UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

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

MEMORANDUM OPINION AND ORDER
(Motions for Summary Judgment)

Pending before the court are several motions for summary judgment. The defendants, Ethicon, Inc. and Johnson & Johnson, Inc. (collectively "Ethicon"), move for summary judgment on all claims [Dockets 125 and 130] and the plaintiffs move for summary judgment on Ethicon's affirmative defense to punitive damages [Docket 148]. For the reasons stated below, Ethicon's Motion for Summary Judgment [Docket 125] is **GRANTED in part** and **DENIED in part**, Ethicon's Motion for Summary Judgment on Punitive Damages [Docket 130] is **DENIED**, and the Plaintiffs' Motion for Partial Summary Judgment on Defendants' Affirmative Defense to Punitive Damages Claims [Docket 148] is **GRANTED**.

I. Background

This case is one of over 40,000 assigned to me by the Judicial Panel on Multidistrict Litigation. This case arises out of injuries allegedly sustained from the implantation of a pelvic mesh product, Ethicon's Gynecare TVT ("TVT"), to treat stress urinary incontinence. The

complaint alleges the following causes of action: 1) negligence; 2) strict liability—design defect; 3) strict liability—manufacturing defect; 4) strict liability—failure to warn; 5) breach of express warranty; 6) breach of implied warranty; 7) loss of consortium; and 8) punitive damages. (*See* Compl. [Docket 1]).

II. Legal Standard

A. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not "weigh the evidence and determine the truth of the matter." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587-88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some "concrete evidence from which a reasonable juror could return a verdict in his [or her] favor." *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere "scintilla of evidence" in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Felty v. Graves Humphreys Co.*, 818

F.2d 1126, 1128 (4th Cir. 1987); *Ross v. Comm'ns Satellite Corp.*, 759 F.2d 355, 365 (4th Cir. 1985), *abrogated on other grounds, Price Waterhouse v. Hopkins*, 490 U.S. 228 (1989).

B. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in multidistrict litigation cases such as this. The choice of law for these pretrial motions depends on whether they involve federal or state law. "When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation." *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). In cases based on diversity jurisdiction, the choice-of-law rules to be used are those of the states where the actions were originally filed. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) ("Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied."); *In re Air Crash Disaster Near Chicago, Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010).

This case was originally filed in the Northern District of Texas. Therefore, I apply Texas choice-of-law rules. Under Texas law, courts apply the "most significant relationship" test, as enunciated by the Restatement (Second) of Conflicts (1971). *See Torrington Co. v. Stutzman*, 46 S.W.3d 829, 848 (Tex. 2000); *Duncan v. Cessna Aircraft Co.*, 665 S.W.2d 414, 420 (Tex. 1984); *Gutierrez v. Collins*, 583 S.W.2d 312, 318 (Tex. 1979). Under that test, a court should consider the following factors in determining which state's laws to apply: "(1) the place where the injury

occurred; (2) the place where the conduct causing the injury occurred; (3) the residence, nationality, and place of business of the parties; and (4) place where the relationship, if any, between the parties is centered." *In re ENSCO Offshore Int'l Co.*, 311 S.W.3d 921, 928 (Tex. 2010); *see also* Restatement (Second) of Conflict of Laws § 145 (1971).

According to the Restatement, this choice of law analysis applies to each individual *issue* in a case, and Texas courts follow this approach. *See Hughes Wood Products, Inc. v. Wagner*, 18 S.W.3d 202, 205 (Tex. 2000) ("[T]he Restatement requires the court to consider which state's law has the most significant relationship *to the particular substantive issue to be resolved.*"); *Duncan*, 665 S.W.2d at 421 ("[I]n all choice of law cases . . . the law of the state with the most significant relationship to the particular substantive issue will be applied to resolve that issue."). The Restatement provides that "[t]he rights and liabilities of the parties with respect to an issue in tort are determined by the local law of the state which, with respect to that issue, has the most significant relationship to the occurrence and the parties . . . ." Restatement (Second) of Conflict of Laws § 145(1) (1971).

Here, the surgery to implant the Ethicon product was performed in Texas and any alleged injuries occurred in Texas. Therefore, I **FIND** that the laws of Texas apply to the issues in this case unless I state otherwise.

III. Analysis

"A product may be unreasonably dangerous because of a defect in marketing, design, or manufacturing." *Am. Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 426 (Tex. 1997). The plaintiffs have brought products liability claims under all three theories, and Ethicon has moved for summary judgment on all three of these theories.

A. Failure to Warn

Ethicon argues that it is entitled to judgment as a matter of law on the plaintiffs' failure to warn claims because the implanting physician, Dr. Boreham, did not read the TVT's Instructions for Use ("IFU") before implanting the device into Ms. Lewis. Therefore, Ethicon contends that the plaintiffs cannot prove that a defective warning, if any, on the IFU caused Ms. Lewis's injuries. I agree.

Texas, like most jurisdictions, follows the learned intermediary doctrine. *See, e.g.*, *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974) (applying Texas law); *Morgan v. Wal-Mart Stores, Inc.*, 30 S.W.3d 455, 461-66 (Tex. App. 2000); *Bean v. Baxter Healthcare Corp.*, 965 S.W.2d 656, 663 (Tex. App. 1998). Under that doctrine, in situations where there is a patient-physician relationship, the manufacturer of a drug or medical device has a duty to warn that extends only to the physician. *See Pustejovsky v. Pliva, Inc.*, 623 F.3d 271, 276 (5th Cir. 2010); *Bean*, 965 S.W.2d at 663. The manufacturer does not have a duty to warn the patient who receives the drug or device. *Pustejovsky*, 623 F.3d at 276.

"In order to recover for a failure to warn under the learned intermediary doctrine, a plaintiff must show: (1) the warning was defective; and (2) the failure to warn was a producing cause of the plaintiff's condition or injury." *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999) (applying Texas law). Ethicon argues that the plaintiffs cannot establish the second element. To prove that a failure to warn caused a plaintiff's injuries, "the plaintiff must show that a proper warning would have changed the decision of the treating physician, i.e., that but for the inadequate warning, the treating physician would have not used or prescribed the product." *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008) (quoting *Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 714 (N.D. Tex. 2000)).

To support its argument that the plaintiffs cannot prove causation, Ethicon relies on the fact that Dr. Boreham admitted that she had not read the TVT's IFU since 2002. (*See* Boreham Dep. [Docket 126-3], at 15:16-18; 60:21-24). Ethicon also cites two cases where courts granted summary judgment to the defendants on failure to warn claims where the treating physicians testified that they had not read or relied on the device IFUs. *See Porterfield v. Ethicon, Inc.*, 183 F.3d 464 (5th Cir. 1999); *Pustejovsky v. Pliva, Inc.*, 623 F.3d 271 (5th Cir. 2010). In *Porterfield*, the implanting physician testified that "at no time prior to" the plaintiff's surgery had he read the product's package insert or any other Ethicon literature. *See Porterfield*, 183 F.3d at 468. The physician stated that he relied on "surgical literature, his own experience, and the experience of his colleagues in weighing the risks and benefits of surgery with the mesh." *Id.* Finally, the physician admitted he was "aware of the possible risks of using the mesh," but he "decided to use it anyway." *Id.* Similarly, in *Pustejovsky*, the treating physician "did not recall ever reading the package insert for the drug or consulting the Physician's Desk Reference." *Pustejovsky*, 623 F.3d at 277.

According to the plaintiffs, there is at least a material dispute of fact whether the allegedly defective IFU caused Ms. Lewis's injuries. They point to the fact that although Dr. Boreham did not read the IFU before every operation, she had read it in 2002, and she expected that important changes to the IFU would be disseminated to her in medical literature or by Ethicon directly. (*See* Boreham Dep. [Docket 180-1], at 124:6-20). The plaintiffs assert that Dr. Boreham's continued reliance on the 2002 IFU was justified because "[e]very IFU used since 2000 has omitted any warning of chronic infection, antibiotic resistant infections, chronic pain, abscesses, vaginal perforation, vaginal scarring, foreign body reaction, shrinkage of the mesh device, curling, roping or deformation of the mesh, dyspareunia, and complications requiring

mesh removal." (Pls.' Resp. in Opp. to Defs.' Mot. for Summ. J. [Docket 180], at 4). The plaintiffs contend that *Porterfield* and *Pustejovsky* are distinguishable because while the physicians in those cases admitted they had never read the product warnings, Dr. Boreham did read the TVT IFU, albeit seven years before Ms. Lewis's surgery.

Despite the plaintiffs' argument, the failure to warn claim must fail. Although Dr. Boreham read the IFU at one time, she admits that she did not rely on it when she prescribed the TVT for Ms. Lewis. (*See* Boreham Dep. [Docket 126-3], at 222:9-15 ("That's right, I did not" rely on the IFU in prescribing the TVT to Ms. Lewis.). Dr. Boreham testified that she relied on Ms. Lewis's "symptoms, her voiding diary, her urodynamics, and physical exam. And then our discussions on her desires." (*Id.* at 218:23-219:9). Therefore, there is no evidence that any additional or stronger warnings on the IFU would have prevented Ms. Lewis's injuries. It is mere speculation that Dr. Boreham would have learned of changes to the IFU without reading it. *See Pustejovsky*, 623 F.3d at 277 (Rejecting plaintiff's arguments as speculation where plaintiff opined that physician might have learned about changes to the product warning in conversations with other physicians or at continuing education seminars.).

The plaintiffs also contend that their failure to warn claim may be based on the warnings given in not only the IFU, but the TVT patient brochures as well. *See, e.g., Pustejovsky*, 623 F.3d at 277 (noting that treating physician had not read the Physician's Desk Reference, discussed side effects with colleagues, or learned about side effects at seminars); *Porterfield*, 183 F.3d at 468 (noting that treating physician had not read "Ethicon literature"). This argument suffers from the same flaws as the plaintiffs' IFU argument. There is no evidence that Dr. Boreham relied on the TVT patient brochure in deciding to prescribe the TVT to Ms. Lewis. The plaintiffs' citations to Dr. Boreham's testimony do not convince me otherwise. *See, e.g.*,

Boreham Dep. [Docket 180-1], at 75:1-8 (stating that Dr. Boreham would have given Ms. Lewis a brochure if she had one and that Dr. Boreham trusts the accuracy of the brochures); 171:18-172:6 (stating that Dr. Boreham would have warned Ms. Lewis about the risks listed in the brochure).

Finally, the plaintiffs assert that Ethicon's motion should be denied because Dr. Boreham never testified that she would have ignored warnings from other sources. *See, e.g., Block v. Woo Young Med. Co.*, 937 F. Supp. 2d 1028, 1035-36 (D. Minn. 2013) (applying North Carolina law) (genuine issue of fact on causation where physician never testified he did not read labels or Dear Doctor letters and never testified that he would have been unresponsive to other warnings). But the burden of proof is on the plaintiffs. The plaintiffs must proffer some evidence that Ethicon's allegedly deficient warnings caused Ms. Lewis's injuries. Without evidence that Dr. Boreham relied on the warnings in the IFU or the patient brochures, the plaintiffs cannot carry their burden at the summary judgment stage. Ethicon is not required to negate the plaintiffs' claim. Rather, Ethicon satisfies its burden of production at the summary judgment stage by demonstrating that the "evidence is insufficient to establish an essential element of the [plaintiffs'] claim." *Celotex Corp. v. Catrett*, 477 U.S. 317, 331, (1986) (Brennan, J. dissenting). Ethicon has done that here.

The plaintiffs have not sustained their burden of proffering evidence on the causation element of their failure to warn claim. Therefore, this claim must fail. *See Celotex*, 477 U.S. at 322-23. Ethicon's motion for summary judgment on the failure to warn claim is **GRANTED**.

B. Design Defect

In Texas, a plaintiff bringing a design defect claim under strict liability must prove by a preponderance of the evidence that (1) the product was unreasonably dangerous due to a defect, (2) "there was a safer alternative design," and (3) "the defect was a producing cause" of the

damages. Tex. Civ. Prac. & Rem. Code Ann. § 82.005; *Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009). To determine whether a product is unreasonably dangerous, Texas courts apply a risk-utility test that considers the following factors:

> (1) the utility of the product to the user and to the public as a whole weighed against the gravity and likelihood of injury from its use;
>
> (2) the availability of a substitute product which would meet the same need and not be unsafe or unreasonably expensive;
>
> (3) the manufacturer's ability to eliminate the unsafe character of the product without seriously impairing its usefulness or significantly increasing its costs;
>
> (4) the user's anticipated awareness of the dangers inherent in the product and their avoidability because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions; and
>
> (5) the expectations of the ordinary consumer.

Am. Tobacco Co. v. Grinnell, 951 S.W.2d 420, 432 (Tex. 1997); *see also Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 256 (Tex. 1999). Whether the product is unreasonably dangerous is generally an issue for the jury. *Timpte Indus.*, 286 S.W.3d at 312; *Am. Tobacco*, 951 S.W.2d at 432.

In addition to the common law requirement that a product was unreasonably dangerous, a plaintiff must prove the statutory requirement that a safer alternative design existed. Tex. Civ. Prac. & Rem. Code Ann. § 82.005(b). The Texas Civil Practice & Remedies Code defines a "safer alternative design" as 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 . . . 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.

Id. That section further states that "[t]his 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. § 321)." *Id.* § 82.005(d).

Ethicon argues that the plaintiffs' design defect claims fail as a matter of law for two reasons: (1) the plaintiffs do not and cannot claim that the TVT is defective as to all patients who use it, and (2) the plaintiffs cannot show a feasible alternative design. I will address each of these arguments.

First, Ethicon appears to argue that there exists an additional element in a design defect claim. According to Ethicon, a design defect plaintiff must show that the product was defective "as to all patients who use it." (Mem. in Supp. of Mot. for Summ. J. [Docket 127], at 12). For support, Ethicon points to the Restatement (Third) of Torts: Product Liability. Under the Restatement, a medical device is not reasonably safe "if the foreseeable risks of harm posed by the . . . medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the . . . medical device *for any class of patients*." Restatement (Third) of Torts: Products Liability § 6(c) (1998) (emphasis added). But, as Ethicon admits, no Texas courts have adopted this provision. (Mem. in Supp. of Mot. for Summ. J. [Docket 127], at 13). Ethicon cites several Texas cases that rely on the Restatement regarding product liability claims in general. *See Bostrom Seating, Inc. v. Crane Carrier Co.*, 140 S.W.3d 681, 683 (Tex. 2004); *Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 257-61 (Tex. 1999); *Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 335-39 (Tex. 1998). None of these cases adopts the specific Restatement provision Ethicon cites. That the Texas Supreme Court has cited to some provisions

of the Restatement in products liability cases does not mean that it has adopted—as law—all of the Restatement's provisions.

Even though no Texas court has adopted Restatement (Third) of Torts: Products Liability §6(c), Ethicon argues that the court in *Ethicon Endo-Surgery, Inc. v. Gillies*, 343 S.W.3d 205 (Tex. App. 2011) (pet. denied), employed similar reasoning. That is not correct. In *Gillies*, the plaintiff non-suited her design defect claim and proceeded on a claim for negligent marketing. *Gillies*, 343 S.W.3d at 209-11. On the negligent marketing claim, the court held that "stating that a product was defectively designed for use in certain situations and, therefore, should not have been marketed at all, does not establish a standard of ordinary care applicable to the marketing of the product for use in other situations." *Gillies*, 343 S.W.3d at 213. The court did not hold that a defective design claim requires a showing that the product is defective as to all persons who use it.

Second, Ethicon argues that the plaintiffs cannot prove that there is a safer alternative design to the TVT under Texas Civil Practice & Remedies Code § 82.005. As previously explained, that 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)." Tex. Civ. Prac. & Rem. Code Ann. § 82.005(d). The Food, Drug, and Cosmetic Act ("FDCA") defines a "device," in relevant part, as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease . . . ." 21 U.S.C. § 321. As an implant intended to cure stress

urinary incontinence, the TVT qualifies as a "device" under the FDCA. Accordingly, the plaintiffs are not required to prove that a safer alternative exists.[1]

For the reasons stated above, Ethicon's motion for summary judgment is **DENIED** with respect to the plaintiffs' design defect claim.

C. Manufacturing Defect

To prevail on a manufacturing defect claim, a plaintiff must show "a manufacturing flaw which renders the product unreasonably dangerous[,] that the defect existed at the time the product left the seller, and that the defect was the producing cause of the plaintiff's injuries." *Gerber v. Hoffmann-La Roche, Inc.*, 392 F. Supp. 2d 907, 922 (S.D. Tex. 2005) (citing *Dico Tire, Inc. v. Cisneros*, 953 S.W.2d 776, 783 (Tex. App. 1997). Ethicon argues that the plaintiffs have failed to proffer any evidence to support the existence of a manufacturing defect. The plaintiffs do not oppose Ethicon's motion for summary judgment on their manufacturing defect claim. Therefore Ethicon's motion for summary judgment is **GRANTED** on the plaintiffs' manufacturing defect claim.

D. Express and Implied Warranties

To recover for the breach of an express or implied warranty, Texas law requires that a plaintiff provide notice to the seller before filing suit. Section 2.607(c)(1) of the Texas Business & Commerce Code mandates that "the buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." Tex. Bus. & Com. Code Ann. § 2.607; *see also Ackermann v. Wyeth Pharm.*, 471 F. Supp. 2d 739, 745 (E.D. Tex. 2006) *aff'd*, 526 F.3d 203 (5th Cir. 2008) ("[T]he Court agrees that to

[1] Although they are not required to establish that a safer alternative design exists, the plaintiffs have proffered extensive evidence of three alternative designs: (1) polyvinylidene fluoride ("PVDF") mesh, (2) polypropylene mesh with larger pores, and (3) mesh constructed from native tissue. (*See* Pls.' Resp. in Opp. to Defs.' Mot. for Summ. J. [Docket 180], at 16-19).

maintain the claim for breach of warranty, notice was required."); *Wilcox v. Hillcrest Mem'l Park*, 696 S.W.2d 423, 424-25 (Tex. App. 1985) ("[S]ection 2.607(c)(1) requires that a buyer notify any seller . . . of the product's alleged defect within a reasonable time of discovering the defect and that failure to do so bars the buyer from any remedy for breach of warranty under the Texas Business & Commerce Code."). The rule applies to manufacturers as well as sellers. *See U.S. Tire-Tech, Inc. v. Boeran, B.V.*, 110 S.W.3d 194, 199 (Tex. App. 2003) ("[U]nder section 2.607(c)(1), a buyer is required to give notice of an alleged breach of warranty to a remote manufacturer.").

The plaintiffs admit that they have presented no evidence of pre-suit notice. (*See* Pls.' Resp. in Opp. to Defs.' Mot. for Summ. J. [Docket 180], at 19). However, they argue that Section 2.607 extends only to *immediate* sellers and manufacturers, not "remote sellers/manufacturers such as [Ethicon]." The plaintiffs thus apparently argue that Section 2.607's pre-suit notice requirement only extends to those sellers or manufacturers who are in privity with the plaintiff. The plaintiffs cite one Texas appellate court for this position. *See Vintage Homes, Inc. v. Coldiron*, 585 S.W.2d 886, 888 (Tex. App. 1979) ("[T]he notice requirement of Section 2.607 applies only as between a buyer and his immediate seller."). However, three other Texas appellate decisions have explicitly disagreed with *Vintage Homes*, holding that Section 2.607 applies to "remote" sellers or manufacturers. *See U.S. Tire-Tech*, 110 S.W.3d at 199 ("[U]nder section 2.607(c)(1), a buyer is required to give notice of an alleged breach of warranty to a remote manufacturer."); *Wilcox*, 696 S.W.2d at 423 (holding that Section 2.607(c)(1) "requires that a buyer notify a *remote* seller of an alleged breach of warranty"); *Bailey v. Smith*, No. 13-05-085-CV, 2006 WL 1360846, at *4-5 (Tex. App. May 18, 2006). Further, the *Wilcox* court noted that the reasoning in *Vintage Homes* is not valid because it relied

on commentary that misquoted Section 2.607. *See Wilcox*, 696 S.W.2d at 425 ("The version discussed by that commentary required that the buyer give note to 'his' seller, while the Texas version of section 2.607(c)(1) requires that notice be given to 'the' seller.").

Federal courts considering this same issue have uniformly held that Section 2.607 applies to "remote" sellers and manufacturers. *See, e.g.*, *Gazal v. Boehringer Ingelheim Pharm., Inc.*, 647 F.3d 833, 841 (8th Cir. 2011) (agreeing with the district court that "the Texas Supreme Court, if confronted with the question, would adopt the majority position and require that a subpurchaser give the seller prior notice of his breach of warranty claim"); *McKay v. Novartis Pharm. Corp.*, 934 F. Supp. 2d 898, 913 (W.D. Tex. 2013) (finding that "the Texas Supreme Court would likely hold that a buyer is required to give notice of an alleged breach of warranty to a remote seller/manufacturer"); *Enpro Sys., Ltd. v. Namasco Corp.*, 382 F. Supp. 2d 874, 890 (S.D. Tex. 2005) (finding that Section 2.607 "extends to buyers who wish to recover damages for breach of warranty from remote sellers or manufacturers").

The clear weight of authority in both Texas and the Eighth Circuit require notice by a buyer to a remote manufacturer. I adopt the reasoning of those cases as noted above and **FIND** that the plaintiffs did not produce such notice.

The plaintiffs argue that the pre-suit notice requirement should not apply in personal injury cases. The plaintiffs contend that the purpose of the notice requirement, which is to "to give the seller an opportunity to inspect the product to determine whether it was defective and to allow the seller an opportunity to cure the breach," *Wilcox*, 696 S.W.2d at 425, is inapplicable in the personal injury context because bodily harm cannot be cured. On its face, the text of Section 2.607 does not include an exception for personal injury cases.

For the reasons stated, I **FIND** that the plaintiffs were required to give notice to Ethicon before bringing suit for breach of warranty. Accordingly, Ethicon's motion for summary judgment on the plaintiffs' warranty claims is **GRANTED**.

E. Negligence

Ethicon moves for summary judgment on all of the plaintiffs' claims premised on negligence. Ethicon argues only that if the plaintiffs' claims for strict liability fall, then so too should the negligence claims. *See Gerber v. Hoffmann-La Roche Inc.*, 392 F. Supp. 2d 907, 923 (S.D. Tex. 2005) (holding that where summary judgment was proper as to strict liability claims for failure to warn, design defect, and manufacturing defect, then those same claims premised on negligence must also fall). As I found above, the plaintiffs' strict liability claims for failure to warn and manufacturing defect do not survive. Accordingly, Ethicon's motion for summary judgment is **GRANTED** with respect to the plaintiffs' claims for negligent failure to warn and negligent manufacturing defect, and it is **DENIED** with respect to the plaintiffs' negligent design defect claim.

F. Loss of Consortium

Ethicon moves for summary judgment on the plaintiffs' loss of consortium claims, arguing that it is a derivative claim and therefore cannot be maintained without the plaintiffs' strict liability and negligence claims. Because the plaintiffs' design defect claims survive, Ethicon's motion for summary judgment with respect to loss of consortium is **DENIED**.

G. Punitive Damages

Both Ethicon and the plaintiffs move for summary judgment in relation to punitive damages. To resolve this issue, I must first determine which state's law applies. As discussed above, Texas law applies generally to this case. Texas courts follow the Restatement (Second)

Conflict of Laws and require that I conduct a choice-of-law analysis with respect to each particular issue. *See* Restatement (Second) of Conflict of Laws § 145(1); *Hughes Wood Products, Inc. v. Wagner*, 18 S.W.3d 202, 205 (Tex. 2000) ("[T]he Restatement requires the court to consider which state's law has the most significant relationship *to the particular substantive issue to be resolved.*").

