UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISVILLE DIVISION

JANNA GARVIN, ET AL.	**PLAINTIFFS**
v.	**No. 3:20-cv-714-BJB**
ETHICON, INC., ET AL.	**DEFENDANTS**

* * * * *

MEMORANDUM OPINION & ORDER

Janna and Michael Garvin sued Ethicon, Inc. and Johnson & Johnson as part of a multi-district litigation consolidated in the Southern District of West Virginia. 2nd Amended Compl. (DN 12) (originally filed in case no. 2:13-cv-19899 (S.D.W. Va.)). Janna Garvin received a TVT-Obturator pelvic mesh implant in February 2011 to treat her stress urinary incontinence. Pl.'s Supp. Fact Sheet (DN 60-1) at 3. After experiencing pain and other medical issues, Garvin underwent three separate surgeries to remove the implant. *Id.* at 4. She alleges product-liability claims based on strict liability, negligence, fraud, and Kentucky's consumer-protection laws for her injuries resulting from the mesh. 2nd Amended Compl. at 4. Her husband, Michael Garvin, seeks to recover for his loss of consortium. *Id.*

After discovery concluded and the dispositive-motions deadline passed, the MDL court transferred the Garvins' lawsuit to this Court. Transfer Order (DN 70). The Defendants, collectively "Ethicon," moved for summary judgment on all claims, DNs 60 & 131, and to exclude testimony from the Garvins' case-specific expert, Dr. Daniel Elliott, DN 62.

Sixteen claims appear on the amended short-form complaint. 2nd Amended Compl. at 4.[1] The Court grants summary judgment to Ethicon on the Garvins' claims for manufacturing defect, strict liability, unjust enrichment, fraudulent concealment, breach of express and implied warranties, and Kentucky Consumer Protection Act. Genuine issues of material fact preclude summary judgment on the other claims.

[1] Although the Complaint lists 18 counts, the final two—"Punitive Damages" and "Discovery Rule and Tolling"—are not stand-alone claims. *See Dalton v. Animas Corp.*, 913 F. Supp. 2d 370, 378 (W.D. Ky. 2012) ("[D]amages are a prayer for relief, not a cause of action."); *Petrey v. Ethicon, Inc.*, No. 5:19-cv-298, 2019 WL 5295185, at *3 (E.D. Ky. Oct. 18, 2019) ("'[D]iscovery rule and tolling' is not a cause of action.").

I. Motions for Summary Judgment

Summary judgment is appropriate when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). The party moving for summary judgment "bears the initial responsibility of informing the district court of the basis for its motion," and must cite evidentiary materials that "demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party meets this burden, the opposing party "must come forward with 'specific facts showing that there is a *genuine issue for trial*.'" *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (quoting FED. R. CIV. P. 56(e)). The existence of "some metaphysical doubt as to the material facts" is insufficient to preclude summary judgment. *Id.* at 586.

Federal courts exercising diversity jurisdiction use "the choice-of-law rules of the forum state … [to] determine what substantive law to apply." *State Farm Mut. Auto. Ins. Co. v. Norcold, Inc.*, 849 F.3d 328, 331 (6th Cir. 2017). Both parties agree that Kentucky law governs these claims. 1st MSJ (DN 61) at 3; 1st Response at 1 n.1. This is correct under Kentucky's "any significant contacts" test, which governs tort claims. *Saleba v. Schrand*, 300 S.W.3d 177, 181 (Ky. 2009). Under that test, the question is simply "whether Kentucky had 'enough' or 'sufficient' contacts to justify applying Kentucky law," not whether the "weighing of interest" would favor Kentucky. *Foster v. Legett*, 484 S.W.2d 827, 829 (Ky. 1972). Kentucky has significant contacts with this case because Janna Garvin was implanted with the TVT-O mesh in Fort Knox, Kentucky. Pl.'s Supp. Fact Sheet at 3. So application of Kentucky law is appropriate. *See Thacker v. Ethicon*, --- F. Supp. 3d ---, No. 5:20-cv-50, 2021 WL 5362076, at *2 (E.D. Ky. Nov. 17, 2021) ("Because Plaintiff, a Kentucky resident, had her implantation surgery in Kentucky, the state with the most significant relationship is Kentucky.").

A. Conceded Claims (Counts II, IV, XV)

The Garvins conceded their claims for manufacturing defect (Count II), strict liability for a defective product (Count IV), and unjust enrichment (Count XV). 1st Response (DN 65) at 1 n.1. Although they have "waived opposition" for those counts, *Scott v. Tennessee*, 878 F.2d 382, *2 (6th Cir. 1989), the Court nevertheless ensures that Ethicon has met its initial burden to prevail on summary judgment for these claims. *Stough v. Mayville Community Schools*, 138 F.3d 612, 614 (6th Cir. 1998).

A manufacturing-defect claim contends that a product is "unreasonably dangerous" because of "an error in the process of manufacture or assembly." *Ford Motor Co. v. McCamish*, 559 S.W.2d 507, 509 (Ky. Ct. App. 1977). To prevail on this claim, a plaintiff must show that "a defective condition attributable to [the manufacturer], existing at the time of delivery … was a proximate cause" of the

plaintiff's injuries. *Briner v. Gen. Motors Corp.*, 461 S.W.2d 99, 103 (Ky. 1970). Ethicon correctly asserts that the Garvins cannot prevail because they have produced "no evidence or expert opinion that the product received by Ms. Garvin deviated from an objective standard or from Ethicon's specifications" or that a deviation "caused injury to Ms. Garvin." 1st MSJ at 7.

Next, Ethicon contends that Kentucky law doesn't recognize a general strict-liability claim for a defective product. *Id.* at 8. Instead, as explained below, plaintiffs wishing to pursue strict-liability claims based on product defects must specify the source of the defect—which could be a manufacturing defect, a defective design, or a failure to warn. *See Edwards v. Hop Sin, Inc.*, 140 S.W.3d 13, 15 (Ky. Ct. App. 2003). So the Garvins' freestanding strict-liability claim fails. To be clear, this doesn't affect their specific products-liability claims—failure to warn and defective design—considered below.

As to unjust enrichment, this claim has three elements: "(1) benefit conferred upon defendant at plaintiff's expense; (2) a resulting appreciation of benefit by defendant; and (3) inequitable retention of benefit without payment for its value." *Jones v. Sparks*, 297 S.W.3d 73, 78 (Ky. Ct. App. 2009). For the retention of the benefit to be "inequitable," Kentucky courts require a showing of bad faith. *See Union Central Life Ins. Co. v. Glasscock*, 110 S.W.2d 681, 685 (Ky. 1937); *Jim Huff Realty v. Tomlin Properties*, No. 2005-ca-2245, 2007 WL 1452596, at *3 (Ky. Ct. App. May 18, 2007). And the plaintiff bears the burden of making a prima facie case of bad faith. *Jim Huff Realty*, 2007 WL 1452596, at *3. Because Ethicon is right that the Garvins haven't made this showing, 1st MSJ at 10, summary judgment to Ethicon is appropriate.

B. Strict Liability – Failure to Warn (Count III).

Under Kentucky law, a plaintiff may bring a strict-liability claim against a manufacturer for a product that is "in a defective condition unreasonably dangerous to the user or consumer or to his property." *Worldwide Equip., Inc. v. Mullins*, 11 S.W.3d 50, 55 (Ky. Ct. App. 1999) (quoting RESTATEMENT (SECOND) OF TORTS § 402A (1965)). A product can be defective in any of three ways: (1) manufacturing defects that deviate from the product's design, (2) defects in the intended design, and (3) products rendered defective by an inadequate warning. *See Edwards*, 140 S.W.3d at 15. A failure-to-warn claim contends that the product is "unreasonably dangerous" because of an unobvious danger that merits a warning. *Ulrich v. Kasco Abrasives Co.*, 532 S.W.2d 197, 200 (Ky. 1976).

But the inadequate warning is merely "one of the factors determining whether the product is unreasonably dangerous," i*d.*, and the factfinder's overall consideration is whether "an ordinarily prudent company … being fully aware of the risk, would not have put it on the market." *Nichols v. Union Underwear Co., Inc.*, 602 S.W.2d

429, 433 (Ky. 1980). And unlike a negligence claim, a strict liability claim doesn't require a showing that "the seller/manufacturer knew or should have known of the defect." *Mullins*, 11 S.W.3d at 56. Instead, "the seller is presumed to have knowledge of the actual condition." *Nichols*, 602 S.W.2d at 433.

To prevail on a failure-to-warn claim, plaintiffs must show (1) a duty to warn, (2) inadequate warnings, and (3) proximate causation. *Stewart v. Gen. Motors Corp.*, 102 F. App'x 961, 964 (6th Cir. 2004). Kentucky applies the "substantial factor test" for proximate causation, which asks whether "the defendant's conduct [was] a substantial factor in bringing about [the] plaintiff's harm." *Morales v. Am. Honda Motor Co., Inc.*, 71 F.3d 531, 537 (6th Cir. 1995). Causation boils down to a question of law when "only one conclusion may reasonably be drawn from the evidence" but is otherwise a question of fact for the jury. *Pathways, Inc. v. Hammons*, 113 S.W.3d 85, 92 (Ky. 2003) (quoting *McCoy v. Carter*, 323 S.W.2d 210, 215 (Ky. 1959)). And under the learned-intermediary rule, which Kentucky has adopted, "providing an adequate warning to the prescribing physician relieves the manufacturer of its duty to warn the patient regardless of how or if the physician warns the patient." *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 765 (Ky. 2004).

Proximate causation is the only disputed prong for this claim, and it's genuinely disputed such that summary judgment would be inappropriate: the Garvins have identified evidence in the record to counter Ethicon's. Janna Garvin admitted that she didn't "go and research" the TVT-O mesh and instead relied "100 percent" on her implanting physician, Dr. Virginia Stokes. J. Garvin Depo. (DN 131-2) at 137. Did Dr. Stokes in turn rely on Ethicon's product information? Some deposition testimony suggests no, as Ethicon contends. When asked if she "rel[ied] on information from Ethicon and J&J … about the risks and benefits," Dr. Stokes replied in the negative and explained she "relied on [her] own self-education." Stokes Depo. (DN 126-1) at 26–27. Dr. Stokes stood by her original recommendation, even with the knowledge that she since gained. *Id.* at 84, 146–47. And had the product contained warnings that about the possibility of pain, inability to have sexual intercourse, and the need for revision surgeries, Dr. Stokes explained she would still focus on "the Green Journal articles," which stated that "the incidents of these adverse reactions is fairly small." *Id.* at 73–74. Finally, Dr. Stokes agreed with the characterization that the TVT-O mesh and similar products "remain a leading option and current gold standard for stress urinary incontinence surgery." *Id.* at 134.

But Dr. Stokes also testified that she relied on Ethicon's representation that "complications with [pelvic mesh devices] were 'extremely low'" when comparing between alternatives. *Id.* at 39. The information she received omitted warnings about "acute and/or chronic pain," "pain with intercourse, which in some patients, may not resolve," "[n]euromuscular problems," and the need for revision surgeries. *Id.* at 71–73. She "had no reason to believe that the TVT-O decision put Ms. Garvin at risk for permanent pain," but "would have at least considered" that in her "risk

benefit analysis." *Id.* at 67. And she would have respected Ms. Garvin's decision had Ms. Garvin "declined the product because of those risks." *Id.* at 71. Although Dr. Stokes believed "the incidents of these adverse reactions [was] fairly small" based on her literature review, she also "would have changed [her] mind" if "Ethicon knew [those risks] and they were not telling people." *Id.* at 73–74. So a genuine dispute exists regarding proximate causation because a reasonable jury could find that an inadequate warning was a substantial factor in the Garvins' injuries given the evidence that Dr. Stokes would have reacted differently with adequate warnings. *See Sexton v. Ethicon*, No. 5:20-cv-282, 2021 WL 4138399, at *4 (E.D. Ky. Sept. 10, 2021) (denying summary judgment to defendant because physician testified that "additional risks may have been helpful to know" and receiving "misleading information from Ethicon … would have influenced his decision"). Accordingly, the Court denies summary judgment on this claim.

C. Strict Liability – Design Defect (Count V)

A design-defect claim asserts that a product's intended design is defective. *Edwards*, 140 S.W.3d at 15. Rather than just criticize the defendant's design, however, the plaintiff must offer "proof of a feasible alternative design" to show that the design is defective. *Toyota Motor Corp. v. Gregory*, 136 S.W.3d 35, 42 (Ky. 2004). And that design must be "safer," meaning that it would prevent the plaintiff's injuries. *Id.* Expert testimony is required if "a proper understanding … requires scientific or specialized knowledge and … cannot be determined intelligently from testimony on the basis of ordinary knowledge." *Commonwealth v. Robbins*, 421 S.W.2d 820, 824 (Ky. 1967). Mere "hypothetica[l]" alternative designs are insufficient; an alternative must be "feasible." *Burgett v. Troy-Bilt LLC*, 579 F. App'x 372, 378–79 (6th Cir. 2014). And an alternative design "must be properly analogous to the product at issue." *Thacker*, 2021 WL 5362076, at *7.

Ethicon contends that the Garvins cannot show a feasible alternative design. 1st MSJ at 4–7. Their expert reports and deposition transcripts identify many alternative designs. 1st Response at 5–6. All their non-surgical and non-mesh designs (such as "behavior modification [and] pelvic floor therapy," *id.* at 6), however, fail as alternatives because they aren't analogous to TVT-O, a surgical, mesh product. *See Burton v. Ethicon Inc.*, No. 5: 20-cv-280, 2021 WL 1725514, at *2 (E.D. Ky. Apr. 30, 2021) ("evidence of surgical procedures not involving mesh has no bearing on the existence of a safer alternative design"); *Thacker*, 2021 WL 5362076, at *7 (same).

But the Garvins have identified at least two alternatives that preclude summary judgment: (1) mesh with lighter weight and more distance between mesh fibers, such as the Ultrapro mesh, and (2) mesh with sealed borders or seams. 1st Response at 6. Dr. Uwe Klinge submitted an expert report explaining the advantages of lightweight mesh with greater distance between the fibers. *See* Klinge Report

(DN 65-4) at 7–15 (discussing foreign body reactions, weight, and pore size).[2] Dr. Klinge explains that implantation of mesh products triggers an "inflammatory process … known as a foreign body reaction." *Id.* at 7. This reaction can become "chronic (permanent) … in a woman's pelvic tissue," meaning that "the woman's body will react to the polypropylene indefinitely." *Id.* at 9. Heavier mesh "increases the risk of injury" because it has a greater surface area which leads to a greater foreign body reaction and inflammatory response. *Id.* at 11. Smaller pores increase the risk because scar tissue may envelop the pores completely, which "leaves no space for further tissue ingrowth and leads to a number of complications including loss of elasticity and pain associated with the rigidity, shrinkage or contraction of the mesh." *Id.* at 11. Dr. Klinge identifies Ethicon's Ultrapro mesh as an example of a product that would be safer than the TVT-O because it is lighter and has larger pores. *Id.* at 36. And it was possible to make meshes like this "by the late 1990's and early 2000's," according to Dr. Klinge, because "the technology of surgical meshes had evolved." *Id.* at 3. This meets all the requirements to qualify as an alternative to TVT-O: evidence that Ultrapro is feasible, safer, and a mesh product. *See Sexton*, 2021 WL 4138399, at *6 (accepting Ultrapro as an alternative).

Ethicon concedes that Ultrapro would "satisfy the 'same product' requirement," but maintains the Garvins haven't offered evidence that it "would have 'prevented the injury.'" 1st Reply (DN 68) at 5. This ignores the opinions offered in earlier sections of the Klinge Report that explain why a lightweight mesh with large pores would reduce the foreign body reaction and loss of elasticity that results in long-term pain. *See* Klinge Report at 7–15. And "sharp pain" and "severe and chronic pelvic pain" are among the injuries Janna Garvin complains of. 1st Response at 2. An alternative, furthermore, needn't prevent an injury entirely; it only must be "safer." *Toyota Motor Corp.*, 136 S.W.3d at 42. Because the Garvins identified evidence of a feasible and safer alternative, summary judgment on this claim is inappropriate.

D. Negligence (Count I) and Gross Negligence (Count XIV)

A negligence claim under Kentucky law has four elements: "(1) a legally-cognizable duty, (2) a breach of that duty, (3) causation linking the breach to an injury, and (4) damages." *Patton v. Bickford*, 529 S.W.3d 717, 729 (Ky. 2016)." Gross negligence requires those four factors and "something more than the failure to exercise slight care" and must involve "malice or willfulness or such an utter and wanton disregard of the rights of others as from which it may be assumed the act was malicious or willful." *City of Middlesboro v. Brown*, 63 S.W.3d 179, 181 (Ky. 2001) (quoting *Cooper v. Barth*, 464 S.W.2d 233, 234 (Ky. 1971)). Kentucky law allows

[2] The Defendants moved to exclude Dr. Klinge's testimony while this case was before the MDL judge. *See In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12–md–2327, 2014 WL 186872, at *5–9 (S.D.W. Va. Jan. 15, 2014). The MDL court found that Dr. Klinge could "testify generally about polypropylene's tendency to degrade, fray, or lose particles and its effect on the human body" in addition to "effective porosity and pore deformation." *Id.* at *7. All the opinions discussed in this section fall within those categories.

plaintiffs to bring defective-design claims "under either a theory of negligence or strict liability." *Ostendorf v. Clark Equip. Co.*, 122 S.W.3d 530, 535 (Ky. 2003).

Ethicon raises only one argument against these claims: that the negligence claim should be dismissed as "duplicative of [Janna Garvin's] strict liability design defect and manufacturing defect claims." 1st MSJ at 9. So it follows, in Ethicon's view, that the gross-negligence claim should be dismissed for the same reason. *Id.* at 1 n.1. But a negligence claim is *not* duplicative of a strict-liability claim. Certainly, some overlap exists between the two, but as the Kentucky Supreme Court explained, "[t]he difference is that negligence depends on what a prudent manufacturer … by the exercise of ordinary care actually should have discovered and foreseen, whereas strict liability depends on what he would have anticipated had he been (but regardless of whether he actually was or should have been) aware of the condition of and potentialities inhering in the product when he put it on the market." *Ulrich*, 532 S.W.2d at 200. While a court reviewing these claims may engage in a similar analysis for each, that partial overlap is not a basis for dismissal, and Ethicon hasn't identified any precedents supporting its view that a products-liability plaintiff cannot also bring a negligence and strict-liability claim. Since Kentucky law allows plaintiffs to maintain both claims, the Court denies summary judgment on them because Ethicon hasn't met its burden to demonstrate its entitlement "to judgment as a matter of law." FED. R. CIV. P. 56(a); *see, e.g.*, *Ostendorf*, 122 S.W.3d at 532 (affirming Court of Appeals, "which reversed the summary judgment on the strict liability and negligent design claims" in favor of the plaintiff).

E. Fraud (Count VI), Constructive Fraud (Count VIII), and Negligent Misrepresentation (Count IX)

Common to all three claims is the requirement of a material misrepresentation, so the Court considers them in tandem. *See Nash-Finch Co. v. Casey's Foods, Inc.*, 762 F. App'x 218, 225 (6th Cir. 2018) (dismissing fraud in the inducement, constructive fraud, and negligent misrepresentation claims for failure to show a material misrepresentation).

- *Fraud*, under Kentucky law, has six elements: "(1) material misrepresentation by the defendant; (2) falsehood; (3) making of a statement known to be false; (4) to induce action by the plaintiff; (5) reliance by the plaintiff; and (6) injury to the plaintiff." *Snowden v. City of Wilmore*, 412 S.W.3d 195, 209 n.10 (Ky. Ct. App. 2013) (enumeration added).
- *Constructive fraud*, by contrast, "arises from the breach of a legal duty which the law would pronounce fraudulent because of its tendency to deceive others, violate confidence, or injure public interest." *Kendrick v. Bailey Vault Co.*, 944 S.W.2d 147, 150 (Ky. Ct. App. 1997).
- *Negligent misrepresentation* regarding a defective product is described in the Third Restatement, which Kentucky has adopted: "One engaged in the business of selling or otherwise distributing products who, in

> connection with the sale of a product, makes a fraudulent, negligent, or innocent misrepresentation of material fact concerning the product is subject to liability for harm to persons or property caused by the misrepresentation." *Giddings & Lewis, Inc. v. Indus. Risk Insurers*, 348 S.W.3d 729, 746 n.11 (Ky. 2011) (quoting RESTATEMENT (THIRD) OF TORTS § 9).

All three require an "[a]ctionable misrepresentation," which according to the Kentucky Court of Appeals, "must relate to a past or present material fact which is likely to affect the conduct of a reasonable man." *McHargue v. Fayette Coal & Feed Co.*, 283 S.W.2d 170, 172 (Ky. 1955). An "opinion or prediction," in contrast, is not actionable. *Id.* Ethicon disputes that the Garvins have actually established a false statement, *see*, *e.g.*, 2nd Reply (DN 140) at 11–13, but did not move for summary judgment on falsity grounds, moving instead on reliance and materiality grounds.

The parties agree that Janna Garvin didn't rely on any representations from Ethicon. *See* 2nd Resp. (DN 136) at 14; 2nd MSJ (DN 131) at 13. Instead, the Garvins contend that Ethicon made two false representations to Dr. Stokes: (1) that TVT-O "withstood the test of time" and (2) that "the risk of complications was 'extremely low.'" 2nd Resp. at 14–15 (quotations omitted). Ethicon argues neither qualifies as an actionable "material misrepresentation" because the plaintiff must receive the misrepresentation in some form, and it's undisputed that only Dr. Stokes read Ethicon's product information. Alternatively, in Ethicon's view, Dr. Stokes didn't rely on these representations. 2nd MSJ at 12–14.

Even assuming that a misrepresentation made to the treating physician could be the basis of a fraud claim, the Garvins cannot recover because of the learned-intermediary rule. *See Corder*, 473 F. Supp. 3d at 762–63 (applying the rule to fraud-based claims). Ethicon didn't make the statement that TVT-O "withstood the test of time." Instead, Dr. Stokes read that in "the Green Journals and Gray Journals," which contained "a lot of studies … that represent this information." Stokes Depo. at 36:5–10; 2nd Resp. at 15 (quoting Stokes Depo. at 36:5–10). Under any of these fraud theories, the Garvins cannot recover for misrepresentations made by an unaffiliated third party.

The second purported misrepresentation about the "extremely low" risk of complications fares better. The Garvins have identified evidence in the record creating a dispute regarding the materiality of that statement and Dr. Stokes's reliance. She testified that the product warnings omitted any discussion of "acute and/or chronic pain," "pain with intercourse, which in some patients, may not resolve," "[n]euromuscular problems," and the need for revision surgeries. Stokes Depo. at 71–73. As discussed earlier, Dr. Stokes wasn't aware of the "risk for permanent pain" and testified she "would have at least considered" that in determining whether to use TVT-O. *Id.* at 67. While evidence certainly shows Dr. Stokes used her own judgment in surveying the literature and assessing the risk, *see id.* at 40, this testimony also indicates the alleged misrepresentation concerning the

likelihood of risk was material to her treatment decision and that she relied on the statement. So a genuine dispute of material fact exists regarding whether the misrepresentation was material and the extent of Dr. Stokes's reliance. This precludes summary judgment to Ethicon on these claims.

F. Fraudulent Concealment (Count VII)

Fraudulent concealment, also known as fraud by omission, requires proof that "(1) the defendant had a duty to disclose the material fact at issue; (2) the defendant failed to disclose the fact; (3) the defendant's failure to disclose the material fact induced the plaintiff to act; and (4) the plaintiff suffered actual damages as a consequence." *Giddings*, 348 S.W.3d at 747. Unlike the fraud-based claims discussed above, this claim requires proof of a material *omission* instead of a material *misrepresentation*. Ethicon contends this claim fails because the Garvins cannot show any omission or inducement to act by the failure to disclose. And the Garvins "waived opposition" on this claim by failing to respond to Ethicon's arguments. Given the lack of any identified evidence indicating an omission or inducement to act, summary judgment in Ethicon's favor is appropriate. *See Scott*, 878 F.2d at *2.

G.Negligent Infliction of Emotional Distress (Count X)

A claim for negligent infliction of emotional distress requires meeting the traditional elements of a negligence action: "(1) the defendant owed a duty of care to the plaintiff, (2) breach of that duty, (3) injury to the plaintiff, and (4) legal causation between the defendant's breach and the plaintiff's injury." *Osborne v. Keeney*, 399 S.W.3d 1, 17 (Ky. 2012). But recovery is limited to "severe or serious emotional injury" which "occurs where a reasonable person, normally constituted, would not be expected to endure the mental stress engendered by the circumstances of the case." *Id.* (internal quotation marks omitted). This ordinarily requires distress that "significantly" affects the plaintiff's "everyday life or require[s] significant treatment." *Id.* Plaintiffs must present "expert medical or scientific proof" to sustain these claims. *Ind. Ins. Co. v. Demetre*, 527 S.W.3d 12, 39 (Ky. 2017).

This claim fails, in Ethicon's view, for failure to provide expert testimony or show a "psychological injury." 1st MSJ at 9; 1st Reply at 7. But neither reason is availing. The Garvins *do* provide expert testimony to support their claims: Dr. Elliott's expert report opined that "complete resolution of [Ms. Garvin's] pelvic pain" was "high unlikely, even with aggressive physical therapy and biofeedback." Elliott Case-Specific Report (DN 62-1) at 45.[3] The resulting "lack of physical intimacy ha[d] already cost Ms. Garvin a major component to her quality of life." *Id.* And under Kentucky caselaw, suffering that derives from physical as opposed to psychological injury may still qualify as a type of emotional distress. *See Demetre*, 527 S.W.3d at 38–39 (classifying "emotional pain and suffering, stress, worry, anxiety, or mental

[3] Ethicon's motion to exclude portions of Dr. Elliott's testimony (DN 63) doesn't affect this analysis because Ethicon didn't seek exclusion of testimony regarding Janna Garvin's current symptoms.

anguish" within category of emotional-distress damages). Ethicon's view that courts cannot consider emotional pain resulting from a physical injury in analyzing NIED claims, moreover, stands in some tension with Kentucky's former rule as well, which *required* physical impact to bring a stand-alone emotional distress claim in the first place. *See Osborne*, 399 S.W.3d at 16–18 (explaining and rescinding impact rule for emotional-distress claims). The Court accordingly denies summary judgment on this claim.

H. Breach of Express & Implied Warranties (Counts XI & XII)

A seller's "affirmation of fact or promise," "description of the goods," or any "sample or model" can constitute an express warranty if made "part of the basis of the bargain." KRS § 355.2-313(1). An implied warranty, on the other hand, "may arise from course of dealing or usage of trade," KRS § 355.2-314(3), or arise by statute, *e.g.*, KRS §§ 355.2-314 (merchantability); 355.2-315 (fitness for particular purpose). Regardless of whether the alleged warranty is express or implied, the plaintiff must be in privity with the seller, a "natural person … in the family or household of [the] buyer," or a guest who could reasonably be expected to "use, consume or be affected by the goods." KRS § 355.2-318; *see Bridgefield Cas. Ins. Co., Inc. v. Yamaha Motor Mfg. Corp. of Am.*, 385 S.W.3d 430, 434 (Ky. Ct. App. 2012).

The Garvins concede that Janna Garvin wasn't in privity with Ethicon and doesn't fit into the third-party categories of § 355.2-318. 1st Resp. at 10. This is correct: she didn't buy the TVT-O implant and isn't a member or guest in the household of a person who did. Instead, the Garvins rely on a narrow purported exception to the privity requirement based on a decision by another judge in this district. *Id.* That decision held that a plaintiff could sue a manufacturer absent privity "where the manufacturer has expressly made warranties directly to the intended consumer of the product." *Levin v. Trex Co., Inc.*, No. 3:10-cv-692, 2012 WL 7832713, at *3 (W.D. Ky. Mar. 5, 2012); *see also Naiser v. Unilever U.S., Inc.*, 975 F. Supp. 2d 727, 740 (W.D. Ky. 2013) (applying *Levin* to sustain breach-of-express-warranty claim based on warranties "clearly intended for the product's consumers"). But neither of the Garvins' breach of warranty claims fit into those narrow exceptions recognized in *Levin* and *Naiser*.

In *Levin v. Trex Company*, the plaintiff purchased allegedly defective decking material manufactured by the defendant and sued for breach of express and implied warranties. 2012 WL 7832713, at *1. To circumvent the privity requirement that would otherwise bar his claim, the plaintiff argued that "privity was created by Defendant's warranty issued directly to the 'individual residential homeowners.'" *Id.* (quoting 1st amended complaint). The court, venturing an *Erie* guess, reasoned that "Kentucky courts would hold that an express warranty action could be maintained in this case" because "the manufacturer's written warranty expressly stated that its warranty ran directly to the intended consumer." *Id.* at *3. The *Naiser* court extended *Levin*'s reasoning to reach cases where the warranty didn't explicitly

identify the end consumer but "was certainly intended for those who would purchase and use [the product]." 975 F. Supp. 2d at 740.

The Garvins haven't identified any express or implied warranties that Ethicon explicitly directed to or "certainly intended" for them. *Id.* Indeed, Janna Garvin's deposition testimony indicates that she didn't research TVT-O implants, relied entirely on Dr. Stokes's judgment, and didn't identify any patient-facing materials that could give rise to such warranties. J. Garvin Depo. at 137. Because the Garvins lack privity, they don't fall into the class of people recognized in § 355.2-318's protection; nor do they fall within the scope of *Naiser* or *Levin*. So the Court grants summary judgment to Ethicon on the breach of express and implied warranty claims.

I. Kentucky Consumer Protection Laws (Count XIII)

The Kentucky Consumer Protection Act prohibits "[u]nfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce." KRS § 367.170(1). To bring a claim, a plaintiff must have privity of contract or a warranty from the seller. *Skilcraft Sheetmetal, Inc. v. Ky. Machinery, Inc.*, 836 S.W.2d 907, 909 (Ky. Ct. App. 1992) ("[A] subsequent purchaser may not maintain an action against a seller with whom he did not deal or who made no warranty for the benefit of the subsequent purchaser."). "Any person bringing an action" under the KCPA must do so "within one (1) year after any action of the Attorney General has been terminated or within two (2) years after the violation of KRS 367.170, whichever is later." KRS § 367.220(5).

Ethicon asserts this claim fails because the Garvins lack privity or a warranty and because the statute of limitations bars the claim. 1st MSJ at 13–15. The Garvins again rely on *Naiser* to argue that a lack of privity doesn't defeat the claim. 1st Resp. at 11 (citing 975 F. Supp. 2d at 740). But the reasons that Janna Garvin doesn't meet the exception remain the same: the Garvins haven't shown a warranty explicitly directed or intended for the end consumer. This claim too fails for lack of privity or warranty. Given that, the Court doesn't reach Ethicon's separate argument based on the statute of limitations.

J. Loss of Consortium (Count XVI)

Kentucky law allows a spouse to "recover damages against a third person for loss of consortium." KRS § 411.145(2). Ethicon's only argument against recovery is that the Garvins cannot recover on this "derivative" claim if Ethicon prevails on all the other claims. 2nd MSJ at 14. Because at least some claims survive, this claim does too.

*** * ***

In sum, the Court denies summary judgment with respect to the claims of negligence, gross negligence, failure to warn, design defect, fraud, constructive fraud, negligent misrepresentation, negligent infliction of emotional distress, and loss of consortium. The Court grants summary judgment to Ethicon on the claims regarding

a manufacturing defect, strict liability, unjust enrichment, fraudulent concealment, breach of express and implied warranties, and Kentucky Consumer Protection Act violation.

II. Motion to Exclude

Ethicon also moved to exclude both the general and case-specific opinions that Dr. Elliott offered. Case-Specific Motion to Exclude (DN 63) at 1. Dr. Elliott submitted an expert report opining that TVT-O mesh shouldn't be used in the pelvic floor and that Ethicon failed to disclose or consider numerous associated risks. Elliott Case-Specific Report at 4. His report also includes case-specific testimony on Mrs. Garvin's medical history and prognosis, parts of which Ethicon doesn't challenge. *Id.* at 35–46. In Ethicon's view, Dr. Elliott is unqualified to offer these opinions, which rest on unreliable methods, and which wouldn't help the jury. *Id.* at 1–2.

Under Federal Rule of Evidence 702, "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise" so long as the testimony satisfies four requirements:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

FED. R. EVID. 702. Trial judges must ensure that expert testimony is relevant and reliable. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993). That is a "flexible" inquiry, *id.* at 594, which affords trial judges "considerable leeway," *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

The Sixth Circuit has interpreted the *Daubert* line of cases and Rule 702 as interposing a three-part requirement: (1) "the witness must be qualified by knowledge, skill, experience, training, or education;" (2) "the testimony must be relevant, meaning that it will assist the trier of fact;" and (3) "the testimony must be reliable," as measured by the sufficiency of its factual basis and the reliability of its methods. *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 528–29 (6th Cir. 2008) (quotation omitted). The proponent of the expert testimony bears the burden of establishing that the testimony meets those requirements by a preponderance of the evidence. *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000).

A. General Opinions

Ethicon challenges these non-case-specific opinions of Dr. Elliott: (1) that TVT Devices are unsafe for surgical treatment of stress urinary incontinence, (2) the duties a device manufacturer owes, (3) polypropylene mesh is carcinogenic, (4) opinions on product warnings, (5) procedures not involving synthetic mesh that are safer alternatives, and (6) the features that render alternatives safer. *See generally* Case-Specific Motion at 1; Wave 10 Motion to Exclude (DN 73-5); Wave 3 Motion to Exclude (DN 72-9).[4] Because the arguments against these opinions differ, the Court takes them up in turn.

1. TVT Devices are unsafe in surgical treatment. The only basis on which Ethicon challenges this opinion is that Dr. Elliott published an article in 2019 that purportedly contradicts statements made in his expert report. Wave 10 Motion at 2–4. This is not a ground to exclude testimony, however, and cross-examination will be the appropriate vehicle to challenge testimony as inconsistent with past statements. *See, e.g.*, *Logan v. Cooper Tire & Rubber Co.*, No. 10-cv-3, 2012 WL 169985, at *2 (E.D. Ky. Jan. 19, 2012) ("Any conflict Cooper Tire contends exists between Cottles' deposition testimony and his Affidavit can be fleshed out during cross-examination."); *Ellerbee v. Ethicon, Inc.*, No. 8:20-cv-1514, 2021 WL 2010641, at *2 (M.D. Fla. May 20, 2021) ("Any alleged inconsistences between his current opinions and the opinions of the article are better addressed through cross-examination than exclusion.").

2. Duties of device manufacturers. Ethicon challenges Dr. Elliott's opinions with respect to research and testing, adverse-event reporting, and physician training on qualification and reliability grounds. Wave 10 Motion at 4–10. *Daubert*'s qualification prong requires courts to determine whether "the nature and extent of that experience" allows an expert to "offer an opinion on a particular subject." *United States v. Cunningham*, 679 F.3d 355, 379 (6th Cir. 2012). An expert can be qualified by "knowledge, skill, experience, training, or education." FED. R. EVID. 702. And testimony is reliable if it is "based upon sufficient facts or data," a "product of reliable principles and methods," and if the expert reliably applied those methods. *In re Scrap Metal Antitrust Litig.*, 527 F.3d at 529 (quotation omitted).

[4] For their arguments on Dr. Elliott's general opinions, both parties directed the Court to the filings for Wave 11 of the MDL. *E.g.*, Motion to Exclude at 1 ("With respect to these general opinions, Defendants adopt the Motion to Exclude … filed in Wave 11."). For the Wave 11 cases, the parties simply adopted their Wave 10 filings, instead of filing new briefs. *See* DNs 73-10, 73-11 (adopting Wave 10 motion to exclude and Wave 10 response for Wave 11 cases). Because the captions for these filings indicate that they're related to Wave 10, the Court refers to them as Wave 10 rather than Wave 11 briefing in hopes (however naive) of minimizing confusion.

a) *Research and testing.* Dr. Elliott offers testimony related to Ethicon's research and development of TVT-O, but the Garvins haven't explained what qualifies him to opine that "when safety issues arose, Ethicon did not conduct testing." Resp. to Wave 3 Motion (DN 72-10) at 14; *Hosbrook v. Ethicon, Inc.*, 2022 WL 136740, at *7 (S.D. Ohio Jan. 12, 2022) ("Dr. Elliott has no experience as a manufacturer in the research and testing of a medical product and Plaintiff's argument that his review of Ethicon's internal documents on testing permit him to opine on this subject is without merit."). Dr. Elliott formed this opinion from a "review of the literature and internal Ethicon documents." Resp. to Wave 3 Motion at 13. While these documents needn't be admissible for Dr. Elliott's opinion to be, Federal Rule of Evidence 703 requires the Court to first conclude that "experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion." And the Garvins haven't shown that doctors generally are qualified to assess product testing, that Dr. Elliott in particular is qualified to do so, or that reviewing external literature and internal corporate documents is a "sound methodology" for determining if testing was appropriate. *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 675 (6th Cir. 2010). Hearing Dr. Elliott opine on internal documents that neither party has characterized as overly complex, moreover, would not necessarily help the jurors, who are "capable of reading that document itself." *Edwards v. Ethicon, Inc.*, No. 2:12–cv–9972, 2014 WL 3361923, at *10 (S.D.W. Va. July 8, 2014). The Court accordingly excludes Dr. Elliott's opinions regarding research and testing on qualification and reliability grounds.

b) *Adverse event reporting.* It's unclear if Dr. Elliott would offer testimony on adverse events generally or on specific ones Ethicon had to report in connection with this case. Ethicon's Wave 10 Motion cites only the Prolift Report, and Prolift is a different product than TVT-O. Wave 10 Motion at 8. To the extent that the Garvins would offer Dr. Elliott's testimony on adverse-event reporting, Judge Goodwin already excluded "opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations." Order regarding Daniel Elliott (DN 72-7) at 11.[5] That decision governs the admission of those opinions absent a showing of extraordinary circumstances, so the Court excludes them. *In re Air Crash Disaster*, 86 F.3d 498, 539 (6th Cir. 1996) ("Under the law of the case doctrine, rulings made at one point in a litigation can become operative law for subsequent portions of the litigation.").

c) *Physician training.* The Wave 10 briefing refers only to Dr. Elliott's Prolift and TVT Secur Reports in seeking to exclude these opinions. Dr. Elliott's report in

[5] In its Wave 10 Motion, Ethicon refers only to adverse-event reporting in connection with the FDA. Wave 10 Motion at 8–9. To the extent Dr. Elliott offers other opinions related to adverse-event reporting beyond those addressed by Judge Goodwin, Ethicon may separately challenge those opinions in a properly presented motion.

this case makes no mention of physician training and the Garvins assert claims only for TVT-O. The Court assumes this briefing is inapplicable to the Garvins' case and denies the motion regarding this opinion without prejudice to re-raising it in a case-specific challenge.

In sum, the Court excludes Dr. Elliott's general opinions related to the duties of device manufacturers, except with respect to physician training, which doesn't appear to be at issue in this case.

3. Polypropylene mesh is carcinogenic. Dr. Elliott opines that "Ethicon should have informed physicians (and therefore patients) that the MSDS ["material safety data sheet"] for its polypropylene noted a risk of carcinogenicity with the use of the plastic." Elliott General Report (DN 73-1, Exhibit D) at 36. Ethicon asserts this opinion is irrelevant and "highly inflammatory" because Janna Garvin hasn't developed cancer. Wave 10 Motion at 10. Relevance is a low bar to meet: "Evidence is relevant if it has *any* tendency to make a fact more or less probable than it would be without the evidence; and the fact is of consequence in determining the action." FED. R. EVID. 401 (emphasis added). And in determining relevancy, trial courts cannot "consider the weight or sufficiency of the evidence." *Robinson v. Runyon*, 149 F.3d 507, 512 (6th Cir. 1998). Even relevant evidence can be excluded, however, "if its probative value is substantially outweighed by a danger of … unfair prejudice." FED. R. EVID. 403. Although Rule 401 requires only some probative value for evidence to be relevant, "the upshot is that evidence that is only slightly probative is more susceptible to exclusion under rule 403." *Jones v. Wiseman*, 838 F. App'x 942, 949 (6th Cir. 2020).

The little probative value of this testimony is "substantially outweighed" by the risk of unfair prejudice. FED. R. EVID. 403. The Garvins assert this testimony is relevant to their failure-to-warn claim because the fact that "implantation of polypropylene led to local sarcomas in lab rats … was never provided to physicians." Resp. to Wave 10 (DN 73-6) at 6. A failure-to-warn claim, as explained above, requires (1) a duty to warn, (2) inadequate warnings, and (3) proximate causation. *Stewart*, 102 F. App'x at 964. Nothing indicates that Janna Garvin currently has or is likely to develop cancer. *See* Elliott Case-Specific Report at 36 (summarizing Mrs. Garvin's past medical history), 37–44 (recapitulating medical history in detail). How an inadequate warning on cancer risk could be a "substantial factor" in bringing about Mrs. Garvin's non-cancerous injuries is unclear. *Morales*, 71 F.3d at 537. And introducing testimony on the carcinogenic properties of this type of mesh poses obvious confusion and prejudice. *See Jackson v. Johns-Manville Sales Corp.*, 750 F.2d 1314, 1321 (5th Cir. 1985) ("danger of unfair prejudice outweighed [the] probative value" for cancer evidence if introduced to show liability). In light of the low probative value and high likelihood of unfair prejudice, the Court excludes this opinion.

4. Product warnings. Dr. Elliott states in his report that "the TVT-O fails to disclose numerous adverse risks," including "[d]eath, pain, chronic pelvic pain, permanent dyspareunia, permanent sexual dysfunction, injury and pain to partner during sexual intercourse, negative impact on sexual function, vagina anatomic distortion, inability to remove the device, permanent risks for erosions, surgical interventions, development of worsening incontinence and urinary dysfunction." Elliott Case-Specific Report at 30–31. He opines the failure to include these known risks "makes the TVT defective." *Id.* at 31. Ethicon concedes that Dr. Elliott "may testify about the specific risk of implanting mesh and whether those risks appeared on the relevant IFU [instructions for use]," but asks the Court to exclude testimony about what *should have* been included in the IFU. Wave 10 Motion at 11 (quotation omitted).

The MDL court held that "an expert who is a urologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU," but he must "possess additional expertise to offer expert testimony about what information should or should not be included in an IFU." Wave 7 Opinion (DN 72-22) at 2. Because "Dr. Elliott does not possess the additional expertise to offer expert testimony about what an IFU should or should not include," Judge Goodwin excluded his testimony on that matter. *Id.*

Courts generally will not "revisit prior decisions … in the absence of extraordinary circumstances such as where the initial decision was clearly erroneous and would work a manifest injustice." *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 817 (1988) (quotation omitted). The Garvins request reconsideration of the MDL ruling "due to Dr. Elliott's extensive experience in the testing and development of medical devices and training of residents with regard to IFUs." Resp. to Wave 10 Motion at 9. They note that Dr. Elliott has researched similar issues, designed his own medical device related to male urinary incontinence, and owns a patent. *Id.* at 10. But the Garvins don't explain how any of these experiences qualify Dr. Elliott to testify regarding what should be included in an IFU or undermine the MDL court's finding that Dr. Elliott lacks experience in drafting IFUs. Nothing in this record suggests that following the MDL court's ruling would be clearly erroneous. *See Burton*, 2020 WL 5809992, at *3 (declining to revisit ruling where plaintiff didn't show MDL ruling was clearly erroneous). Accordingly, the Court excludes testimony on what should be included in an IFU, but permits Dr. Elliott to testify regarding specific risks and whether they were included in the IFU.

5. Non-mesh alternatives. Dr. Elliott's report identifies a number of purported alternatives to TVT-O, including non-surgical treatments and products that don't have mesh. Elliott Case-Specific Report at 5–8. This list includes "behavior modification," "medication," and "pessaries," a "non-surgical approach to the treatment of stress incontinence." *Id.* at 6. An "alternative" used to prove a design

defect under Kentucky law "must be properly analogous to the product at issue." *Thacker*, 2021 WL 5362076, at *7. Non-mesh alternatives, as explained above in section I.C, are not analogous to TVT-O, which is a *mesh* product. So the Court excludes testimony on non-mesh alternatives as irrelevant and potentially confusing. *See In re Scrap Metal Antitrust Litig.*, 527 F.3d at 528–29 (evidence must be relevant, "meaning that it will assist the trier of fact") (quotation omitted).

6. Features that would lead to safer alternatives. Dr. Elliott opines that "heavyweight, small pore meshes are associated with excessive foreign body reaction, chronic inflammation, bridging fibrosis, scar plate formation, and consequential shrinkage of the mesh." Elliott Case-Specific Report at 15. Cutting the mesh mechanically instead of with lasers additionally increases "fraying" which can "lead to increased urinary retention, erosions, extrusions and exposures of the mesh into vaginal tissues, and particles of the mesh migrating into surrounding vaginal tissues causing pain." *Id.* at 20. Dr. Elliott formed these opinions based on reviewing studies, clinical data, and Ethicon's own documents. *Id.* at 15–19. Ethicon objects to these opinions as unreliable because Dr. Elliott "has not conducted studies" himself and "has never treated a patient for SUI [stress urinary incontinence] … with a lighter weight, larger pore mesh." Wave 3 Motion at 7–8.

The MDL court previous reserved judgment on the reliability of Dr. Elliott's testimony regarding pore size and mesh weight, but granted Ethicon's motion and excluded Dr. Elliott's testimony that laser cut mesh is safer. Wave 7 Opinion at 9–10. Because the Garvins haven't asked the Court to revisit the ruling on laser-cut versus mechanically cut mesh, the Court follows Judge Goodwin's ruling for the MDL. *See* Resp. to Wave 10 Motion at 18. So the only issue remaining is the reliability of the proposed testimony on pore size and mesh weight.

An expert's testimony must be "the product of reliable principles and methods" and must "reliably appl[y] the principles and methods to the facts of the case." FED. R. EVID. 702(c)–(d). Trial courts must ensure that an expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co., Ltd.*, 526 U.S. at 152. To that end, a challenge to reliability requires determining "whether the reasoning or methodology underlying the testimony is scientifically valid and … whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93.

"[L]eading medical literature and [the expert's] extensive professional experience" can provide a "solid foundation" for expert testimony. *Clark v. W&M Kraft, Inc.*, 476 F. App'x 612, 617 (6th Cir. 2012) (quoting *Glaser v. Thompson Med. Co., Inc.*, 32 F.3d 969, 972 (6th Cir. 1994)). Ethicon takes issue with Dr. Elliott's extrapolation of studies involving hernia treatment and prolapse to treatment of

stress urinary incontinence, but Rule 702 doesn't require "this type of specificity." *Dixon v. Grand Trunk W. R.R. Co.*, 259 F. Supp. 3d 702, 708 (E.D. Mich. 2016) (rejecting argument that experts couldn't rely on general studies about the risks associated with tasks similar—but not identical—to those at issue). And "[c]ourts have admitted expert testimony as reliable where experts extrapolate their opinions from their knowledge and experience combined with a review of relevant scientific literature." *In re Heparin Prods. Liability Litig.*, 803 F. Supp. 2d 712, 738 (N.D. Ohio 2011).

Nowhere do the Rules of Evidence require an expert to have personally conducted the studies he relies on. Nor do the Rules forbid extrapolation from existing data. These are common sources and methods that physicians use to reach medical decisions. *Clark*, 476 F. App'x at 617. Given that Dr. Elliott reached his conclusions based on his experience and education, informed by the existing literature, the Court allows his testimony on the impact of pore size and mesh weight.

B. Case-Specific Opinions

Ethicon challenges only two case-specific opinions.

First, Dr. Elliott would testify that "Ms. Garvin was not able to make a fully informed medical decision regarding the implantation of the TVT-O polypropylene mesh because Ethicon failed to fully disclose the risks, complications (both early and late), and the consequences thereof, in Ethicon's Instructions for Use." Elliott Case-Specific Report at 45. Ethicon takes issue with the latter part of the statement relating to undisclosed risks and objects on qualification and relevance grounds. Case-Specific Motion at 2–3. Neither warrants exclusion. The Court's ruling on general product-warning opinions applies with equal force here: Dr. Elliott may testify to specific risks of implantation and whether those risks appeared in the IFU, but he may not testify to what information *should* be included in an IFU. *See above* at subsection II.A.4; Wave 7 Opinion at 2. And these opinions remain relevant because a genuine dispute exists regarding whether additional warnings would have changed Dr. Stokes's decision. *See above* at subsection I.B.

Second, Dr. Elliott opines that Janna Garvin is "unlikely to ever regain the benefit of physical intimacy again in her life" absent a reduction in her symptoms and may experience "long-term negative impact leading to feelings of isolation, loneliness, depression and suicide." Elliott Case-Specific Report at 45. Dr. Elliott cites two studies to support his opinion. *Id.* In Ethicon's view, this opinion is excludable because Kentucky law requires future conditions to be "probable"—instead of merely possible—and because the opinion is unreliable. Case-Specific Motion at 4.

Kentucky law permits compensation for "the increased likelihood of future complications" where "substantial evidence of probative value" supports that

likelihood. *Davis v. Graviss*, 672 S.W.2d 928, 932 (Ky. 1984), *overruled on other grounds*. Juries may consider expert testimony in awarding compensation for "future physical pain and mental suffering … and, if there is evidence to support it, for future medical expenses." *Cap. Holding Corp. v. Bailey*, 873 S.W.2d 187, 195 (Ky. 1994). As part of the damages determination, juries "should take into consideration the degree of the likelihood of future harm" and "apportion damages" accordingly. *Id.* While the juries may consider the degree of harm in determining *damages*, they must still find that "causation is probable and not merely possible" in order to hold a defendant *liable* for those injuries in the first place. *Davis*, 672 S.W.2d at 932; *see also Kemper v. Gordon*, 272 S.W.3d 146, 151 (Ky. 2008) ("Psychiatric evidence established that this [future] mental anguish was a probability, not a mere chance.").

Dr. Elliott's opinions satisfy the Kentucky standard for compensable future damages. His opinions on Garvin's future conditions rest on his medical education, experience, review of the medical literature, and a physical examination of Garvin. Elliott Case-Specific Report at 45. He testified that he holds these opinions "with a high degree of medical certainty." *Id.* The Kentucky Supreme Court has held that a medical doctor's testimony about future medical treatment was "sufficiently probative to support an award for future medical expenses." *Cincinnati Ins. Co. v. Samples*, 192 S.W.3d 311, 318 (Ky. 2006); *see also Sexton*, 2021 WL 4138399, at *10 (Kentucky law permits medical expert's testimony on "future damages").

And these opinions aren't unduly speculative. Expert testimony needn't "be 'known' to a certainty" in order to be admissible. *Daubert*, 509 U.S. at 590. Instead, reliability demands only that "the opinion has a reasonable factual basis." *United States v. L.E. Cooke Co., Inc.*, 991 F.2d 336, 342 (6th Cir. 1993). Dr. Elliott prognosticates, based on his examination of Janna Garvin's current symptoms, that she will be unable to engage in physical intimacy and draws on the medical literature to determine other long-term implications of Garvin's condition. Elliott Case-Specific Report at 45. This is a reliable methodology for a doctor to use to diagnose a patient. *Dickenson v. Cardiac & Thoracic Surgery of E. Tenn.*, 388 F.3d 976, 982 (6th Cir. 2004) (doctor may rely on "extensive relevant experience"); *Gass v. Marriott Hotel Servs., Inc.*, 558 F.3d 419, 428 (6th Cir. 2009) ("professional education or experience" qualify doctors to testify on diagnoses). Like a sister court has found, Dr. Elliott's opinion "rests on a 'reliable foundation'" and is admissible. *Orr v. Ethicon, Inc.*, No. 2:20-cv-110, 2020 WL 9073528, at *11 (E.D. Tenn. Sept. 11, 2020) (quoting *In re Scrap Metal Antitrust Litig.*, 527 F.3d at 530).

* * *

To recap, the Court grants Ethicon's motion in part and excludes only the following testimony:

a. research and testing regarding manufacturer duties;

b. adverse event reporting;
c. carcinogenic nature of polypropylene mesh;
d. general content of an IFU;
e. non-mesh alternatives; and
f. the safety of laser-cut mesh relative to mechanically cut mesh.

And the Court denies Ethicon's motion with respect to the following:

a. the safety of TVT devices in surgical treatment;
b. the safety of alternative products with larger pores and lightweight mesh;
c. risks that were not disclosed in Ethicon's IFU for TVT-O; and
d. Janna Garvin's future conditions.

ORDER

The Court grants in part and denies in part Ethicon's motions for summary judgment (DNs 60 & 131) and Ethicon's motion to exclude (DN 62).

Benjamin Beaton, District Judge
United States District Court

July 22, 2022