design claim because the plaintiffs have proffered evidence of alternative designs. (*See* Mem. Op. & Order [Docket 194], at 12 n.1).

#### **IV. Conclusion**

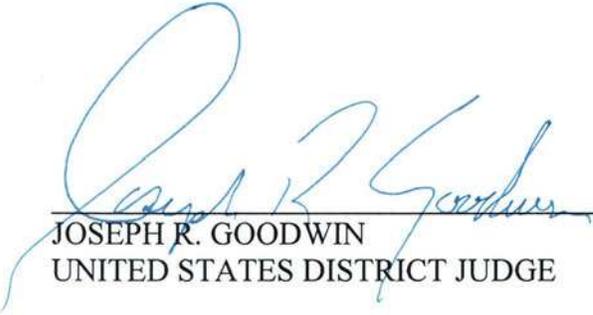
For the reasons stated above, I **REVERSE** my earlier holding in my summary judgment opinion (*see* Mem. Op. & Order [Docket 194], at 11-12) and **FIND** that the plaintiffs are required to establish the existence of a safer alternative as part of their strict liability defective design claim.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

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<sup>1</sup> The Texas Practice Guide states that “[t]he requirement to show a ‘safer alternative design’ does not apply . . . to toxic and environmental torts, or to cases involving a prescription drug or medical device.” 1 Tex. Prac. Guide Pers. Inj. 2d § 4:348 (2013). But it does not cite any cases or authorities for this assertion. Further, the Houston Law Review Article was authored prior to the Texas Supreme Court's express adoption of the safer alternative design requirement in *Caterpillar*. *See* Jeffrey Nolan Diamant, *Texas Senate Bill 4: Product Liability Legislation Analyzed*, 31 Hous. L. Rev. 921 (1994).

ENTER: February 3, 2014



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JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE