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In re ETHICON, INC., Pelvic Repair System Products Liability Litigation.
This Document Relates To
Carolyn Lewis et al.
v.
Ethicon, Inc. et al. Case No. 2:12–cv–4301.

Nos. 2:12–MD–02327, 2327.
|
Feb. 3, 2014.

MEMORANDUM OPINION AND ORDER

(Motion to Reconsider)

JOSEPH R. GOODWIN, District Judge.

***1** Pending before the court is the Plaintiffs' Motion to Reconsider and Clarify Summary Judgment Order and *Daubert* Order [Docket 205]. As discussed below, the motion is **DENIED.**

I. Background

On January 15, 2014, I entered memorandum opinions and orders resolving the parties' motions for summary judgment and motions to exclude or limit expert testimony. The plaintiffs ask that I reconsider or clarify several of those rulings. I address each of those rulings below.

II. Legal Standard–Reconsideration

Rule 54(b) of the Federal Rules of Civil Procedure governs reconsideration here. *See Fayetteville Investors v. Commercial Builders, Inc.,* 936 F.2d 1462, 1469–70 (4th Cir.1991) (finding district court properly reconsidered an interlocutory order under Rule 54(b)); *In re Digitek Prods. Liab. Litig.,* MDL No.1968, 2010 WL 5396377, at * 1 n. 2 (S.D.W.Va. Oct. 20, 2010); *Bragg v. Robertson,* 183 F.R.D. 494, 495–96 (S.D.W.Va.1998) (stating that "the Court retains power to amend interlocutory orders to achieve complete justice"). Rule 54(b) states:

> [A]ny order or other decision, however designated, that adjudicates fewer than all of the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities.

Fed.R.Civ.P. 54(b). "Notwithstanding that precept, it is improper to file a motion for reconsideration simply to ask the Court to rethink what the Court had already thought through—rightly or wrongly." *Mt. Hawley Ins. Co. v. Felman Prod., Inc.,* No. 3:09–cv–00481, 2010 WL 1404107, at *2 (S.D.W.Va. Mar. 30, 2010).

Additionally, although a "motion for reconsideration under Rule 54(b) is not subject to the strictures of a Rule 60(b) motion," this district has been "guided by the general principles of Rules 59(e) and 60(b)" in determining whether a Rule 54(b) motion should be granted. *Shrewsbury v. Cyprus Kanawha Corp.,* 183 F.R.D. 492, 493 (S.D.W.Va.1998). In that regard, the Fourth Circuit has recognized three grounds for amending a judgment: "(1) to accommodate an intervening change in controlling law; (2) to account for new evidence not available at trial; or (3) to correct a clear error of law or prevent manifest injustice." *Pac. Ins. Co. v. Am. Nat. Fire Ins. Co.,* 148 F.3d 396, 403 (4th Cir.1998). Such motions "may not be used, however, to raise arguments which could have been raised prior to the issuance of the judgment, nor may they be used to argue a case under a novel legal theory that the party had the ability to address in the first instance." *Id.* Finally, "reconsideration of a judgment after its entry is an extraordinary remedy which should be used sparingly." *Id.* (quoting 11 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 2810. 1, at 156–57 (3d ed.2012)).

III. Analysis

***2** The plaintiffs ask that I reconsider four separate rulings. The first three are *Daubert* rulings wherein I excluded the plaintiffs' expert testimony. The last one is a grant of summary judgment against the plaintiffs on their failure to warn claim.

A. Secondary Infections

First, the plaintiffs argue that I should reconsider my *Daubert* orders excluding opinions related to secondary infections. The plaintiffs take issue with my discussion of Dr. Klinge, where I stated that his opinions regarding secondary infections "appear to be limited to cases where mesh remains in the body." (Mem. Op. & Order (*Daubert* Mots.) [Docket 195], at 10). I wrote that "Dr. Klinge does not offer opinions on secondary infections where the mesh has been explanted, as is the case with Ms. Lewis. Dr. Klinge's opinions regarding secondary infections therefore do not fit the facts of this case...." (*Id.* at 10–11). The plaintiffs argue that I should reconsider this holding because Ms. Lewis has not had her mesh *fully* explanted. Even so, I held that secondary infections were not "a fact in issue" because Ms. Lewis did not experience a secondary infection. (*Id.* at 16). "Three separate physicians, Dr. Zimmern, Dr. Sexton, and Dr. Zheng, testified that Ms. Lewis did not suffer from a secondary infection.... The plaintiffs do not dispute this testimony." (*Id.* at 16–17). Therefore, it is clear that whether Ms. Lewis's mesh has been fully explanted does not change an independent, principal basis of my holding regarding secondary infection opinions. The plaintiffs' motion to reconsider this ruling is **DENIED.**

B. Dr. Klinge's Explant Analysis

Second, the plaintiffs argue that I should reconsider my *Daubert* ruling excluding Dr. Klinge's analysis of explanted mesh samples. I determined that Dr. Klinge's analysis of 485[1] mesh explants from the Institute for Pathology, Düren, was unreliable because "Dr. Klinge does not state how he selected these particular explants, or whether 485 is a large sample size of the Institute's collection." (*Id.* at 13). The plaintiffs now state that the 485 explants reviewed by Dr. Klinge "constitute the entirety of a pelvic floor explant registry[.]" (Pls.' Mot. to Reconsider and Clarify Summ. J. Order and *Daubert* Orders ("Pls.Mot.") [Docket 205], at 3). Nowhere in Dr. Klinge's report does he state that the 485 meshes constitute the entirety of the collection. In fact, Dr. Klosterhalfen's deposition testimony, cited by the plaintiffs for that proposition, suggests the opposite. He stated that "[a]t 2008 or end of 2008, I had about 180 [samples], and up to now, I have now I think it's up to 600." (Klosterhalfen Dep. [Docket 205–2], at 163). I can find no basis in the evidence for the plaintiffs' assertion that the 485 explants examined by Dr. Klinge constituted the entirety of the collection.

1 The plaintiffs' briefing states that Dr. Klinge analyzed 483 mesh explants, but Dr. Klinge's report puts this number at 485. (*See* Pls.' Mot. to Reconsider and Clarify Summ. J. Order and *Daubert* Orders [Docket 205], at 3; Pls.' Reply to Defs.' Resp. in Opp. to Pls.' Mot. to Reconsider and Clarify Summ. J. and Daubert Orders [Docket 217], at 2; Klinge Report [Docket 132–3], at 69). I will accordingly use the number provided by Dr. Klinge in his report.

The plaintiffs also argue that Dr. Klinge's analysis is reliable because Ethicon, not Dr. Klinge or Dr. Klosterhalfen, "provided the mesh explants." (Pls.' Mot. [Docket 205], at 4). This argument is a rehash of the plaintiffs' earlier argument, therefore rendering it improper in a motion to reconsider. *See Mt. Hawley Ins. Co. v. Felman Prod., Inc.,* No. 3:09–cv–00481, 2010 WL 1404107, at *2 (S.D.W.Va. Mar. 30, 2010). In any event, whether Ethicon provided the mesh explants, as the plaintiffs contend, or Ethicon merely facilitated the creation of the collection, as Ethicon contends, Dr. Klinge's opinions do not pass muster under *Daubert.* He has given no explanation as to whether 485 is a representative sample size or how he chose the particular explants analyzed. (*See* Klinge Report [Docket 132–3], at 69). Therefore, I have no information as to the "potential rate of error" inherent in Dr. Klinge's observations. *See Daubert v. Merrell Dow Pharm., Inc.,* 509 U.S. 579, 594 (1993). Further, Dr. Klinge has provided no indication that his observations can be or have been tested. *Id.* at 593. The *Daubert* analysis requires me to assess whether "the reasoning or methodology underlying the testimony is scientifically valid[.]" *Id.* at 592–93. But here, without any information about Dr. Klinge's methodology in his report, I am left to simply trust that his observations are methodologically sound. That I cannot do. The plaintiffs' motion to reconsider this ruling is **DENIED.**

C. Evidence of Inadequate Warnings

***3** Third, the plaintiffs seek clarification regarding the exclusion of testimony related to inadequate warnings. I granted summary judgment on the plaintiffs' failure to warn and breach of warranty claims, and I excluded several proposed experts whose testimony related solely to those claims. The plaintiffs now argue that this expert testimony is relevant to establish defective design and punitive damages. The parties have also filed briefs on whether the TVT IFU and patient education materials are relevant to establish a design defect. [2] (*See* Pls.' Trial Br. on Evidentiary Issues Regarding the Admissibility of IFU and Patient Education Materials [Docket 219] and Defs.' Resp. to Pls.' Trial Br. [Docket 223]). My discussion that follows addresses both the plaintiffs' motion to reconsider my *Daubert* ruling and the parties' supplemental briefs on the admissibility of the IFU and patient educational materials.

2 Although the plaintiffs filed a "trial brief," not a motion, the plaintiffs request specific relief in the form of a ruling that "the IFU for the TVT, and Ethicon's patient education materials regarding the TVT, are relevant to the Plaintiffs' strict liability-design defect claim." (Pls.' Trial Br. on Evidentiary Issues Regarding the Admissibility of IFU and Patient Education Materials [Docket 219], at 3).

In design defect cases, evidence of the following factors of risk and utility may be admissible:

> (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., Inc. v. Grinnell, 951 S.W.2d 420, 432 (Tex.1997). The plaintiffs point to the fourth and fifth factors to support their argument that evidence of inadequate warnings is probative of their design defect claim. The plaintiffs contend that those two factors "are focused on 'users' and 'consumers' of the product, assessing the user's awareness of dangers, based on either obvious conditions or warnings; and the 'ordinary consumer's' expectations." (Pls.' Trial Br. on Evidentiary Issues Regarding the Admissibility of IFU and Patient Education Materials [Docket 219], at 5). The plaintiffs believe that the terms "user" and "consumer" refer to both a physician and patient in a medical device case. (*Id.* at 5).

Ethicon disagrees. Ethicon contends that "consumer" and "user" in Texas's risk-utility test refer to the physician, not the patient, in a medical device case. (*See* Defs.' Resp. to Pls .' Trial Br. [Docket 223], 2–4). Ethicon argues that the plaintiffs' interpretation is incompatible with the learned intermediary doctrine. (*Id.* at 3). Ethicon asserts that a design defect theory based on inadequate warnings is subsumed by a failure to warn claim, and a judgment dismissing the failure to warn claim precludes any design defect claim based on failure to warn. (*Id.* at 5). Finally, Ethicon argues that the fourth risk-utility factor is not applicable where, as here, there is no allegation that "the alleged dangers of the *design* of TVT could be avoided by a warning[.]" (*Id.* at 8).

***4** I adopt Ethicon's position and **FIND** that evidence of allegedly inadequate warnings is not relevant to the design defect claim in this case. First, in a medical device or drug case, the learned intermediary rule applies. *See, e.g., Reyes v. Wyeth Labs .,* 498 F.2d 1264, 1276 (5th Cir.1974) (applying Texas law); *Centocor, Inc. v. Hamilton,* 372 S.W.3d 140, 157 (Tex.2012); *Guzman v. Synthes (USA),* 20 S.W.3d 717, 720 n. 2 (Tex.App.1999); *Bean v. Baxter Healthcare Corp.,* 965 S.W.2d 656, 663 (Tex.App.1998). Under that rule, a manufacturer may discharge its duty by warning a physician, not the end user. *See Pustejovsky*

v. Pliva, Inc., 623 F.3d 271, 276 (5th Cir.2010); *Bean,* 965 S.W.2d at 663. The policy behind the rule is that "only the doctor could understand the propensities and dangers involved in the use of a given drug [or medical device]." *Alm v. Aluminum Co. of Am.,* 717 S.W.2d 588, 592 (Tex.1986); *see also* Restatement (Third) of Torts: Prod. Liab. § 6 cmt.b ("The rationale supporting this 'learned intermediary' rule is that only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy."). Therefore, Ethicon's duty to warn did not extend to Ms. Lewis. The plaintiffs may not circumvent the learned intermediary rule by introducing evidence or argument that suggests or otherwise implies that Ethicon had a duty to warn Ms. Lewis. Any arguments that inadequate warnings caused Ms. Lewis's injuries are subsumed by the failure to warn claim, which has been dismissed. *See Gonzalez v. Bayer Healthcare Pharm., Inc.,* 930 F.Supp.2d 808, 820 (S.D.Tex.2013) ("Plaintiff's claims for defective design, marketing defect, breach of express and implied warranties, negligence and gross negligence ... are in actuality disguised failure-to-warn [and] fraud-by-omission claims.... Plaintiff cannot employ such characterizations to plead around the learned intermediary doctrine, which is clearly applicable here.").

The plaintiffs' reliance on *Ethicon, Inc. v. Parten,* 520 S.W.2d 527 (Tex.App.1975), is misplaced. First, that case was not a design defect case; it was a manufacturing defect and failure to warn case. *Id.* Second, the plaintiffs' argument that the *Parten* opinion "expressly describes the physician as a user or consumer, and the patient as a consumer" is inapplicable here. (Pls.' Trial Br. on Evidentiary Issues Regarding the Admissibility of IFU and Patient Education Materials [Docket 219], at 5). The court based that holding on statements in the Restatement (Second) of Torts § 402A. *Parten,* 520 S.W.2d at 533. The court did not review or mention the design defect risk-utility factors at issue here because those factors had not yet been articulated by the Texas Supreme Court. *See Turner v. Gen. Motors Corp.,* 584 S.W.2d 844, 846 (Tex.1979). Further, the Texas Supreme Court had not yet adopted the learned intermediary rule. *See Alm,* 717 S.W.2d at 592. Accordingly, *Parten* is of little relevance here.

***5** The second reason I reject the plaintiffs' position is that warnings are simply not applicable to this particular design defect claim. The Texas Supreme Court has stated that "[t]he risk-utility analysis does not operate in a vacuum, but rather in the context of the product's intended use and its intended users." *Timpte Indus ., Inc. v. Gish,* 286 S.W.3d 306, 312 (Tex.2009). Therefore, not all factors of the risk-utility test will be equally applicable in all cases. *See, e.g., id.* at 312–15 (stressing the obvious dangers of climbing to the top of a trailer ladder); *Hernandez v. Tokai Corp.,* 2 S.W.3d 251, 259–60 (Tex.1999) (analyzing cigarette lighter's risk and utility in light of the product's intended adult users); *Caterpillar, Inc. v. Shears,* 911 S.W.2d 379, 384 (Tex.1995) (analyzing risk and utility of removable rollover cover on a front-end loader considering the loader's intended use in low-clearance areas).

The warning in this case does not address a safe *method* or *manner* of using the TVT. Instead, the warning's only function is to *inform* users of the TVT's risks so that they may choose to take it or leave it. In a design defect case, "whether the product contained a warning and the nature of the warning are relevant to the issue of whether the product was unreasonably dangerous. A warning that alerted users to the dangers involved in using the product and instructed them in how to avoid those dangers could significantly reduce those dangers without impairing the utility of the product to society." *Carter v. Johns–Manville Sales Corp.,* 557 F.Supp. 1317, 1320 (E.D.Tex.1983). There is no way that the TVT's design can be used in a *safer* manner by following the warning. A physician simply implants the device or chooses an alternative treatment. The warning serves only to inform physicians of the risks of implanting the device.

Texas cases make clear that warnings are relevant to defective design only where the warnings address the method or manner of using the design safely. For example, in *Genie Industries, Inc. v. Matak,* the court considered warnings that instructed users not to reposition an aerial work lift when the platform was elevated. *See* No. 13–11–00050–CV, 2012 WL 6061779, at *3–4 (Tex.App. Dec. 6, 2012). Thus, the warning instructed users not to misuse the lift because misuse could result in the lift tipping over, which it did. In *Timpte Industries, Inc. v. Gish,* the plaintiff was injured when he fell off the top rung of a

ladder affixed to the back of a trailer. *See* 286 S.W.3d 306, 308 (Tex.2009). The plaintiff stated that the ladder was defectively designed because it allowed people to climb to the top rung. *Id.* at 309. The court disagreed, stating that, among other things, the manufacturer had warned users "to always maintain three-point contact with the trailer, which is impossible for a user standing on the top rail." *Id.* at 314. In *Whitmire v. Terex Telelect, Inc.,* the plaintiff was injured when operating a "digger derrick" attached to the bed of a heavy duty pickup truck while the truck was moving. *See* 390 F.Supp.2d 540, 544 (E.D.Tex.2005). The court found a genuine issue of material fact existed on the defective design claim partly because the plaintiff's expert testified that neither the digger derrick nor pickup truck cab contained warnings against users remaining in the derrick's operator chair while the truck was moving. *See id.* at 552.

***6** Each of the warnings in these cases concerned the proper and safe use of the product. They are unlike the TVT's warning, which simply informs users of the product's risks and enables them to decide whether they want to use the product at all. Complaints about the inadequacies of such a warning are quintessentially considered as a failure to warn claim. *Cf. Smith v. Aqua–Flo, Inc.,* 23 S.W.3d 473, 480 (Tex.App.2000) ("A marketing defect is found if the lack of adequate warnings or instructions renders an otherwise adequate product unreasonably dangerous. A design defect focuses on a defect in the product itself, and whether safer designs for the product were available.") (internal citations and quotations omitted); *Benavides v. Cushman, Inc.,* 189 S.W.3d 875, 881 (Tex.App.2006) ("A marketing defect claim and a design defect claim are clearly distinct and separable." (internal quotations removed). Therefore, evidence of the TVT's allegedly inadequate warning is not relevant to the design defect claim.

Third, I would exclude this evidence under Federal Rule of Evidence 403. Admitting evidence of inadequate warnings poses a substantial risk of confusing and misleading the jury into believing that there is a failure to warn claim. Yet the probative value of this evidence is scant because the plaintiffs no longer have such a claim, they cannot show that an inadequate warning caused Ms. Lewis's injuries, and the warning does not relate to using the TVT in a safe manner.

The plaintiffs additionally argue that evidence of inadequate warnings is relevant to their punitive damages claim under New Jersey law. To receive a punitive damages award, a plaintiff must prove "by clear and convincing evidence, *that the harm suffered was the result of the defendant's acts or omissions,* and such acts or omissions were actuated by actual malice or accompanied by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or omissions." N.J. Stat. Ann. § 2A:15–5.12(a) (emphasis added). Because the plaintiffs failed to proffer evidence that inadequate warnings caused Ms. Lewis's injuries, those warnings are not relevant to the punitive damages claim.

For the reasons stated above, I **DENY** the plaintiffs' motion to reconsider my *Daubert* ruling on expert testimony related to the failure to warn and breach of warranty claims. I also **FIND** that evidence related to the TVT's IFU and patient education brochures is not relevant to the plaintiffs' design defect claim or punitive damages claim.

D. Failure to Warn Claim

The plaintiffs finally ask me to reconsider my summary judgment ruling on the failure to warn claim. I held that the plaintiffs failed to proffer evidence that any inadequate warning caused Ms. Lewis's injuries. (*See* Mem. Op. & Order (Mots. for Summ. J.) [Docket 194], at 7). My ruling was based on, among other things, the fact that Dr. Boreham, Ms. Lewis's treating physician, testified that she had not read the IFU since 2002 and that she did not rely on the IFU in prescribing the TVT. (*See* Boreham Dep. [Docket 126–3], at 218:14–22). In prescribing the TVT, Dr. Boreham took into account 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).

***7** The plaintiffs now argue that "[j]ust because Dr. Boreham did not rely upon the IFU to *prescribe* the TVT, however, does not mean that she did not rely upon it in *providing informed consent* to Mrs. Lewis." (Pls.' Mot. [Docket 205], at 7). First, the plaintiffs have already made this argument in their initial briefing. (*See* Pls.' Resp. in Opp. to Defs.' Mot. for Summ. J. [Docket 180], at 8–12).

For this reason alone, their motion is inappropriate and without merit.

Second, the duty to warn in this context extended only to Dr. Boreham. *See Pustejovsky v. Pliva, Inc.,* 623 F.3d 271, 276 (5th Cir.2010); *Bean v. Baxter Healthcare Corp.,* 965 S.W.2d 656, 663 (Tex.App.1998). Dr. Boreham had not read the IFU since 2002, and she prescribed the TVT based on a number of factors other than Ethicon's warnings. Any better warning, therefore, would not have reached Dr. Boreham. Accordingly, the plaintiffs are unable to show that an inadequate warning caused Ms. Lewis's injuries. *See Ackermann v. Wyeth Pharm.,* 526 F.3d 203, 208 (5th Cir.2008) ("Even if the physician is not aware of a risk, 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.") (internal quotations omitted). The plaintiffs' motion on this issue is accordingly **DENIED.**

IV. Conclusion

As discussed above, the Plaintiffs' Motion to Reconsider and Clarify Summary Judgment Order and *Daubert* Order [Docket 205] is **DENIED.**

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

All Citations

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