UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	**CIVIL ACTION NO. 2:12-md-02327** **MDL No. 2327**
This Document Applies To All Actions	:	Judge Joseph R. Goodwin

PLAINTIFF CAROLYN LEWIS'S SUPPLEMENTAL BRIEF ON DIRECTED VERDICT ISSUES

Plaintiff Carolyn Lewis respectfully submits this brief in response to the Court's request for supplemental briefing on these two issues: whether Plaintiff must prove that a product defect caused her injuries, or simply that the product caused her injuries; and, whether the Plaintiff has established specific causation in support of her negligence claim. Plaintiff's counsel understands the first question to be purely legal, and the second question to require an analysis of the evidence. As explained below, the Court should conclude that Plaintiff merely must draw a causation connection between the defective product and the Plaintiff's injuries, and that Plaintiff has raised a jury question on specific causation with regard to her negligence claim.

I. The Court Should Conclude That Texas Law Requires Only that the Plaintiff Connect the Defective Product to the Plaintiff's Injuries.

Although the Texas authorities are somewhat unclear, the Court should conclude that the requisite standard of proof on Plaintiff's strict liability-design defect claim is whether the defective product (the TVT) caused Plaintiff's injuries.[1] As cited in Plaintiff's initial brief, the Texas Supreme Court wrote, shortly after Tex. Civ. Prac. & Rem. Code 82.005 was enacted in

[1] As described in Plaintiff's prior brief, *see* Doc. No. 287, she has met the causation requirement even if she must tie her injuries to specific defects. However, the Court asked for further briefing on the specific legal issue of the standard of proof, so this brief will not lay out that alternative argument.

1993, that "[u]nder traditional products liability law, the plaintiff must prove the defendant supplied the product that caused the injury." *Firestone Steel Products Co. v. Barajas*, 927 S.W.2d 608, 614 (Tex. 1996) (emphasis added). *See also* 59 Tex. Jur. 3d Products Liability § 49 (stating that "products liability imposes strict liability on the manufacturer of an unreasonably dangerous product that is a producing cause of a plaintiff's injuries") (emphasis added).

Other cases have described the inquiry in that manner, including at least two federal cases. In 2005, the Western District of Texas assessed a design defect claim involving a lighter under the common law[2] and denied the defendant's summary judgment arguments on the issue of causation. The court wrote that "[u]nder Texas law, a products liability plaintiff need only show that the defendant's allegedly defective product was, more likely than not, a substantial factor in bringing about the harm sustained." *Bigelow v. New York Lighter Co.*, 2005 US Dist. LEXIS 47871, at *36 (W.D. Tex. June 27, 2005), citing *IPCO-G.&C. Joint Venture v. A.B. Chance Co.*, 65 S.W.3d 252, 261 (Tex. App.–Houston 2001) (noting the plaintiff's "burden of showing that the defendant's offending conduct, or allegedly defective product, was more likely than not, a substantial factor in bringing about the harm sustained"). In addressing a *Daubert* motion in a drug case, the Western District of Texas described the necessary testimony on specific causation as being "that the product was more likely to have caused a plaintiff's injuries than any other potential cause." *Newton v. Roche Laboratories, Inc.*, 243 F. Supp. 2d 672, 683 (W.D. Tex. 2002).

In addition, the manner in which courts have analyzed certain cases indicates that the inquiry focuses on the product, however the test may be framed. For instance, a Texas Supreme Court case, the court held that summary judgment was inappropriate on a manufacturing defect

[2] It is not entirely clear why the court did not apply Section 82.005, but the court cited case law for the causation standard, and it arrived at a different standard than the one in the statute.

claim, even though the plaintiff had not produced any evidence on the reason that the cigarettes at issue were allegedly defective. Rather, the experts' opinions "were based on generic smoking studies that did not isolate individual brands of cigarettes and their individual effects." *Am. Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 434 (Tex. 1997).[3] The court deemed that testimony to be sufficient on causation. *Id.* Similarly, in *Temple EasTex, Inc. v. Old Orchard Creek Partners, Ltd.*, 848 S.W.2d 724 (Tex. App.–Dallas 1992), the court assessed the evidence as to causation on a design defect claim and concluded: "Viewing this evidence and the inferences flowing therefrom in the light most favorable to the verdict, there is some evidence that Temple EasTex's fiberboard proximately caused Old Orchard's damages." *Id.* at 734. Therefore, the Court of Appeals focused its inquiry on whether the fiberboard, the allegedly defective product, had caused the plaintiff's injuries.

A frequently cited Restatement provision provides further support for the idea that the product is the focus of the inquiry. Texas courts regularly cite to Restatement (Second) of Torts § 402A in establishing guidelines for common-law strict liability claims. *See, e.g.*, *Grinnell*, 951 S.W.2d at 426; *Barajas*, 927 S.W.2d at 613. That section describes the product liability inquiry as follows: "(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property." Rest. 2d Torts § 402A. The structure of the sentence indicates that the word "thereby" refers back to the word "sells." In other words, one who sells a defective product is liable for harm caused by that sale. Nothing in the Restatement definition requires a connection between the harm and a specific defect.

[3] There was also a design-defect claim in *Grinnell*, but causation was not analyzed. With common-law product liability claims, there is no indication of any difference in the standard for manufacturing defect or design defect claims. The case law relies generally on the Restatement, as noted above, and the Restatement does not distinguish among types of strict liability claims in evaluating causation. *See* Rest. 2d Torts § 402A.

In comment c., the Restatement discusses the policy behind the provision, stating that "the justification for the strict liability has been said to be that the seller, by marketing his product for use and consumption, has undertaken and assumed a special responsibility toward any member of the consuming public who may be injured by it." Rest. 2d Torts § 402A cmt. c. Certainly, that policy is furthered by an interpretation that subjects the seller of an unreasonably dangerous product to liability if that unreasonably dangerous product harms a consumer. The policy is not served by letting sellers of unreasonably dangerous products to escape liability if the plaintiff cannot tie the harm to a specific defect. Thus, the Restatement indicates that the causation inquiry should focus on the defective product, not on specific defects.

The Court asked the parties to consider a 1984 Texas Supreme Court case, *Lucas v. Texas Industries, Inc.*, 696 S.W.2d 372 (Tex. 1984). The *Lucas* case states that "a plaintiff must establish "(1) the defective and unreasonably dangerous condition of the defendant's product and (2) a causal connection between such condition and the plaintiff's injuries or damages." *Id.* at 377. The court's decision was not based on causation; the court simply concluded that there was insufficient evidence of a product defect. *Id.* at 378. Thus, the court did not explain what it meant by those words, and the phrasing of the inquiry had no bearing on the result. At first blush, it may seem that the phrase "such condition" refers to the alleged defect. But the context is important. In Texas, whether a product is "unreasonably dangerous" is determined by a risk-utility balancing test. *Grinnell*, 951 S.W.2d at 432. Thus, the phrase "such condition" in *Lucas* likely refers generally to the unnecessarily dangerous nature of the product, rather than to any specific defect. Thus, *Lucas* indicates the need to draw a link between the unreasonably dangerous product and the harm. Further, the formulation of the test was not important to the decision in Lucas, which was not based on causation at all. The Court should give more weight

to the Supreme Court's later summary judgment ruling in *Grinnell*, which focused on the experts' ability to tie the product in with the harms, not on the specific alleged defect. *Grinnell*, 951 S.W.2d 434. In that case, the nature of the inquiry was actually decisive.

For all of these reasons, the Court should conclude that, with respect to Plaintiff's design defect claim, her burden is to demonstrate that the TVT caused her injuries.

II. Plaintiff Has Established a Jury Question as to Proximate Causation Because the Harms Suffered by Mrs. Lewis Were Foreseeable to Ethicon.

Although the legal standard is slightly different, the Court should conclude that Plaintiff has put forth the necessary evidence to create a jury question on the issue of proximate causation for essentially the reasons outlined in Plaintiff's prior brief. (*See* Doc. No. 287).

"To prevail on a claim of negligence against the supplier of an allegedly defective product, a plaintiff must prove a legal duty owed to the plaintiff by the defendant, breach of that duty, and damages to the plaintiff proximately caused by the breach of the duty." *Dewayne Rogers Logging, Inc. v. Propac Industries, Ltd.*, 299 S.W.3d 374, 385 (Tex. App.–Tyler 2009).

Proximate causation is slightly different from the "producing cause" standard used for strict liability claims. "Proximate cause consists of two elements: (1) cause in fact and (2) foreseeability." *Russell Equestrian Center, Inc. v. Miller*, 406 S.W.3d 243, 249 (Tex. App.–San Antonio 2013). "Cause in fact denotes that the negligent act or omission was a substantial factor in bringing about the injury and without which no harm would have been incurred." *Id.* "Foreseeability means that the actor, as a person of ordinary intelligence, should have anticipated the dangers that his negligent act created for others." *Id.* "[B]oth negligence and proximate cause may be inferred from the circumstances surrounding an event, so that it is not necessary to prove these elements of a cause of action by direct and positive testimony." *Id.*

The factual predicate for Plaintiff's negligence claim is largely the same as for Plaintiff's design defect claim. As described in Plaintiff's initial brief in design defect issues, Ethicon's TVT product was defective primarily because it is a heavyweight, small-pore mesh, and because it is a mechanically cut mesh. The heavyweight, small-pore nature of the mesh leads to foreign body response, scarring, fibrotic bridging, shrinkage and nerve entrapment, which causes pain for the patient.[4] The mesh also degrades in the body, leading to chronic inflammation.[5] Plaintiff has further alleged that the TVT product was unreasonably dangerous when implanted in Mrs. Lewis because it was mechanically cut, which leads to fraying, roping, curling, and particle loss.[6] These problems, in turn, cause pain, dyspareunia, and urinary retention for the patient.[7] For her negligence claim, Plaintiff asserts that Ethicon breached a duty to her by failing to remedy these problems with the mesh, and that Ethicon's failure to do so was a proximate cause of her injuries.

Thus, the evidence as to liability is similar to the liability evidence on the design defect claim, and the evidence on cause-in-fact is essentially the same as with the "producing cause" standard analyzed in Plaintiff's prior brief. That brief, therefore, is incorporated by reference here. The additional element needed for causation on a negligence claim is the element of foreseeability. *See Miller*, 406 S.W.3d at 249. So at this stage, Plaintiff must establish that a reasonable jury could conclude that it was foreseeable to Ethicon can that its negligent design of the TVT mesh would cause injuries to patients such as Mrs. Lewis.

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[4] See Plaintiff's Initial Brief, Doc. 287, at p. 5, citing Klosterhalfen Dep. at 51:23-25, 71:18-24, 83:01-08, 83:24-84:06, 88:08-15, 42:06-20.

[5] *Id.* at p. 4, citing Klosterhalfen Dep. at 74:06-75:01, 89:08-15.

[6] *Id.* at pp. 5-6, citing Trial Tr. Day 2 at 61:19-22, 85:18-25; Kammerer Dep. at 190:11-18 and Exhibit 3428; Kammerer Dep. at 214:01-23; Brown May 06, 2005 e-mail, Plaintiff's Exhibit 3162.

[7] *Id.* at pp. 10-11, citing Trial Tr. Day 2 at 77:19-78:4, 75:17-76:3; Trial Tr. Day 4 at 84:7-13; Trial Tr. Day 2 at 100:4-19.

The pain and dyspareunia that were experienced by Mrs. Lewis were foreseeable. For instance, Meng Chen, who was associate medical director with Ethicon beginning in 2006, testified that she was responsible for reviewing patient complaints.[8] As part of that role, she had discussions with patients who experienced "serious life-changing pain" while using the TVT.[9] Further, Ms. Chen was asked specifically about dyspareunia, which was Mrs. Lewis's primary injury.

> Q. And you're aware of patient reports where the patient has told you, I didn't know that for the rest of my life that when I made love to my partner, I would have pain, I would have painful intercourse for the rest of my life, nobody told me there was a risk.
>
> You've had those discussions, right?
>
> THE WITNESS: I'm aware of such reports from patients, yes.[10]

Dr. Piet Hinoul, worldwide medical director for Ethicon's energy franchise, further acknowledged that Ethicon it "theoretically … would have been a possibility" even at the time of the TVT launch that patients would suffer from lifelong painful sex, and that Ethicon knew about the possibility of nerve damage causing lifelong pain.[11]

And even if it is necessary to establish foreseeability within the context of particular design defects, Plaintiff can make that showing. For instance, as to the effect of pore size, Ethicon would clearly have understood the benefits of lighter-weight, larger-pore mesh, as they were using such mesh in other products, including the Ultrapro mesh that was used in the pelvic floor.[12] As early as 2003, Ethicon was experimenting with lighter-weight, larger-pore meshes, in an effort to improve the TVT product.[13] Ethicon also embarked on a project called Scion in an

[8] Chen Dep. at 219:05-11.
[9] *Id.* at 223:01-07.
[10] *Id.* at 227:16-24.
[11] Hinoul Dep. at 580:12-581:03.
[12] Smith Dep. at 433:02-14.
[13] *Id.* at 494:01-495:01.

attempt to develop a better mesh product.[14] However, that project was not well funded, and eventually it was scrapped for business reasons.[15]

Meanwhile, the problems caused by the mechanical cutting of the mesh were clearly foreseeable, as evidenced by Ethicon's internal documents. Gene Kammerer, an engineering fellow at Ethicon, was asked about an Ethicon study that stated, "it is of utmost importance that the mesh is cuttable and that it does not fray or release particles after cutting. The small particles migrate and cause pain during intercourse."[16] He also discussed his own study from April 2006, in which he concluded that laser-cut mesh "functions better" than mechanically cut mesh, because there is less fraying, particle loss, roping, and permanent narrowing of the mesh with laser cutting.[17] A 2005 e-mail from Allison London Brown, a product director for Ethicon, stated that the mechanically cut mesh "is perceived by some physicians as inferior and we do get a high number of complaints on linting and roping (mesh particles falling off and the material stretching to the point of being a string)."[18] These documents indicate that the problems associated with the mechanically cut mesh were foreseeable.

In addition, Daniel Lamont, Ethicon's director of post-marketing surveillance, testified as follows:

> Q. Ethicon chose to continue to sell this mechanically cut mesh despite knowing that it had the potential for degradation, particles floating around in women's bodies, stretching, and roping, correct?
>
> THE WITNESS. With the potential, yes.[19]

[14] *Id.* at 490:02-10.
[15] *Id.* at 491:04-13, 540:04-07.
[16] Kammerer Dep. at 190:11-18 and Exhibit 3428, p. 20.
[17] *Id.* at 214:01-23.
[18] Brown May 06, 2005 e-mail, Plaintiff's Exhibit 3162.
[19] Lamont Dep. at 30:18-24.

There could be no clearer indication of foreseeability than that testimony by Mr. Lamont. Thus, in addition to having sufficient evidence on the question of cause-in-fact, for the reasons expressed in Plaintiff's initial brief on directed verdict issues, Plaintiff has put forth sufficient evidence from which the jury could conclude that the harms suffered by Mrs. Lewis were foreseeable to Ethicon. Therefore, proximate causation is a question for the jury.

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Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
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Master File No. 2:12-MD-02327

MDL No. 2327

JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

THIS DOCUMENT RELATES TO:

CAROLYN LEWIS, ET AL. V ETHICON, INC.

Case No. 2:12-CV-04301

CERTIFICATE OF SERVICE

I hereby certify that on February 18, 2014, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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