Because the purpose of punitive damages is to punish misconduct, Ethicon asserts that the law of New Jersey—the place where the alleged misconduct occurred—should apply. *See* Restatement (Second) of Conflict of Laws § 145, cmt e ("[W]hen the primary purpose of the tort rule involved is to deter or punish misconduct, the place where the conduct occurred has peculiar significance."); *see also Tobin v. AMR Corp.*, 637 F. Supp. 2d 406, 422 (N.D. Tex. 2009) (applying Texas law for punitive damages where injury occurred in Illinois but the defendants' corporate decisions were made in Texas). Although the plaintiffs expressly claim that they do not "concede that New Jersey's" law applies, they appear to assume that it does, and they do not assert that the law of any other state applies to their punitive damages claim. (*See* Pls.' Mem. of Law in Supp. of Mot. for Partial Summ. J. on Defs.' Affirmative Defense to Punitive Damages Claims [Docket 149], at 1, n. 2).

The focus of the punitive damages inquiry is Ethicon's corporate conduct, and that conduct allegedly occurred in New Jersey. Therefore I **FIND** that New Jersey law applies to the plaintiffs' punitive damages claim.

Applying New Jersey law, I now turn to the substance of the parties' motions. Ethicon moves for summary judgment on the punitive damages claim by asserting that the New Jersey Product Liability Act ("NJPLA") precludes a punitive damages recovery in this case. (*See* Mot. for Summ. J. on Punitive Damages [Docket 130]). The plaintiffs move to preclude the

defendants from using that same argument as an affirmative defense. (*See* Pls. Mot. for Partial Summ. J. on Defs.' Affirmative Def. to Punitive Damages Claims [Docket 148]).

The NJPLA provides that manufacturers of medical devices are immune from punitive damages awards where their products have been approved, licensed, or generally recognized as safe and effective by the FDA. The relevant statute reads, in pertinent part,

> Punitive damages shall not be awarded if a drug or device or food or food additive which caused the claimant's harm *was subject to premarket approval or licensure by the federal Food and Drug Administration* under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq. *and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations*, including packaging and labeling regulations. . . . For purposes of this subsection, the terms "drug", "device", "food", and "food additive" have the meanings defined in the "Federal Food, Drug, and Cosmetic Act."

N.J. Stat. Ann. § 2A:58C-5 (emphasis added).[2] Ethicon contends that the FDA has endorsed and recognized the safety and effectiveness of the TVT in its 510(k) clearance. Ethicon's arguments are the same as those I address in my Memorandum Opinion and Order (Motion in Limine No. 1, Summary Judgment Motions on 510(k) Issue) issued this same day. For the reasons set out in that opinion, the FDA has not "approved or licensed" or "generally recognized" the TVT as "safe and effective." N.J. Stat. Ann. § 2A:58C-5. Therefore, I **FIND** that Ethicon is not immune from punitive damages pursuant to the NJPLA.

Based on the forgoing, Ethicon's motion for summary judgment on punitive damages is **DENIED**, and the plaintiffs' motion for summary judgment on Ethicon's NJPLA affirmative defense is **GRANTED**.

[2] A portion of this statute, which I have omitted and which is not applicable here, was stricken by a New Jersey appellate court as preempted by federal law. *See McDarby v. Merck & Co., Inc.*, 949 A.2d 223 (N.J. Super. Ct. App. Div. 2008).

IV. Conclusion

As discussed above, Ethicon's Motion for Summary Judgment [Docket 125] is **GRANTED in part** and **DENIED in part**, Ethicon's Motion for Summary Judgment on Punitive Damages [Docket 130] is **DENIED**, and the Plaintiffs' Motion for Partial Summary Judgment on Defendants' Affirmative Defense to Punitive Damages Claims [Docket 148] is **GRANTED**.

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

ENTER: January 15, 2014

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE