IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

JO HUSKEY, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:12-cv-05201

ETHICON, INC., et al.,

Defendants.

MEMORANDUM OPINION & ORDER

Pending before this court is Defendants Ethicon, Inc. & Johnson & Johnson's Renewed Motion for Judgment as a Matter of Law or, in the Alternative, for a New Trial ("Motion") [Docket 437]. The plaintiffs have responded [Docket 439], making the matter ripe for decision. For the reasons stated below, the Motion is **DENIED**.

I. Background

This case was the first bellwether jury trial within the Ethicon, Inc. MDL, MDL 2327. At present, the Ethicon, Inc. MDL is the largest MDL in the country, containing over 26,000 individual cases. The Judicial Panel on Multidistrict Litigation assigned the Ethicon, Inc. MDL to this court, along with six other MDLs concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). More than 70,000 cases are currently pending in the MDLs. Jo and Allen Huskey ("the plaintiffs") filed this particular action against Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon"), alleging injuries

associated with implantation of the TVT Obturator System ("TVT-O"), a polypropylene-based, transvaginal mesh product manufactured by Ethicon to treat SUI.

Mrs. Huskey's implantation surgery was performed by Dr. Gretchen Byrkit on February 23, 2011. (Statement of Undisputed Facts Regarding Jo Huskey's Medical History & Condition [Docket 215] ¶ 25). At a post-operative visit on March 9, 2011, Dr. Byrkit examined Mrs. Huskey and noticed eroded mesh on the right side of the vagina. (Id. ¶ 27). The erosion persisted over the next few months and caused Mrs. Huskey to experience painful sexual intercourse. (Id. ¶ 28). When revision surgery did not resolve the mesh erosion, Dr. Byrkit referred Mrs. Huskey to Dr. Sohail Siddique, who had specific experience with mesh erosion. (Id. ¶¶ 28–29).

Dr. Siddique met with Mrs. Huskey on August 29, 2011. (Id. ¶ 30). Mrs. Huskey complained of pelvic pain and dyspareunia (pain with sexual intercourse). (Id.). After examining Mrs. Huskey, Dr. Siddique observed the exposed mesh and recommended excision, though he noted that due to the placement of the mesh in the obturator space, he could not remove it all. (Id. ¶¶ 30–31). Dr. Siddique performed the excision surgery on November 18, 2011. (Id. ¶ 33). He ultimately removed six centimeters of mesh from what he described as a "chronically infected space" and left the portions that were retracted around the pubic bone. (Id.). Mrs. Huskey's pain returned after the excision surgery, and steroid injections, though successful at first, have provided minimal relief. (Id. ¶ 36).

Since removal of the sling, Mrs. Huskey continues to have constant pelvic and vaginal pain that is exacerbated by physical activity. (Id. ¶ 41). She has also experienced recurrence of SUI, pain in her bladder, dyspareunia, and sacroiliac joint pain. (Id. ¶¶ 39–41). Attributing these injuries to the TVT-O, Mrs. Huskey and her husband filed suit against Ethicon on September 6, 2012. (See generally Short Form Compl. [Docket 1]). Trial began on August 25, 2014. After nine days of

trial, the plaintiffs ultimately presented four claims to the jury: strict liability for defective design; strict liability for failure to warn; negligence; and loss of consortium. (See Verdict Form [Docket 402]).[1] The jury returned a verdict in favor of the plaintiffs on all claims. In so doing, the jury awarded $3,070,000 in compensatory damages to Mrs. Huskey, in addition to $200,000 to Mr. Huskey for loss of consortium. (Id.).

At the conclusion of the plaintiffs' case, Ethicon orally moved for judgment as a matter of law on each claim pursuant to Federal Rule of Civil Procedure 50(a). (Trial Tr. (Aug. 29, 2014) [Docket 388], at 94:15–18). I granted the motion in part with respect to the issue of punitive damages and deferred ruling on the remaining claims. (Id. at 114:18–115:3). Then, at the close of its case, Ethicon renewed its Rule 50(a) motion for judgment as a matter of law, and I again deferred ruling. (Trial Tr. (Sept. 4, 2014) [Docket 428], at 78:24–25). I now consider Ethicon's post-verdict renewed motion for judgment as a matter of law pursuant to Rule 50(b), along with its alternative motion for a new trial under Rule 59(a)(1)(A).[2]

II. Renewed Motion for Judgment as a Matter of Law

A. Legal Standard

Pursuant to Federal Rule of Civil Procedure 50(a), a court may grant judgment as a matter of law "[i]f a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Fed. R. Civ. P. 50(a). When considering a party's motion for judgment as a matter of law, the court must "view the evidence in the light most favorable" to the non-moving party and "draw

[1] The court dismissed the plaintiffs' other claims upon a motion for summary judgment. (See Mem. Op. & Order (Mots. for Summ. J.) [Docket 272]).

[2] The governing substantive law, as I have previously held in this case, is that of Illinois. (See Mem. Op. & Order (Mots. for Summ. J.) [Docket 272], at 5).

all reasonable inferences in his favor without weighing the evidence or assessing the witnesses' credibility." Baynard v. Malone, 268 F.3d 228, 234–35 (4th Cir. 2001). Judgment as a matter of law is inappropriate if a reasonable jury could find in favor of the non-moving party. Id. at 235. On the other hand, a court may grant judgment as a matter of law if the "evidence presented supports only one reasonable conclusion as to the verdict." Bank of Montreal v. Signet Bank, 193 F.3d 818, 831 (4th Cir. 1999).

Rule 50 also states that "[i]f the court does not grant a motion for judgment as a matter of law made under Rule 50(a), the court is considered to have submitted the action to the jury subject to the court's later deciding the legal questions raised by the motion." Fed. R. Civ. P. 50(b). After the matter is submitted to the jury, the Rules allow a movant to file a renewed motion for judgment as a matter of law. Id. "When a jury verdict has been returned, judgment as a matter of law may be granted only if, viewing the evidence in a light most favorable to the non-moving party (and in support of the jury's verdict) and drawing every legitimate inference in that party's favor, the only conclusion a reasonable jury could have reached is one in favor of the moving party." *Int'l Ground* Transp. v. Mayor & City Council of Ocean City, Md., 475 F.3d 214, 218–19 (4th Cir. 2007).

While courts should not simply rubber stamp a jury's verdict, judgment as a matter of law is a remedy to be applied sparingly and only in the most extraordinary circumstances. 9B Charles Wright & Arthur Miller, Federal Practice and Procedure § 2524 (3d ed. 2008); see also, e.g., Sawyer v. Asbury, 861 F. Supp. 2d 737, 743–44 (S.D. W. Va. 2012) (submitting the case to the jury despite "deep concerns" but granting post-verdict motion for judgment as a matter of law where video evidence contradicted trial testimony). Put simply, a court "may not disturb the [jury] verdict where there was sufficient evidence for a reasonable jury to find in the non-movant's favor." Dotson v. Pfizer, Inc., 558 F.3d 284, 292 (4th Cir. 2009).

B. Discussion

I decline to disturb the jury's verdict in this case because, as explained below, a reasonable jury could find in favor of the plaintiffs on each of their claims. The evidence on the defective design claim is particularly strong and is capable of upholding the verdict on its own. Thus, I begin there before turning to Ethicon's Motion regarding the plaintiffs' other theories of liability.

a. Design Defect

Illinois requires a plaintiff to prove five factors to succeed on a strict liability claim under a theory of design defect: "(1) a condition of the product as a result of [] design, (2) that made the product unreasonably dangerous, (3) and that existed at the time the product left the defendant's control, and (4) an injury to the plaintiff, (5) that was proximately caused by the condition." Mikolajczyk v. Ford Motor Co., 901 N.E.2d 329, 345 (Ill. 2008), opinion modified on denial of *reh'g* (Dec. 18, 2008). The second element, that the condition made the product "unreasonably dangerous," can be proven through either the consumer-expectations test or the risk-utility test. Id. at 351–52. The consumer-expectations test "is a single-factor test" that asks the jury to determine "whether the product is unsafe when put to a use that is reasonably foreseeable considering its nature and function." Id. at 352. In contrast, the risk-utility test is a "multifactor analysis" that integrates consumer expectations along with "a broad range" of other factors, such as the "magnitude and probability of the foreseeable risks of harm[;] the instructions and warnings accompanying the product[;] the likely effects of an alternative design on production costs; the effects of the alternative design on product longevity, maintenance, repair, and esthetics; and the range of consumer choice among products." Id. (citing Restatement (Third) of Torts: Prods. Liab. § 2 cmt. f (1998)).

Which of these two tests should be charged to the jury depends on the evidence presented by the parties at trial:

> [W]hen the evidence presented by either or both parties supports the application of this integrated [risk-utility] test, an appropriate instruction is to be given at the request of either party. If, however, both parties' theories of the case are framed entirely in terms of consumer expectations, including those based on advertising and marketing messages, and/or whether the product was being put to a reasonably foreseeable use at the time of the injury, the jury should be instructed only on the consumer-expectation test.

Id. Here, the parties presented evidence pertinent to both the consumer-expectations test and the risk-utility test. Therefore, I instructed the jury in accordance with the integrated test set forth in the Illinois Pattern Civil Jury Instructions, which provide as follows: "When I use the expression 'unreasonably dangerous,' I mean that the risk of danger inherent in the design outweighs the benefits of the design when the product is put to a use that is reasonably foreseeable considering the nature and function of the product." See Ill. Pattern Civ. Jury Instructions § 400.06A.[3]

Ethicon states three reasons for why it is entitled to judgment as a matter of law on the plaintiffs' design defect claim. First, Ethicon contends that comment k of the Restatement (Second) of Torts ("Restatement") § 402A applies to this case and acts as a bar to the plaintiffs' design defect claim. Second, Ethicon asserts that no reasonable juror could find that the TVT-O is unreasonably dangerous. And third, in Ethicon's view, the plaintiffs were required to show that a specific design defect caused Mrs. Huskey's injuries and failed to do so.

[3] Specifically, I instructed the jury as follows: "A product is unreasonably dangerous when the risk of danger inherent in the design outweighs the benefits of the design when the product is put to a use that is reasonably foreseeable considering the nature and function of the product." (Trial Tr. (Sept. 4, 2014) [Docket 428], at 222:1–5). This was the instruction proposed by both parties. (See Pls.' Resp. to the Court's Questions Regarding Cmt. k & the Significance of "Standard of Care" Test. on Pls.' Design Defect Claims [Docket 391], at 5–6 ("Plaintiffs propose that the Illinois Pattern Instructions relating to the risk-utility test should be followed in this case."); Defs.' Proposed Jury Instructions [Docket 349], at 11 (quoting Ill. Pattern Civ. Jury Instructions § 400.06A)).

i. Comment k

Comment k provides an exemption to strict liability for products that can be categorized as "[u]navoidably unsafe." Restatement § 402A cmt. k. According to comment k, such products, when "properly prepared and accompanied by proper directions and warning," are not "defective[,] nor [are they] unreasonably dangerous." Id. (emphasis in original). The comment illustrates by example: the "unavoidable high degree of risk" presented by the rabies vaccine is "fully justified," given that "the disease itself invariably leads to a dreadful death." Id. Manufacturers of products like this—when the product has been properly prepared, marketed, and labeled—are "not to be held to strict liability for unfortunate consequences attending their use, merely because [they] have undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." Id.

I recently wrote at length on the purpose and import of comment k, concluding that comment k is, in essence, nothing more than another name for the risk-utility test. See Mullins v. Ethicon, Inc., __ F. Supp. 3d __, at *4–9 (S.D. W. Va. 2015), available at 2015 WL 4635573. Thus, in the states that have adopted a form of the risk-utility test, comment k is a "redundant," "useless relic" reflective of an era from decades past, when courts relied exclusively on the consumer-expectations test in product liability cases. Id. at *8. My reasoning in Mullins is apropos to the matter at hand. Because Illinois already provides for a risk-utility test, see Mikolajczyk, 901 N.E.2d at 347, the analysis set forth by comment k adds nothing to Ethicon's defense. In fact, Illinois's interpretation of comment k burdens Ethicon with proving the TVT-O is unavoidably unsafe. See Glassman v. Wyeth Labs., Inc., 606 N.E.2d 338, 342 (Ill. App. Ct. 1992) ("[A] defendant has the burden to demonstrate that a product comes under comment k's protection."). To do this, Ethicon must show that the risks of the TVT-O, no matter how high, are "fully justified" (i.e., outweighed)

by the "apparent[] useful[ness] and desirab[ility]" (i.e., utility) of the TVT-O. Restatement § 402A cmt. k.

Illinois courts, which apply comment k on a "case by case basis," have identified products that could possibly satisfy this standard. Glassman, 606 N.E.2d at 342. In Glassman, for example, the court explained that

> [a]n oral contraceptive is an apparently useful and desirable product, and comment k should apply to a particular oral contraceptive if the conditions of comment k are met, i.e., the product is unavoidably unsafe and is properly prepared, and there are adequate directions and warnings.

Id. The court concluded, however, that the defendant–manufacturer had not shown, as a matter of law, that the oral contraceptive was unavoidably unsafe, and as a result, summary judgment under comment k was not proper. Id. at 343. Ethicon suffers from the same shortcomings here.

On the one hand, Ethicon presented evidence that the TVT-O is an improvement over other types of SUI treatments, such as anterior repairs or open abdominal procedures. Dr. David Robinson, former Worldwide Medical Director at Ethicon, testified that unlike these latter invasive procedures, which carry risks of bleeding, infection, and recurrence, the TVT-O results in fewer postoperative complications and has a shorter recovery time. (Robinson Dep. Tr. [Docket 415-3], at 1149:20–1150:11; 1151:10–16;[4] see also Trial Tr. (Sept. 3, 2014) [Docket 427], at 66:10–12; 75:11–20 (testimony by Dr. Christina Pramudji that the TVT-O procedure, which requires a small incision, allows for faster recovery and is a better alternative to the invasive abdominal procedures)). In addition, Ethicon offered evidence that the TVT-O is considered the "gold standard" or "the best that [physicians] have to offer at the time to a patient." (Robinson Dep. Tr. [Docket 415-3], at 1152:8–23).

[4] Video of Dr. Robinson's deposition testimony was played for the jury during the trial. (See Trial Tr. (Aug. 27, 2014) [Docket 386], at 96:20–97:10).

But the plaintiffs also produced significant evidence on the TVT-O's risks. Dr. Bruce Rosenzweig, a urogynecologist and expert witness in this case, testified that polypropylene mesh can "degrade," "shrink and contract," "deform," and result in "chronic foreign body reaction and chronic inflammation." (Trial Tr. (Aug. 26, 2014) [Docket 385], at 32:15–18). He further explained that these problems cannot always be resolved by removing the mesh because there can be "scarring," "nerve irritation," and "residual mesh left in various areas that you can't get out, such as in muscle." (Id. at 32:21–23). Dr. Rosenzweig concluded that, in his opinion, the TVT-O's "risks outweigh its benefits." (Id. at 35:4–13). Urologist and expert witness Dr. Jerry Blaivas agreed, opining that symptoms of pain and dyspareunia "persist," even if the visible exposed mesh is removed. (Trial Tr. (Aug. 28, 2014) [Docket 387], at 171:17–25; 200:7–17). The jury heard evidence indicating that these risks posed by the TVT-O could have been avoided, or at least reduced, in several ways. (See, e.g., Trial Tr. (Aug. 25, 2014) [Docket 384], at 145:8–18 (testimony by Dr. Scott Guelcher that "minimiz[ing] the amount of polypropylene that's present in the mesh" can lessen the foreign body reaction); Trial Tr. (Aug. 26, 2014) [Docket 385], at 67:4–68:16 (testimony by Dr. Rosenzweig that laser-cut mesh, such as that used in the TVT-O, is "stiffer" than mechanical-cut mesh, which can result in "further irritat[ion of] nerves and muscles"); id. at 40:22–41:6; 49:13–15: 52:20–23 (testimony by Dr. Rosenzweig that the insertion of mesh near the obturator space is "inappropriate" and "especially concerning" due to nerves and muscles in that area that can be irritated by the foreign body reaction)).[5]

[5] Ethicon argues that the existence of alternative products and treatments for SUI does not preclude application of comment k. (Defs.' Mem. in Supp. [Docket 438], at 10 ("[C]omment k protect[s] manufacturers of desirable and useful products, . . . even if the benefits could be obtained with another product[.]" (quoting Glassman, 606 N.E.2d at 342))). The testimony recounted here, however, does not go to the existence of alternative treatments for SUI but instead presents evidence of alternative design decisions that Ethicon could have made to avoid the risks posed by the TVT-O. This evidence is key to the availability of comment k as a defense. "After all, a product is not unavoidably unsafe if it could be made safer through a reasonable alternative design." Mullins, __ F. Supp. 3d at *7 n.9; see also Grundberg v. Upjohn Co., 813 P.2d 89, 92 (Utah 1991) ("The purpose of comment k is to protect from strict liability

From this evidence, a reasonable jury could conclude that the high risks of the TVT-O are not justified by the benefits, and as a result, the TVT-O cannot, as a matter of law, qualify as an unavoidably unsafe product. Ethicon, having failed to meet its burden, cannot save itself from the jury's verdict on design defect by appealing to comment k's exemption.

Before moving on, I quickly address Ethicon's briefing related to the interaction between comment k and product warnings. Ethicon contends that "the comment k inquiry consists of two independent steps": first, whether the product is unavoidably unsafe, and second, whether the product was properly prepared and accompanied by proper warning. (Defs.' Reply [Docket 440], at 9–10). This reading of comment k is overbroad. Once a product has been deemed unavoidably unsafe (the benefits outweigh the risks), comment k immunizes it from a design defect claim. Alternatively, if a product is not deemed to be unavoidably unsafe (the benefits do not outweigh the risks), which was the finding in this case, comment k has no effect. In either case, the comment k inquiry ends upon determination that the product is or is not unavoidably unsafe. Ethicon's second step is not part of the analysis. Rather, the second step goes to the strict liability claims of failure to warn and manufacturing defect, which are separate and distinct from a claim of design defect.[6]

ii. Unreasonably Dangerous

Next, Ethicon argues that it is entitled to judgment on the design defect claim because no reasonable juror could conclude that the TVT-O is unreasonably dangerous. Again, determining

products that cannot be designed more safely.").

[6] Comment k mentions the need for "proper[] preparation" and "proper warning[s]" only to emphasize that even if a product is unavoidably unsafe, and thereby immune from a design defect claim, it can still be the subject of a warning defect or manufacturing defect claim. See Dan B. Dobbs et al., 2 The Law of Torts § 461 (2d ed. 2011) ("Manufacturing flaws and warning defects d[o] not obtain Comment k's dispensation."). Put differently, "comment k excepts unavoidably unsafe products from strict liability only to the extent that the plaintiff alleges a design defect; comment k's immunity from strict liability does not extend to strict liability claims based on manufacturing flaw or an inadequate warning." Grundberg, 813 P.2d at 92.

unreasonable dangerousness in this case called for application of the risk-utility test. See supra at 5–6. The jury must weigh the utility of the design against the "risk of harm created," and "[i]f the likelihood and gravity of harm outweigh the benefits and utilities of the product, the product is unreasonably dangerous." Calles v. Script-Tokai Corp., 864 N.E.2d 249, 257 (Ill. 2007) (internal citations omitted). This analysis is no different than that required to determine applicability of comment k. Therefore, I can dispose of Ethicon's argument in the same way I did in the previous section. In short, while Ethicon produced evidence of the TVT-O's usefulness and benefits, see supra at 8, the plaintiffs countered with evidence of the TVT-O's high risks of injury and how Ethicon could have mitigated those risks through alternative designs, see supra at 9. Taking the evidence as a whole and viewing it in the light most favorable to the plaintiffs, it is clear that reasonable persons could balance the risks and benefits against Ethicon. As a result, I cannot displace the jury's verdict on these grounds. See Duke v. Uniroyal Inc., 928 F.2d 1413, 1417 (4th Cir. 1991) ("[If] a reasonable jury could return a verdict in favor of the plaintiffs, the court must defer to the judgment of the jury.").

iii. Non-Specific Defect

Finally, Ethicon argues that the plaintiffs did not establish the causation element of their design defect claim. In particular, Ethicon asserts that the plaintiffs were required to prove that a specific defect in the TVT-O caused Mrs. Huskey's injuries, but they failed to do so. As an initial matter, courts in Illinois "have generally held that a plaintiff need not pinpoint the specific defect in a product in order to recover under strict liability." Doyle v. White Metal Rolling & Stamping Corp., 618 N.E.2d 909, 915–16 (Ill. App. Ct. 1993). But here, the plaintiffs did identify several

specific defects in the TVT-O. Furthermore, they provided evidence that these defects proximately caused Mrs. Huskey's injuries, at least in part.[7]

Proximate cause can be established either by direct evidence or by circumstantial evidence. Stojkovich v. Monadnock Bldg., 666 N.E.2d 704, 709 (Ill. App. Ct. 1996); see also Olson v. Williams All Seasons Co., 974 N.E.2d 914, 921 (Ill. App. Ct. 2012) ("[P]roximate cause can be sufficiently established by circumstantial evidence when an inference can reasonably be drawn from it."). Circumstantial evidence is evidence "from which a [factfinder] may infer other connected facts which usually and reasonably follow, according to the common experience of mankind." Id. (quoting Housh v. Swanson, 869 N.E.2d 321, 323 (Ill. App. Ct. 1990)). When a plaintiff relies on circumstantial evidence, she must show that the evidence "support[s] an inference which is reasonable and probable, not merely possible." Stojkovich, 666 N.E.2d at 709. She does not have to show, however, that the circumstantial evidence "exclude[s] all other possible inferences." Id. Put simply, "[i]f as a matter of ordinary experience a particular act or omission might be expected, under the circumstances, to produce a particular result, and that result in fact has followed, the conclusion may be permissible that the causal relation exists." Id. at 710 (quoting W. Keaton, Prosser & Keeton on Torts § 41, at 270 (5th ed. 1984)).

The plaintiffs' design defect claim focused on four alleged defects: (1) the tendency of the polypropylene material to erode; (2) the use of laser-cut mesh; (3) the placement of the TVT-O in the obturator space; and (4) the use of heavyweight mesh in the TVT-O. I **FIND** that the plaintiffs demonstrated sufficient circumstantial evidence to support proximate causation for at least one of these defects such that a reasonable jury could find in their favor on the design defect claim.

[7] "It is well settled that a defendant need not be the only cause to be held liable for an injury; rather, it is sufficient that the defendant is a cause." Voykin v. Estate of DeBoer, 733 N.E.2d 1275, 1279 (Ill. 2000) (emphasis in original).

For example, with respect to the alleged defect of using heavyweight mesh, Dr. Scott Guelcher, a chemical engineer and expert witness, testified that because polypropylene is particularly susceptible to oxidation, (Trial Tr. (Aug. 25, 2014) [Docket 384], at 115:10–21), the foreign body response can "lead to changes in the polypropylene structure." (Id. at 104:11–15). After elaborating on these changes, Dr. Guelcher concluded that the more polypropylene surface present in the body, the "greater [these] changes would be [and] the more hazardous they could be." (Id. at 145:8–15). In other words, the foreign body response to polypropylene is "elevated" when more polypropylene is present. (Id. at 103:1–7). Dr. Rosenzweig explained that the TVT-O is made of a heavyweight mesh (Prolene mesh), meaning that "there is more mesh in the pelvic floor." (Trial Tr. (Aug. 26, 2015) [Docket 385], at 39:23–40:8). Like Dr. Guelcher, Dr. Rosenzweig opined that "[t]he more mesh there is in the pelvis, the more of a foreign body response." (Id. at 40:10–11). In turn, the foreign body response causes pain, "redness," "irritation," and "inflammation." (Id. at 40:12–19). Dr. Rosenzweig ultimately concluded that the TVT-O "is unsuitable for implantation into the human body for SUI treatment" because the product is "made from a heavyweight mesh." (Id. at 35:21–23).

Dr. Blaivas provided specific causation testimony to connect the effects of heavyweight mesh to Mrs. Huskey's injuries. He explained that his examination of Mrs. Huskey revealed "chronic[] inflammation" and "chronic pelvic pain," which he believes was caused by the body's reaction to the mesh. (Trial Tr. (Aug. 28, 2014) [Docket 387], at 153:8–14; 156:10–15; 160: 22–161:5). Indeed, Dr. Blaivas does not know of any other cause for "this particular constellation of symptoms." (Id. at 173:6–11). Although Dr. Blaivas did not directly state that the heavyweight condition of the TVT-O proximately caused Mrs. Huskey's chronic inflammation and pain, a jury could readily reach this inference, taking Drs. Guelcher, Rosenzweig, and Blaivas's testimony as

a whole. Such an inference would be reasonable and probable.[8] It is therefore sufficient to establish circumstantial proof of proximate causation, even if other logical inferences could have been drawn from the doctors' testimony. See Mort v. Walter, 457 N.E.2d 18, 21 (Ill. 1983) ("[T]he use of circumstantial evidence is not limited to those instances in which the circumstances support only one logical conclusion. Instead, circumstantial evidence will suffice whenever an inference may be reasonably be drawn.").

Because a reasonable jury could find that the risks of the TVT-O outweigh the benefits and that the heavyweight condition of the TVT-O caused Mrs. Huskey's injuries, I must **DENY** Ethicon's Motion with respect to the plaintiffs' design defect claim.

b. Failure to Warn

A manufacturer has a duty to warn of a product's "dangerous propensities" for which "there is unequal knowledge with respect to the risk of harm." Salerno v. Innovative Surveillance Tech., Inc., 932 N.E.2d 101, 109–10 (Ill. App. Ct. 2010). To recover in a strict product liability action under a theory of failure to warn, the plaintiff must prove that the defendant–manufacturer failed to disclose an unreasonably dangerous propensity of the product, which resulted in injury to her. See Mikolajczyk v. Ford Motor Co., 901 N.E.2d 329, 335 (Ill. 2008), opinion modified on denial *of reh'g* (Dec. 18, 2008); see also Woodill v. Parke Davis & Co., 402 N.E.2d 194, 196 (Ill. 1980) ("It is well recognized that a failure to warn of a product's dangerous propensities may serve as the basis for holding a manufacturer or seller strictly liable in tort."). In the case of prescription medical devices, Illinois applies the learned intermediary doctrine, which directs the

[8] The same inference could reasonably be made with respect to the other three defects alleged by the plaintiffs, namely, the erosion of polypropylene, the use of laser-cut mesh, and the placement in the obturator space. But I need not address the evidence presented on these defects because, as explained above, a reasonable jury could find in favor of the plaintiffs based on the heavyweight-mesh theory of design defect.

manufacturer's duty to warn to the prescribing physician rather than the ultimate consumer or patient. See Hansen v. Baxter Healthcare Corp., 764 N.E.2d 35, 42 (Ill. 2002). The medical device manufacturer, however, need not warn about "risks already known to the medical community." Id.

In light of these principles, the plaintiffs' burden at trial was to show that Ethicon failed to warn Dr. Byrkit about a dangerous condition of the TVT-O, not already known to the medical community, and that the lack of warning proximately caused Mrs. Huskey's complained-of injuries. Ethicon's Motion homes in on the causation element of the failure to warn claim, arguing that the plaintiffs did not prove (1) that Dr. Byrkit would have changed her decision to implant the TVT-O had she been adequately warned or (2) that Dr. Byrkit relied on the Instructions for Use ("IFU") for the TVT-O when treating Mrs. Huskey.

i. *Physician's Change in Decision*

With respect to the first argument, Ethicon contends that because Dr. Byrkit testified that she "would use the TVT-O again" for a patient with the same symptoms as Mrs. Huskey, the lack of warning could not have caused Mrs. Huskey's alleged injuries. (Defs.' Mem. in Supp. [Docket 438], at 3–4 (quoting Byrkit Dep. Tr. [Docket 413-20], at 279:1–10)). Ethicon's argument rests on the assumption that Illinois law requires a plaintiff to show, as part of her prima facie case, that the physician would have changed her prescribing decision had the manufacturer provided an adequate warning. As several federal district courts have observed, however, "the Supreme Court of Illinois has not spoken on this issue clearly." Giles v. Wyeth, Inc., 500 F. Supp. 2d 1063, 1066 (S.D. Ill. 2007); see also, e.g., Mason v. Smithkline Beecham Corp., No. 05-1252, 2010 WL 2697173, at *9 (C.D. Ill. July 7, 2010) ("The Illinois Supreme Court has not determined what elements a plaintiff must prove in order to prevail on the issue of proximate causation in a failure-to-warn case.").

There is considerable reason for this court to believe, based on the holdings of other federal district courts, that the Supreme Court of Illinois would not agree with Ethicon's interpretation of the law and would adopt the heeding presumption for failure to warn claims. Under the heeding presumption, a court presumes that warnings, if given, will be heeded and followed by the learned intermediary. Applying this presumption "relieves the plaintiff of her burden" of proving that her prescribing physician would have acted differently under adequate warnings. Giles, 500 F. Supp. 2d at 1069. A number of federal cases involving Illinois law have employed this analysis. See id. (predicting that the Supreme Court of Illinois would adopt a rebuttable heeding presumption in cases involving the learned intermediary doctrine); Rutz v. Novartis Pharm. Corp., No. 12-cv-0026-MJR, 2012 WL 6569361, at *7 (S.D. Ill. Dec. 17, 2012) (holding that "the heeding presumption is a natural result of or corollary to the learned intermediary doctrine" and as a result, "if [a physician] were considered a learned intermediary, there is a presumption that he would have heeded an adequate warning about [a particular risk]"); Erikson v. Baxter Healthcare, Inc., 151 F. Supp. 2d 952, 970 (N.D. Ill. 2001) ("[T]he plaintiffs are entitled at this stage to a presumption that a learned intermediary would have heeded the warnings given. . . . [W]hat a physician might or might not have done had he been adequately warned is not an element the plaintiff must prove as part of her case."); Noyola v. Johnson & Johnson, No. 85 C 2184, 1986 WL 14657, at *4 (N.D. Ill. Dec. 16, 1986) ("What a physician might or might not have done had he been adequately warned is not an element plaintiff must prove as part of her case.").

I find these cases informative and well-reasoned. However, I do not need to predict whether the Supreme Court of Illinois would follow suit because the plaintiffs presented sufficient evidence at trial demonstrating that Dr. Byrkit would have acted differently had she been warned about the TVT-O's increased risks for active women:

> Q: If you had been told that it shouldn't be implanted in women who are active, actively exercising, fit women, if you had been told that it shouldn't be implanted in those women, would you still have implanted it in Jo Huskey?
>
> A: I don't think I would.

(Byrkit Dep. Tr. [Docket 413-20], at 96:2–7).[9]

Ethicon argues that Dr. Byrkit's testimony is inconsequential because the plaintiffs "offered no evidence that would support [the] contraindication" that the TVT-O should not be implanted in active women. (Defs.' Mem. in Supp. [Docket 438], at 4). This argument overlooks several pieces of key evidence presented at trial. First, the plaintiffs admitted notes from a meeting Ethicon had with co-inventor of the TVT-O, Professor Jean de Leval, where Professor de Leval pointed out that the "presence of tape in the adductors" can contribute to pain, particularly in "young, active and/or sportive patients." (Pls.' Ex. 13036 [Docket 412-7], at 1).

Then, Dr. Rosenzweig testified that when tape is placed inside the adductor muscles (as it is in the TVT-O surgery), the body's reaction to it can irritate the obturator nerve, resulting in both thigh pain and groin pain. (See Trial Tr. (Aug. 26, 2014) [Docket 385], at 52:20–23, 54:24–55:7). In his experience, this pain can last "much longer" than is indicated by the IFU, which states that patients might experience "transient leg pain lasting 24 to 48 hours." (Id. at 81:7–14). According to Dr. Rosenzweig, the IFU's failure to explain the risks of extended leg pain is one example of its inadequacy. (Id. at 77:22–84:1, 85:4–6). He also emphasized that an IFU must provide information on the patients the product is "contraindicated for," that is, "who should not get the device." (Id. at 75:14–19).

[9] Video of Dr. Byrkit's deposition testimony was played for the jury during the trial. (See Trial Tr. (Aug. 26, 2014) [Docket 385], at 168:21–22).

Expert testimony from Dr. Blaivas put Dr. Rosenzweig's testimony into context. He explained that due to the high "propensity for causing groin and thigh pain," the TVT-O operation is not preferred for "physically active" women like Mrs. Huskey. (Trial Tr. (Aug. 28, 2014) [Docket 387], at 219:8–12). The jury also heard evidence that Mrs. Huskey experienced such pain, which increased with physical activity. (Trial Tr. (Aug. 27, 2015) [Docket 386], at 80:9–20 (testimony from Gretchen Dean, Mrs. Huskey's former physical therapist, that Mrs. Huskey was complaining of "right sacroiliac pain [that] would sometimes go . . . down her leg," and "activity increased her symptoms")).

From this evidence and expert testimony, a reasonable jury could conclude that the IFU was inadequate in that it lacked a contraindication for the type of pain that active women can experience, and that Dr. Byrkit would not have implanted the TVT-O in Mrs. Huskey had she been aware of such a contraindication.[10] Accordingly, judgment as a matter of law is not appropriate on this basis.

ii. Reliance and Awareness of Risks

Ethicon's next attack on proximate causation relates to Dr. Byrkit's knowledge of the IFU and the TVT-O's risks. First, Ethicon argues that the allegedly inadequate IFU could not have caused Mrs. Huskey's injuries because the plaintiffs have not produced any evidence that Dr. Byrkit relied on the IFU in treating Mrs. Huskey. During her deposition, Dr. Byrkit gave conflicting testimony on this matter. Twice, she testified that she read the IFU before performing

[10] Illinois requires expert testimony to substantiate a failure to warn claim in cases where the duty to warn is to a prescribing physician. See N. Trust Co. v. Upjohn Co., 572 N.E.2d 1030, 1038 (Ill. App. Ct. 1991). Ethicon argues that the plaintiffs did not meet this requirement because they "failed to adduce expert testimony that the TVT-O should not be used in active women." (Defs.' Reply [Docket 440], at 5). I disagree. As demonstrated above, Drs. Rosenzweig and Blaivas's testimony, when taken together, provide the expert testimony needed for the jury to conclude that the IFU for the TVT-O lacked a necessary contraindication.

the implantation surgery on Mrs. Huskey. (Byrkit Dep. Tr. [Docket 413-20], at 31:15–18; 67:5–11). But later on, she testified that the last time she read the IFU was when she first began using the TVT-O to treat SUI. (Id. at 206:6–9). The jury is tasked with sorting out Dr. Byrkit's testimony and judging her credibility. See *Int'l Ground Transp. v. Mayor & City Council of Ocean City, Md.*, 475 F.3d 214, 221 (4th Cir. 2007) ("[The court] may not substitute [its] judgment for that of the jury or make credibility determinations."). Thus, because there is evidence in the record from which a reasonable jury could infer that Dr. Byrkit relied on the IFU in treating Mrs. Huskey, I must defer to the verdict on this point.

Ethicon also contends that it is entitled to judgment because Dr. Byrkit was "well aware of the risk of pain associated with the TVT-O procedure." (Defs.' Mem. in Supp. [Docket 438], at 5). In Illinois, a manufacturer's duty to warn does not extend to risks "already known by those to be warned." Proctor v. Davis, 682 N.E.2d 1203, 1211 (Ill. App. Ct. 1997)). Here, although Dr. Byrkit indicated that she understood that the risks of pain associated with the TVT-O ranged "from mild to severe [and] from temporary to permanent," (Byrkit Dep. Tr. [Docket 413-20], at 148:13–17), a reasonable jury could infer from her testimony that she was unaware of several other types of risks posed by the TVT-O. For instance, Dr. Byrkit had no knowledge of contraindications for active patients, (id. at 94:3–95:5), nor did she know that the mesh itself could cause infection, (id. at 85:22–86:5). Similarly, Dr. Byrkit seemed unaware of any relationship between the amount of mesh material in the implant and the risk of complications. (See id. at 120:24–121:3 ("[I] would expect potentially less mesh could result in less potential complication. But I don't know that for certain."). These risks were developed by expert testimony at trial. See supra at 17–18 (contraindications for active patients); (Trial Tr. (Aug. 26, 2014) [Docket 385], at 32:13–18 (testimony by Dr. Rosenzweig on complications caused by mesh); Trial Tr. (Aug. 25, 2014)

[Docket 384], at 103:1–7 (testimony by Dr. Scott Guelcher on the effect "more mesh" has on the body)).

Giving the plaintiffs the "benefit of all inferences," I **FIND** that a reasonable jury could return a verdict in their favor on the failure to warn claim. Duke v. Uniroyal Inc., 928 F.2d 1413, 1417 (4th Cir. 1991). Therefore, Ethicon's Motion on this cause of action is **DENIED**.

c. Negligence

The plaintiffs' negligence claim centered on two theories, negligent design and negligent failure to warn. In its Motion, Ethicon simply argues that the "negligence claim is based on the same facts and duties as the strict-liability design-defect and warning claims and thus fails for the same reasons." (Defs.' Mem. in Supp. [Docket 438], at 17).

Under Illinois law, "the key question in a negligent-design case is whether the manufacturer exercised reasonable care in designing the product." Jablonski v. Ford Motor Co., 955 N.E.2d 1138, 1154 (Ill. 2011). This analysis "is essentially identical" to the risk-utility balancing test used for strict liability claims. Id. at 1155. Indeed, the Supreme Court of Illinois has said that any distinction between the claims of negligent design and strict liability for design defect "is mere semantics." Id. Accordingly, the same reasoning applied to Ethicon's Motion regarding design defect applies to the claim of negligent design, and Ethicon's Motion is **DENIED**. See supra at 5–14.

The difference between strict liability and negligence for a failure to warn claim is slightly more pronounced, the former focusing on the *industry's* knowledge and the latter focusing on the parti*cular defendant's* knowledge. See Werckenthein v. Bucher Petrochemical Co., 618 N.E.2d 902, 908 (Ill. App. Ct. 1993) ("[S]trict liability for failure to warn requires evidence of the industry's knowledge of the product's dangerous propensity, and it turns on the nature of the

product and the adequacy of the warning; negligence focuses on the particular defendant's knowledge and conduct."); see also Baltus v. Weaver Div. of Kidde & Co., 557 N.E.2d 580, 585 (Ill. App. Ct. 1990) (stating that "the distinction between claims in negligence and strict liability lies in the fault concept"). For purposes of Ethicon's Motion, however, the result is the same. The plaintiffs presented sufficient evidence on Ethicon's knowledge of dangerous propensities of the TVT-O and failure to warn about those propensities such that a reasonable jury could conclude that Ethicon was negligent. (See, e.g., Pls.' Ex. 13036 [Docket 412-7], at 1 (notes from a meeting between Ethicon and Professor de Leval held on January 23, 2009, demonstrating Ethicon's knowledge that the "presence of tape in the adductors" can contribute to pain, particularly in "young, active and/or sportive patients")). Accordingly, Ethicon's Motion regarding negligent failure to warn is **DENIED**.

d. Loss of Consortium

The jury awarded $200,000 to Mr. Huskey for his loss of consortium claim, which arose from his wife's claims against Ethicon. (Verdict Form [Docket 402]). Seeing no argument otherwise, I **FIND** that Mr. Huskey's loss of consortium claim survives along with his wife's claims. See, e.g., Blagg v. Ill. F.W.D. Truck & Equip. Co., 572 N.E.2d 920, 924 (Ill. 1991) (explaining that a loss of consortium action is "predicated on the claim of the directly injured spouse," and the basis for recovery "is interference with the continuance of a healthy and happy marriage and injury to the conjugal relation"). Ethicon's Motion on this point is therefore **DENIED**.

e. Preemption

Ethicon's final basis for judgment as a matter of law rests on the doctrine of preemption. In short, Ethicon argues that because the Prolene suture component of the TVT-O has satisfied the

FDA's premarket approval process, the plaintiffs' claims are preempted to the extent they concern mesh degradation. I thoroughly addressed this argument at the summary judgment stage. (See generally Mem. Op. & Order (Mots. for Summ. J.) [Docket 272]). I concluded that "[p]reemption is based on FDA premarket approval of a medical device, not its component parts." (Id. at 22). As a result, the fact that the Prolene suture underwent premarket approval "is irrelevant" to the preemption of claims concerning the TVT-O, which has only received approval under the FDA's less-stringent 510(k) process. (Id.). I see no reason to deviate from this ruling. Therefore, I **ADOPT** it here and **FIND** that preemption is not warranted in this case. Ethicon's Motion based on the doctrine of preemption is **DENIED**.[11]

III. Motion for a New Trial

Having denied Ethicon's Renewed Motion for Judgment as a Matter of Law in its entirety, I now turn to Ethicon's Motion for a New Trial.

A. Legal Standard

Rule 59 allows a court to grant a new trial "for any reason for which a new trial has heretofore been granted in an action at law in federal court." Fed. R. Civ. P. 59(a)(1)(A). The Fourth Circuit has set forth a three-prong standard to govern Rule 59 motions:

> [I]t is the duty of the judge to set aside the verdict and grant a new trial, if he is of the opinion that (1) the verdict is against the clear weight of the evidence, or (2) is based upon evidence which is false, or (3) will result in a miscarriage of justice, even though there may be substantial evidence which would prevent the direction of a verdict.

Atlas Food Sys. & Servs., Inc. v. Crane Nat'l Vendors, Inc., 99 F.3d 587, 594 (4th Cir. 1996) (internal citations and brackets omitted). When considering a motion for a new trial, the "crucial

[11] For additional discussion on this issue, see Bellew v. Ethicon, Inc., No. 2:13-cv-22473, 2014 WL 6674424 (S.D. W. Va. Nov. 24, 2014).

inquiry," particularly when employing the third prong, is "whether an error occurred in the conduct of the trial that was so grievous as to have rendered the trial unfair." Bristol Steel & Iron Works v. Bethlehem Steel Corp., 41 F.3d 182, 186 (4th Cir. 1994) (emphasis added).

The decision to grant or deny a new trial "is within the sound discretion of the trial court." Cline v. Wal-Mart Stores, Inc., 144 F.3d 294, 301 (4th Cir. 1998). Moreover, the discretion bestowed under Rule 59 "should be exercised sparingly." United States v. Arrington, 757 F.2d 1484, 1486 (4th Cir. 1985); see also United States v. Perea, 458 F.2d 535, 536 (10th Cir. 1972) ("A motion for a new trial is generally not regarded with favor, and is granted only with great caution." (emphasis added)). Below, I conclude that Ethicon has fallen far short of clearing the high bar set by Rule 59.

B. Discussion

Ethicon asserts three grounds for a new trial: (1) the jury's findings were against the clear weight of the evidence; (2) the court should have given the jury an instruction based on comment k; and (3) several of the court's evidentiary rulings prejudiced Ethicon.

a. Verdict Against the Clear Weight of the Evidence

When ruling on a motion for a new trial based on the sufficiency of the evidence, the court enjoys "wider" discretion than when ruling on a motion for judgment as a matter of law. McCracken v. Richmond, F. & P. R. Co., 240 F.2d 484, 488 (4th Cir. 1957). In the latter instance, the court must view the evidence in the light most favorable to the non-moving party and resolve any conflict on the non-movant's behalf. If there is substantial evidence in support of the plaintiff's case, the court may not direct a verdict against her, "even though [it] may not believe [her] evidence or may think that the weight of the evidence is on the other side." Id. (quoting Garrison v. United States, 62 F.2d 41, 42 (4th Cir. 1932)). On a motion for a new trial, however, the court

must exercise its "independent judgment after a weighing of all the evidence and any other pertinent factors" and "determin[e] whether the verdict was against the clear weight of the evidence or would result in a miscarriage of justice." Williams v. Nicols, 266 F.2d 389, 393 (4th Cir. 1959). In any event, the court may not "reweigh the evidence and set aside the jury verdict merely because the jury could have redrawn different inferences or conclusions or because judges feel that other results are more reasonable." Lee v. Adrales, 778 F. Supp. 904, 907 (W.D. Va. 1991) (citation omitted); see also 6A J. Moore, *Moore's Federal Practice* ¶ 59.08[5] (stating that the court should "abstain from interfering with the verdict unless it is quite clear that the jury has reached a seriously erroneous result"). Applying this less-stringent standard to the case at bar, I do not believe that Ethicon has made the required showing to warrant a new trial.

First, Ethicon insists that the evidence on the failure to warn claim "conclusively disproved" any causal link between an inadequacy in the TVT-O's IFU and Dr. Byrkit's decision to use the product. (Defs.' Mem. in Supp. [Docket 438], at 19). As the discussion above makes clear, this is not the case. Although Dr. Byrkit testified that she would use the TVT-O again, she also conveyed a lack of awareness about several of the specific risks associated with the TVT-O, including the risks to active women. See supra at 19. Then, she confirmed that had she known of the contraindication for active women, she would not have performed the implantation surgery on Mrs. Huskey. See supra at 16–17. Furthermore, Dr. Byrkit testified to relying on other sources of information in addition to the TVT-O's IFU, not exclusive of it. (See Byrkit Dep. Tr. [Docket 413-20], at 31:15–18 ("Q: What about the Instructions for Use, would you have read the Instructions For Use before you implanted the product? A: Yes.")). While Dr. Byrkit's testimony may be imprecise at times, when considered as a whole, it supports a finding of proximate causation. As a

result, I **FIND** that the jury's verdict on the failure to warn claim is aligned with the clear weight of the evidence.

I reach the same conclusion for the design defect claim and negligence claim. The plaintiffs presented a wide array of expert testimony that demonstrated the high risks of the TVT-O and the injuries that can result from its use. See supra at 9. In addition, the plaintiffs presented compelling evidence indicating that Mrs. Huskey experienced such injuries from certain conditions of the TVT-O. See supra at 13. The jury also heard evidence indicating that Ethicon knew about the risks associated with the TVT-O. See supra at 20–21. Ethicon's proof on the TVT-O's benefits, though also persuasive, was not overwhelming or incontrovertible. Thus, considering the case in its entirety, I do not find the jury's verdict to be erroneous.

Absent such a finding, Ethicon's Motion on this issue must be **DENIED**.

b. Jury Instruction on Comment k

Ethicon next argues that it is entitled to a new trial because the court did not instruct the jury on comment k. A district court is accorded "'much discretion' to fashion the charge" to the jury. Noel v. Artson, 641 F.3d 580, 586 (4th Cir. 2011) (quoting Teague v. Bakker, 35 F.3d 978, 985 (4th Cir. 1994)). The Fourth Circuit Court of Appeals has held that a court abuses its discretion in declining to give an instruction proposed by a party "only when the requested instruction (1) was correct; (2) was not substantially covered by the court's charge to the jury; and (3) dealt with some point in the trial so important, that failure to give the requested instruction seriously impaired that party's ability to make its case." Id. at 586–87 (internal quotation marks omitted).

Above, I found that the principles of comment k are already embodied in Illinois's risk-utility test, which was charged to the jury in this case. See supra at 6. Ethicon disagrees and argues that the court's instruction on the risk-utility test does not cover "the special risk-benefit

considerations that govern prescription-only medical devices like TVT-O." (Defs.' Mem. in Supp. [Docket 438], at 20). Specifically, Ethicon argues, an instruction about comment k was necessary to inform the jury that any inherent risks in the TVT-O do not necessarily make it unreasonably dangerous.

I find that the general risk-utility test can fully and adequately account for a product's "inherent risks."[12] A knife, for example, makes many tasks simpler but can also cause injury. The risk of causing injury is inherent to the knife's design—it would be very difficult, or even impossible, to make a knife that does not cut human skin yet cuts other materials effectively. Similarly, gasoline, which carries the risk of explosion, also has great utility, allowing for efficient transportation of goods and persons. Even a fondue pot has inherent risks. See Rock v. Oster Corp., 810 F. Supp. 665, 667 (D. Md. 1991) (acknowledging the inherent risk of a hot fondue pot being tipped over in application of the risk-utility test). The general risk-utility test works well for these products, allowing the jury to account for their utility as well as their risks, inherent or otherwise. The TVT-O is not unique simply because it is a prescription medical device. Rather, the medical benefits and side effects are factors for the jury to consider in weighing the product's risks against its utility.[13]

[12] In fact, the instruction to the jury specifically directed the jurors to consider the TVT-O's inherent risks of danger. (See Trial Tr. (Sept. 4, 2014) [Docket 428], at 222:1–5).

[13] Ethicon's interpretation of comment k as a remedy to the "clash between medical-malpractice and product-liability law," (Defs.' Mem. in Supp. [Docket 438], at 21–22), is unpersuasive and has no effect on this ruling. Ethicon argues that a product cannot meet the standard of care for physicians—the TVT-O is considered the "gold standard" by some physician groups—and, at the same time, be deemed unreasonably dangerous. But, with a closer look, this seeming conflict is resolved not by comment k but by recognizing the difference between the standard of care for physicians and the standard of care for manufacturers. The former is based on the customs of medical professionals in a particular community. See Dan B. Dobbs et al., 2 The Law of Torts § 292 (2d ed. 2011) ("[T]he 'standard' in medical cases is conceived of as the specific procedure or medical conduct that the relevant medical community considered to be acceptable at the time of the alleged negligence."). The latter turns on conformity with the "design standards of the industry." Anderson v. Hyster Co., 385 N.E.2d 690, 692 (Ill. 1979). Conceivably, therefore, a doctor whose sole wrong was using a product later found to be defectively designed would not be liable for medical malpractice so long as doctors in his or her community also routinely used the product.

The cases Ethicon cites in support of its position are easily distinguishable. In Ortho Pharmaceutical Corp. v. Heath, the Supreme Court of Colorado held that the defendant "was entitled to an instruction based on the comment k defense." 722 P.2d 410, 416 (Colo. 1986), overruled in part on other grounds by Armentrout v. FMC Corp., 842 P.2d 175 (Colo. 1992). This holding makes sense, given that the lower court had also failed to give an instruction on the general risk-utility test, which the Supreme Court of Colorado found to be reversible error. Id. at 415. Mele v. Howmedica, Inc. involved a similar situation. 808 N.E.2d 1026 (Ill. App. Ct. 2004). The Appellate Court of Illinois, First District, held that the lower court should have instructed the jury on the risk-utility test. Id. at 1045–46. It also held that the lower court "erroneously excluded evidence of the product's benefits and risks," which would go to the question of unreasonable dangerousness under the risk-utility test, as well as the comment k defense. Id. at 1042. Unlike these cases, I instructed the jury on the risk-utility test. The jury found that the TVT-O's risks outweigh its utility. A duplicative instruction—not to mention, one that would have reversed the burden onto Ethicon, see Glassman v. Wyeth Labs., Inc., 606 N.E.2d 338, 343 (Ill. App. Ct. 1992)—is unlikely to have changed this outcome.

Because the principles of comment k were substantially covered in the court's instructions on the risk-utility test, there is no cause for a new trial based on the jury charge. Ethicon's Motion on this point is **DENIED**.

c. Evidentiary Rulings

Ethicon's last argument for a new trial concerns this court's evidentiary rulings. The Supreme Court has stated that "alleged substantial errors in admission or rejection of evidence" may warrant a new trial. Montgomery Ward & Co. v. Duncan, 311 U.S. 243, 251 (1940). To succeed on this theory, Ethicon must demonstrate that the alleged evidentiary errors were

"substantial." Id. (emphasis added); see also Creekmore v. Maryview Hosp., 662 F.3d 686, 693 (4th Cir. 2011) (holding that the court will not set aside a judgment on this basis "unless justice so requires or a party's substantial rights are affected"). As explained below, none of Ethicon's arguments—taken individually or together—convey the substantial error required to secure a new trial.

i. Exclusion of FDA Evidence

Ethicon argues that this court's exclusion of the TVT-O's clearance under the FDA's 510(k) process, along with other FDA-related evidence, was prejudicial and entitles Ethicon to a new trial. I have addressed this argument multiple times throughout the course of these MDLs, each time reaching the same conclusion: the modest probative value of such evidence is substantially outweighed by the risk of unfair prejudice, specifically, the risk of confusing and misleading the jury. See, e.g., Cisson v. C. R. Bard, Inc., __ F. Supp. 3d __, at *3–5 (S.D. W. Va. 2015), available at 2015 WL 566959; Lewis v. Johnson & Johnson, 991 F. Supp. 2d 748, 754 (S.D. W. Va. 2014); Sanchez v. Boston Scientific Corp. (Sanchez I), No. 2:12-cv-05762, 2014 WL 4059214, at *15 (S.D. W. Va. Aug. 18, 2014).

Federal Rule of Evidence 401 provides that evidence is relevant if "it has a tendency to make a fact more or less probable than it would be without the evidence." Fed. R. Evid. 401. In light of the Supreme Court's precedent on the meaning and purpose of 510(k), I see little relevance in the fact that the TVT-O was cleared under this regulation. In Medtronic, Inc. v. Lohr, the Supreme Court held that compliance with 510(k) focuses on "equivalence, not safety" and that products entering the market through the 510(k) process have "never been formally reviewed [for] safety or efficacy." 518 U.S. 470, 493 (1996). If 510(k) does not go to a product's safety and efficacy—the "very subjects" of the plaintiffs' products liability claims, Riegel v. Medtronic, Inc.,

552 U.S 312, 322 (2008)—then evidence of Ethicon's compliance with 510(k) has no relevance to the state law claims in this case and was properly excluded by the court. See Fed. R. Evid. 402 ("Irrelevant evidence is not admissible."). In a similar vein, evidence regarding the FDA process that the Prolene suture underwent, which this court excluded, says little about the safety and effectiveness of the final product, the TVT-O. See Lewkut v. Stryker Corp., 724 F. Supp. 2d 648, 656 (S.D. Tex. 2010) ("To require that a distinction be drawn between the approval process of the individual components of a system and the system itself, would, it seems, add a level of complication to the medical device approval process not anticipated by Congress, the FDA, or medical device manufacturers.").

Even if evidence on FDA rules and regulations had some relevance to this case, the balancing test set forth in Federal Rule of Evidence 403 nevertheless forecloses Ethicon's argument in favor of a new trial. Rule 403 provides that a court "may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. In previous cases, I explained how FDA evidence succumbs to this rule:

> Jurors are likely to believe that FDA enforcement relates to the validity of the plaintiffs' state law tort claims, which it does not. [Furthermore,] the jury may attach undue significance to an FDA determination, and [] alleged shortcomings in FDA procedures are not probative to a state law products liability claim.

Lewis, 991 F. Supp. 2d at 754–55 (internal quotations omitted); see also Sanchez v. Boston Scientific Corp. (Sanchez II), No. 2:12-cv-05762, 2014 WL 4851989, at *35 (S.D. W. Va. Sept. 29, 2014) ("[T]estimony about the requirements of the FDCA, which are not at issue in this case, could lead to more confusion about [the state law claims] than enlightenment."). Additionally,

admitting FDA evidence might have provoked the parties to engage in a time-consuming mini-trial on whether Ethicon in fact complied with its regulations. In short, because going down the road of federal regulatory schemes—which do not concern any of the state law claims at issue—would risk confusing and misleading the jury, this court was correct in excluding FDA evidence.

ii. Rulings on Expert Testimony

Ethicon also disputes this court's rulings regarding the testimony of two expert witnesses. First, Ethicon contends that the court improperly overruled objections to Dr. Blaivas's testimony about the risks of mesh devices known to the medical community and about alternative devices used to treat pelvic disorders. I disagree. Dr. Blavias's testimony on pelvic surgeons' general knowledge of risks is not speculative, given that Dr. Blaivas, as a urologist who performs mesh explant surgeries, belongs to that medical community. Moreover, the scope of the medical community's knowledge affects the plaintiffs' failure to warn claim. See Hansen v. Baxter Healthcare Corp., 764 N.E.2d 35, 42 (Ill. 2002) (explaining that "a prescription medical device manufacturer need not provide a warning of risks already known to the medical community."). And Dr. Blaivas's testimony about other medical devices was a proper question for redirect-examination intended to clarify the meaning of the term "gold standard," which Ethicon had raised during cross-examination. See United States v. Wiley, 846 F.2d 150, 156 (2d Cir. 1988) ("Redirect examination may be used to rebut false impressions that arise from cross-examination, . . . and the scope of such an examination is a matter confided to the district court's discretion[.]").

Second, Ethicon argues that the court incorrectly and prejudicially excluded Dr. Pramudji's opinion that Mrs. Huskey may suffer from interstitial cystitis. Prior to trial, I excluded this opinion because it had no support in the record. Mrs. Huskey was never diagnosed with interstitial cystitis, despite having been examined by multiple physicians. (See Mem. Op. & Order (Daubert Mots.)

[Docket 271], at 48–49). Ethicon did not produce any support for such a diagnosis at trial either. Therefore, the court's exclusion of Dr. Pramudji's testimony, which had no reliable basis, was proper under Federal Rule of Evidence 702. See Fed. R. Evid. 702 (allowing expert opinion testimony only if the opinion "is the product of reliable principles and methods").

Whether these evidentiary rulings were correct or not, Ethicon has provided no persuasive argument that they resulted in a miscarriage of justice such that it is entitled to a new trial. Therefore, Ethicon's Motion on this point is **DENIED**.

IV. Conclusion

Ethicon has asked this court to discard the jury's unanimous decision and direct a verdict in its favor pursuant to Rule 50(b), which allows for a directed verdict only if no reasonable jury could find in the plaintiffs' favor. Alternatively, Ethicon has asked for a new trial pursuant to Rule 59, which allows for a do-over only if a grievous error occurred that rendered the trial unfair. Both courses of action require the court to desert the jury's verdict, and consequently, neither should be taken lightly. Indeed, the remedies of a directed verdict or a new trial should be applied only in exceptional circumstances. Ethicon has failed to show that such circumstances exist here. Thus, applying the hesitancy and caution that a district court must employ in these circumstances, I **DENY** Ethicon's Renewed Motion for Judgment as a Matter of Law or, in the Alternative, for a New Trial ("Motion") [Docket 437].

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

ENTER: August 19, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE