UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION at LEXINGTON

CHASTITY SEXTON,	)	
	)	
Plaintiff,	)	Civil Case No.
	)	5:20-cv-282
v.	)	
	)	
ETHICON, INC. and JOHNSON & JOHNSON,	)	**MEMORANDUM OPINION AND ORDER**
	)	
Defendants.	)	

***

Plaintiff Chastity Sexton filed suit against Defendants Ethicon, Inc. and Johnson and Johnson (collectively "Ethicon") alleging several claims arising out of the surgical implantation of a product, the TVT-Exact, manufactured by Ethicon to treat female stress urinary incontinence. [DE 1]. Before the Court are Ethicon's Motion for Partial Summary Judgment [DE 32], Motion to Limit the Case-Specific Opinions and Testimony of Bruce Rosenzweig, M.D [DE 34], and Supplemental Motion for Summary Judgment [DE 69]. For the reasons set forth below, Ethicon's Motion for Partial Summary Judgment [DE 32], Motion to Limit the Case-Specific Opinions and Testimony of Bruce Rosenzweig, M.D [DE 34], and Supplemental Motion for Summary Judgment [DE 69] will be granted in part and denied in part.

I. BACKGROUND

This matter was originally part of MDL 2327, 2:12-md-2327, a multidistrict litigation involving pelvic repair system products, and later transferred to this Court by the United States District Court for the Southern District of West Virginia. [DE 56]. This case involves surgical mesh products manufactured and sold by Ethicon to treat female stress urinary incontinence. The device at issue is Ethicon's TVT-Exact, which was implanted in Plaintiff. The TVT-Exact is a pelvic mesh device that is intended to provide support to the urethra.

Prior to transfer, Ethicon filed a Motion for Partial Summary Judgment [DE 32] on most but not all of Sexton's substantive claims. [DE 32; DE 33]. Ethicon also filed a Motion to Limit the Case-Specific Opinions and Testimony of Bruce Rosenzweig, M.D [DE 34]. After transfer, Ethicon filed a Motion for Leave to File Supplemental Dispositive Motion Based on the Legal Insufficiency of Plaintiff's Sole Case-Specific Expert [DE 65] seeking leave to file a proposed Supplemental Motion for Summary Judgment [DE 65-8] moving for summary judgment on Plaintiff's remaining claims, which the Court granted, [DE 68]. If the Court were to grant Ethicon's still pending Motion for Partial Summary Judgment [DE 32] and Supplemental Motion for Summary Judgment [DE 69], this case would be disposed of in its entirety.

II. DISCUSSION

A. SUMMARY JUDGMENT

"The court shall grant summary judgment if 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). "A genuine dispute exists on a material fact, and thus summary judgment is improper, if the evidence shows 'that a reasonable jury could return a verdict for the nonmoving party.'" *Olinger v. Corporation of the President of the Church*, 521 F. Supp. 2d 577, 582 (E.D. Ky. 2007) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986)). Stated another way, "[t]he mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff." *Anderson*, 477 U.S. at 252. "The central issue is 'whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.'" *Pennington*, 553 F.3d at 450 (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52 (1986).

The moving party has the initial burden of demonstrating the basis for its motion and identifying those parts of the record that establish the absence of a genuine issue of material fact. *Chao v. Hall Holding Co., Inc.*, 285 F.3d 415, 424 (6th Cir. 2002). The movant may satisfy its burden by showing "that there is an

absence of evidence to support the non-moving party's case." *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). Once the movant has satisfied this burden, the non-moving party must go beyond the pleadings and come forward with specific facts demonstrating the existence of a genuine issue for trial. Fed. R. Civ. P. 56; *Hall Holding*, 285 F.3d at 424 (citing *Celotex*, 477 U.S. at 324). Moreover, "the nonmoving party must do more than show there is some metaphysical doubt as to the material fact. It must present significant probative evidence in support of its opposition to the motion for summary judgment." *Hall Holding*, 285 F.3d at 424 (internal citations omitted).

The Court "must construe the evidence and draw all reasonable inferences in favor of the nonmoving party." *Pennington v. State Farm Mut. Automobile Ins. Co.*, 553 F.3d 447, 450 (6th Cir. 2009) (citing *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986)). However, the Court is under no duty to "search the entire record to establish that it is bereft of a genuine issue of material fact." *In re Morris*, 260 F.3d 654, 655 (6th Cir. 2001). Rather, "the nonmoving party has an affirmative duty to direct the court's attention to those specific portions of the record upon which it seeks to rely to create a genuine issue of material fact." *Id.*

1. MOTION FOR PARTIAL SUMMARY JUDGMENT

Ethicon moves for summary judgment on the following claims:

> negligence (to the extent it is based on negligent failure to warn or negligent manufacturing defect)(Count I); strict liability-manufacturing defect (Count II); strict liability-failure to warn (Count III); strict-liability-defective product (Count IV); common law fraud (Count VI); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent misrepresentation (Count IX); negligent infliction of emotional distress (to the extent based on negligent failure to warn or negligent manufacturing defect) (Count X); breach of express warranty (Count XI); breach of implied warrant (Count XII); violation of consumer protection laws (Count XIII); gross negligence (to the extent based on negligent failure to warn or negligent manufacturing defect) (Count XIV); and unjust enrichment (Count XV).

[DE 32, at 1]. In response to Ethicon's Motion for Partial Summary Judgment [DE 32], Sexton concedes her claims for strict liability-manufacturing defect (Count II), strict liability-defective product (Count IV), and breach of express (Count XI) and implied warranty (Count XII) fail and argues, "Counts I, III, V, IX, X, XIII, XIV, XV, XVII, and XVIII should proceed to trial." [DE 36, at 1]. The Motion [DE 32] will be granted with respect to the conceded claims. Additionally, Plaintiff's claims for punitive damages (Count XVII) and discovery rule and tolling (Count XVIII) are not separate causes of action under Kentucky law and must be dismissed. *Cutter v. Ethicon, Inc.*, No. CV 5:19-443-DCR, 2020 WL 109809, at *10 (E.D. Ky. Jan. 9, 2020) (citations omitted) ("A claim for punitive damages is not a separate cause of action, but a remedy potentially available for another cause of action."); *id.* (citing *Petrey v. Ethicon, Inc.*, No. 5: 19-298-DCR, 2019 WL

5295185, at *3 (E.D. Ky. Oct. 18, 2019) ("Discovery rule and tolling" is not a separate cause of action under Kentucky law.)).

Plaintiff does not dispute that Kentucky substantive law applies in this case, [DE 36, at 2], so the Court will not undertake an independent choice-of-law analysis. *Ashbrook v. Ethicon Inc.*, 514 F. Supp. 3d 971, 974 (E.D. Ky. 2021) (citing *Gahafer v. Ford Motor Co.*, 328 F.3d 859, 861 (6th Cir. 2003)).

a. FAILURE TO WARN

To survive summary judgment on her failure to warn claims, Plaintiff must provide evidence that shows Ethicon (1) had a duty to warn; (2) the warnings given were inadequate; and (3) the inadequate warnings were the proximate cause of her injuries. *See Manuel v. Traditional Sporting Goods, Inc.*, No. 5:09-cv-406, 2011 WL 6091710, at * 6 (E.D. Ky. Dec. 7, 2011) (citing *Stewart v. General Motors,* 102 F. App'x 961, 964 (6th Cir. 2004)). Kentucky applies the learned intermediary doctrine, meaning that "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) (citation omitted). Ethicon argues Plaintiff cannot prove causation. [DE 33, at 5-7]. "'[U]nder Kentucky law, causation or proximate cause is defined by the substantial factor test: was the defendant's conduct a substantial factor in bringing about plaintiff's harm?'" *Cutter,* 2020 WL

109809, at *10 (quoting *Morales v. American Honda Motor Co. Inc.*, 71 F.3d 531, 537 (6th Cir. 1995)). "'Causation is an element which may be proved by circumstantial evidence, and in that situation the evidence must be sufficient to tilt the balance from possibility to probability.'" *Id.*

Here, Ethicon cites several cases where summary judgment was granted because Plaintiff presented no evidence that their physician either relied on or reviewed a manufacturer's warning. [DE 33, at 6 (citing *Logan v. Cooper tire & Rubber Co.*, No. 10-cv-303-KSF, 2011 WL 2471374, at *3 (E.D. Ky. 2011)), n.1 (citing *Lewis v. Johnson & Johnson*, 601 F. App'x 205, 208 (4th Cir. 2015) ("When a physician relies on her own experience and examination of a patient in deciding to prescribe a device, and not on the device's warning, the warning is not the cause of the patient's injury."); *Felan v. Bos. Sci. Corp.*, No. 2:12-cv-08384, 2015 WL 2137180, at *4 (S.D. W. Va. May 7, 2015); *Jones v. C.R. Bard, Inc.*, No. 2:11-cv-114, 2013 WL 5591948, at *6 (S.D. W. Va. June 4, 2013))]. However, as Ethicon admits, the implanting physician in this case, Dr. Voss, read the Instructions for Use ("IFU") and relied on it in part. [DE 33, at 7]. Ethicon discounts Dr. Voss's review of the IFU because he "did not rely upon it to be the sole source of information when learning of the risks of the TVT Exact surgery," *id.*, but whether the IFU was Dr. Voss's sole source of information is inconsequential. Instead, the relevant inquiry is

whether Dr. Voss relied on the IFU. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736, 742 (S.D. W. Va. 2014) (finding that a physician who reviewed the IFU but could not recall when they last reviewed it was distinguishable from *Lewis v. Johnson & Johnson*, wherein the physician testified they did not rely on the IFU). There is sufficient evidence that Dr. Voss relied on the IFU.

Ethicon briefly discusses its alternative argument that Plaintiff has failed to show that different or additional warnings from Ethicon would have changed Dr. Voss decision to recommend the TVT Exact to Plaintiff. [DE 33, at 6-7 (citing *Clark v. Danek Med., Inc.*, No. 3:94-cv-634-H, 1999 WL 613316, at *6 (W.D. Ky. Mar. 29, 1999) (finding that a plaintiff must "show some evidence from which a jury might conclude that an adequate warning would have altered the conduct that led to the injury")). The Parties disagree whether Plaintiff is required to prove that Dr. Voss would have acted differently if he received more information from Ethicon. However, like the Court in *Huskey*, this Court need not determine whether such a requirement exists because Plaintiff has shown evidence that Dr. Voss may have acted differently had he been given more information or if he learned the information provided in the IFU was inaccurate. *See Huskey*, 29 F. Supp. 3d at 743 n.3 ("I need not resolve this issue here because the plaintiffs presented evidence demonstrating that Dr. Byrkit would have acted differently.").

In *Huskey*, Ethicon argued the physician would not have changed her decision to prescribe TVT-O had Ethicon provided a better warning. *Huskey*, 29 F. Supp. 3d at 743. The *Huskey* court found the physician's testimony was inconsistent. Specifically, the physician testified that she didn't think she would have implanted TVT-O if she were told it should not have been implanted in fit, active women, like the plaintiff, but she later testified she would use TVT-O again in a patient with the same signs and symptoms as the plaintiff and continued to use TVT-O in her practice. *Id*. The *Huskey* court concluded the conflicting testimony demonstrated the existence of a genuine dispute of fact on the issue of causation.

Like it did in *Huskey*, Ethicon argues Dr. Voss would not have changed his decision to recommend TVT-Exact had Ethicon provided a better warning, asserting, "Dr. Voss testified that even with a revision of the wording in the IFU, he still would have used TVT Exact with Ms. Sexton as long as information was not withheld relating to an increased percentage of adverse effects." [DE 33, at 7]. Ethicon further asserts that Dr. Voss still stands by his decision to use TVT-Exact and continues to use it in his practice. *Id*. However, Plaintiff presents Dr. Voss's testimony showing that he was under the assumption the information Ethicon provided him was accurate, that he identified additional risks found in Ethicon's IFU after Plaintiff's procedure that were not present in the IFU prior to the procedure, that the additional risks may have

been helpful to know, and that if he, in fact, received misleading information from Ethicon, that would have influenced his decision to use their product. *See* [DE 36, at 7-8]. At minimum, Plaintiff has presented enough evidence to create a genuine dispute of material fact on the issue of causation, and Ethicon's request for summary judgment on Plaintiff's failure to warn claims will be denied.

b. FRAUD AND WARRANTY

Ethicon argues Plaintiff's claims for common law fraud (Count VI), fraudulent concealment (Count VII), constructive fraud (Count VIII), negligent misrepresentation (Count IX), and violation of consumer protection laws (Count XIII) should be dismissed because they are duplicative of Plaintiff's failure to warn claims. [DE 33, at 8]. Ethicon further argues that even if Plaintiff's fraud claims (Counts VI, VII, VIII, and IX) are not dismissed as duplicative, they should fail as a matter of law due to lack of reliance. *Id.* at 9. While Plaintiff contests Ethicon's arguments concerning violation of consumer protection laws (Count XIII), namely the Kentucky Consumer Protection Act ("KCPA"), she does not argue her claims for common law fraud (Count VI), fraudulent concealment (Count VII), and constructive fraud (Count VIII) should proceed to trial. *See* [DE 36, at 1]. She does assert that her claim for negligent misrepresentation (Count IX) should proceed to trial, but she fails to either elaborate why the claim

should proceed to trial or contest Ethicon's arguments for why negligent misrepresentation should be dismissed as a claim. Accordingly, the Court will grant Ethicon's Motion [DE 32], insofar as it pertains to Plaintiff's claims for common law fraud (Count VI), fraudulent concealment (Count VII), constructive fraud (Count VIII), and negligent misrepresentation (Count IX), and consider whether Plaintiff's KCPA claim (Count XIII) can survive summary judgment.

i. KENTUCKY CONSUMER PROTECTIONS ACT

Ethicon asks the Court to dismiss Plaintiff's KCPA claim for several reasons. However, the Court will not address each of Ethicon's arguments for dismissal individually because the need for dismissal of Plaintiff's KCPA claim is clear. The KCPA states, "Unfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful." K.R.S. § 367.170. "A private cause of action exists for '[a]ny person who purchases . . . goods . . . primarily for personal, family or household purposes and thereby suffers any ascertainable loss of money or property, real or personal' as a result of a violation of the statute." *Burton v. Ethicon Inc.*, No. 5:20-cv-280-DCR, 2020 WL 5809992, at *8 (E.D. Ky. Sept. 29, 2020); *see also* K.R.S. § 367.220.

Here, Plaintiff's KCPA claim must be dismissed because there is no privity of contract between Plaintiff and Ethicon. Plaintiff

argues the subsequent purchaser exception found in *Bosch v. Bayer Healthcare Pharmaceuticals*, 13 F. Supp. 3d 730, 751 (W.D. Ky. 2014) and *Naiser v. Unilever U.S. Inc.*, 975 F. Supp. 2d 727, 743 (W.D. Ky.) applies. [DE 36, at 10 (citations omitted)]. However, as the Honorable Danny C. Reeves, Chief United States District Judge for the Eastern District of Kentucky, found in *Burton*, no judges in this district have adopted the exception created in *Naiser*. *Burton*, 2020 WL 5809992, at *8. Like Judge Reeves, the undersigned will also decline to apply the exception created in *Naiser*. Moreover, the Court further agrees with Judge Reeves's finding that a device used by a physician during surgery is unlikely to constitute a consumer product as defined by the KCPA. *Id*. Accordingly, the Court will grant Ethicon's request to dismiss Plaintiff's KCPA claim (Count XIII).

c. UNJUST ENRICHMENT

Ethicon argues Plaintiff's claim for unjust enrichment (Count XV) should be dismissed because "Plaintiff's allegations sound in tort, rather than contract or quasi-contract, and she cannot prove that Ethicon inequitably retained a benefit conferred by her." [DE 33]. Plaintiff contends Ethicon's conclusory argument fails to meet its burden under *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986).

"Upon filing a motion for summary judgment, the moving party has the initial burden of establishing that there are no issues of

material fact regarding an essential element of the non-moving party's claim." *Burton*, 2020 WL 5809992, at * 9 (citing *Moldowan v. City of Warren*, 578 F.3d 351, 374 (6th Cir. 2009)). "This is not accomplished by 'emphatic say-so' or conclusory allegations that the plaintiff has no evidence to prove her claim." *Id.* (citing *Sideridraulic Sys. SpA v. Briese Schffahrts GmbH & Co. KG*, No. 10-715, 2011 WL 3204521, at *2 n.3 (S.D. Ala. July 26, 2011)). "Instead, the movant must demonstrate that the available evidence establishes that there is no genuine issue of material fact." *Id.* (citing *Dobrowski v. Jay Dee Contractors, Inc.*, 571 F.3d 551, 554 (6th Cir. 2009); *Hem v. Toyota Motor Manuf.*, 09-CV-888, 2010 WL 11434981 (D. N.M. Dec. 12, 2010)). "The movant may fulfill this burden by making 'reference to materials on file,' and by pointing out the absence of specific facts that are required for the success of the plaintiff's claim." *Id.* (citing *Corder v. Ethicon, Inc.*, 473 F. Supp. 3d 749, 771 (E.D. Ky. 2020)).

Here, Ethicon's fails to meet its burden by only offering a conclusory argument, so the Court will deny its Motion [DE 33], insofar as it pertains to Plaintiff's claim for unjust enrichment (Count XV).

2. SUPPLEMENTAL MOTION FOR SUMMARY JUDGMENT

In its Supplemental Motion [DE 69], Ethicon argues, "Plaintiff's sole case-specific expert, Dr. Bruce Rosenzweig, does not offer the opinions Plaintiff needs to establish a prima facie

case on her claims for design defect and negligent infliction of emotional distress." The Court will consider Plaintiff's claims for design defects and negligent infliction of emotional distress ("NIED") in turn.

a. DESIGN DEFECTS

"'Kentucky applies a risk-utility test in design defect cases.'" *Burgett v. Troy-Bilt LLC*, 579 F. App'x 372, 378 (6th Cir. 2014) (quoting *Toyota Motor Corp. v. Gregory*, 136 S.W.3d 35, 42 (Ky. 2004)). The test is "whether an ordinarily prudent company being fully aware of the risk, would not have put the product on the market." *Id.* "'[D]esign defect liability requires proof of a feasible alternative design.'" *Id.*; *see also Owens v. Ethicon, Inc.*, 2020 WL 1976642, at *3 (E.D. Ky. Apr. 24, 2020) (citing *Bosch v. Bayer Healthcare Pharm., Inc.*, 13 F. Supp. 3d 730, 742 (W.D. Ky. 2014)); *Burton*, 2020 WL 5809992, at *4. Not only must the alternative design be feasible, but it must also be safer, *Low v. Lowe's Home Centers, Inc.*, 771 F. Supp. 2d 739, 741 (E.D. Ky. 2011) (citing *Gregory*, 136 S.W.3d at 42), and have been able to prevent the injury, *Cummins v. Bic USA, Inc.*, 835 F. Supp. 2d 322, 326 (W.D. Ky. 2011) (citing *Gregory*, 136. S.W.3d at 42). "[T]he onus is on Plaintiffs to provide expert testimony setting forth 'competent evidence of some practicable, feasible, safer, alternative design.'" *Estate of Bigham v. DaimlerChrysler Corp.*,

462 F. Supp. 2d 766, 773 (E.D. Ky. 2006) (citing *Gray v. General Motors Corp.*, 133 F. Supp. 2d 530, 535 (E.D. Ky. 2001)).

Here, Plaintiff contends Dr. Rosenzweig's testimony shows three feasible and safer alternatives, namely "a mesh sling with less polypropylene, such as Ultrapro; a mesh sling made with PVDF material[, such as Dynamesh]; and biologic slings that do not use mesh[, such as Repliform]." [DE 70, at 2 (citing [DE 70-1, at 18]), 8]. Courts considering the use of biologic slings, or similar products and procedures that do not use mesh, have found that such products and procedures fail to show a feasible, safer alternative design because they are not, in fact, alternative designs to mesh products. *See Burton*, 2020 WL 5809992, at * 4-5; *Owens*, 2020 WL 1976642, at *3-4; *Burris v. Ethicon, Inc.*, No. 3:20-cv-1450, 2021 WL 3190747, at *5-9 (N.D. Ohio July 28, 2021). This Court agrees and will find Plaintiff's design defect claims, insofar as they pertain to biologic slings, fail because she has not shown proof of a feasible, safer alternative design that would have prevented her injuries.

Regarding products such as Ultrapro and those using PVDF material, Ethicon argues Plaintiff cannot show that such products are a feasible, safer alternative because they have not been approved by the FDA for use in a mesh sling. [DE 69-1, at 8-11]. While that may be the case, Ethicon fails to cite any authority requiring FDA approval for a product to be a feasible, safer

alternative. Moreover, this argument has been rejected in both *Bell v. Ethicon, Inc.*, No. 4:20-CV-3678, 2021 WL 1111071, at *7 (S.D. Texas Mar. 23, 2021) and the MDL court, *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2327, 2020 WL 1060970, at *3 (S.D.W. Va. Feb. 13, 2020); *Bellew v. Ethicon, Inc.*, No. 2:13-CV-22473, 2014 WL 12685965, at *6 (S.D.W. Va. Nov. 20, 2014).

The Court also finds Ethicon's arguments that Dr. Rosenzweig's lack of certainty about Ultrapro as an alternative and Ethicon's previous abandonment of a project utilizing a sling with a mesh that was like Ultrapro after the FDA initially refused clearance render products like Ultrapro to be infeasible alternatives to be unavailing. Likewise, the Court finds Ethicon's argument that Ultrapro is not a feasible, safer alternative simply because it also contains polypropylene mesh to be lacking. It is arguable that less polypropylene mesh could have resulted in less harm to Plaintiff than that found in the product used in her treatment. The test is whether there was a *safer* design alternative that would have prevented Plaintiff's injuries not whether there was a design alternative that eliminated all risks with absolute certainty. Less polypropylene mesh may have prevented, or at least lessened, Plaintiff's injuries. Ethicon may cross-examine Dr. Rosenzweig at trial about the feasibility and safety concerns of products that are not FDA approved and whether less polypropylene

mesh would have been safer and introduce evidence regarding the denial of its past product, but the Court will deny its Supplemental Motion [DE 69], insofar as it pertains to products with less polypropylene, such as Ultrapro, and those using PVDF material, as a genuine dispute of material fact exists regarding their use as alternatives to the TVT-Exact.

b. NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

In addition to Ethicon's argument that Dr. Rosenzweig's testimony is insufficient to establish a NIED claim, Ethicon argues Plaintiff's NIED claim (Count X) should be dismissed because "NIED is a 'gap-filler' tort under Kentucky law and does not constitute a stand-alone claim when it is based on the same factual allegations and evidence as the plaintiff's traditional tort claims. [DE 69-1, at 11 (citations omitted)]. In response, "Plaintiff concedes that she does not have an independent [NIED] claim. However, under Kentucky law, she may testify as to her own garden-variety emotional distress as part of her damages deriving from her other causes of action." [DE 70, at 2]. Plaintiff continues, "While Ethicon is correct that there is no expert testimony supporting an independent NIED claim, such testimony is not needed to seek damages for garden variety emotional distress, associated with other claims." *Id.* at 16 (citing *Indiana Ins. Co. v. Demetre*, 527 S.W.3d 12, 38–39 (Ky. 2017)). Since Ethicon's

request to dismiss Plaintiff's NIED claim is undisputed, it will be granted.

B. EXPERT TESTIMONY

Ethicon moves to limit the case-specific opinions and testimony of Plaintiff's expert, Dr. Bruce Rosenzweig, arguing his opinions are "speculative, unreliable, and otherwise inadmissible." [DE 35, at 1]. Specifically, Ethicon requests that the Court preclude Dr. Rosenzweig from offering the following opinions: (1) opinions derived from allegedly inadmissible general opinions, such as opinions about Ethicon's state of mind, knowledge, and conduct, the adequacy of Ethicon's warnings, Plaintiff's complications caused by the degradation and other alleged biomaterial properties of her mesh implant, and the availability of safer alternative designs and procedures; (2) opinions about the adequacy of the implanting physicians informed consent process; (3) opinions about degradation, rigidity, roping, stiffening, curling, or cording; (4) opinions that the use of an alternative design or procedure would have prevented Plaintiff's injuries; (5) opinions concerning Plaintiff's need for future surgical intervention and prognosis; and (6) opinions that Plaintiff's TVT-Exact implant had "defects" or was "defective." *Id.* at 1-2.

Pursuant to Federal Rule of Evidence 702, expert testimony is admissible if it will "'help the trier of fact to understand the

evidence or to determine a fact in issue' and (1) is 'based upon sufficient facts or data' and (2) is 'the product of reliable principles and methods' which (3) has been reliably applied 'to the facts of the case.'" *Huskey*, 29 F. Supp. 3d at 701 (quoting Fed. R. Evid. 702). Expert testimony is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The Court of Appeals for the Sixth Circuit sets forth the following three requirements for the admissibility of expert testimony under Rule 702:

> "First, the witness must be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Second, the testimony must be relevant, meaning that it "will assist the trier of fact to understand the evidence or to determine a fact in issue." *Id.* Third, the testimony must be reliable. *Id.*"

In re Davol, Inc., Case Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6605542, at *3 (S.D. Ohio Sept. 1, 2020) (citing *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008)). The Court need not analyze all three requirements where Ethicon argues Dr. Rosenzweig's opinions only fail to satisfy one or two of the requirements, as it will not create arguments that are absent from the pleadings.

"Arguments regarding the weight to be given to any testimony or opinions of an expert witness are properly left to the jury." *In re Davol, Inc.*, 2020 WL 6605542, at *3 (citing *In re Scrap Metal Antitrust Litig.*, 527 F.3d at 531-32). "Vigorous cross-

examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596. The burden is on the party proffering the expert testimony to demonstrate by a preponderance of proof that the opinions of their experts are admissible. *In re Davol, Inc.*, 2020 WL 6605542, at *3 (citing *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir. 2001)). "Any doubts regarding the admissibility of an expert's testimony should be resolved in favor of admissibility." *Id.* (citing Fed. R. Evid. 702 Advisory Committee's Notes, 2000 amend).

1. ETHICON'S STATE OF MIND, KNOWLEDGE, AND CONDUCT

Ethicon argues Dr. Rosenzweig's opinions regarding Ethicon's state of mind, knowledge, and conduct should be excluded. [DE 35, at 4]. Citing the expert testimony restrictions imposed in *Huskey* regarding state of mind testimony, Plaintiff asserts that her counsel and Dr. Rosenzweig "understand the limitations the Court has placed on expert testimony," and "Dr. Rosenzweig will not run afoul of the Court's directives." [DE 37, at 5]. The Court will reiterate the holding in *Huskey* on this question and clarify what Plaintiff must not do at trial.

First, Dr. Rosenzweig "may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his . . . opinions." *Huskey*, 29 F. Supp. 3d at 702-03. However,

Dr. Rosenzweig may not opine on matters related to Ethicon's state of mind, knowledge, or corporate conduct and ethics. *Id.* at 703. He must also refrain from "stat[ing] a legal standard or draw[ing] a legal conclusion by applying law to the facts . . . ." *Id.* Accordingly, the Court will grant Ethicon's Motion [DE 34] in part, insofar as it pertains to state of mind testimony, with the understanding that Plaintiff will not seek to introduce this evidence to the jury. If Plaintiff does attempt to introduce state of mind testimony at trial, it will be against Plaintiff's assurances that it would not do so, and the Court expects Ethicon to rightfully object at that time.

2. ADEQUACY OF ETHICON'S WARNINGS

Ethicon argues Dr. Rosenzweig is not qualified to opine on the adequacy of Ethicon's warnings for the TVT-Exact. [DE 35, at 4]. However, as both the *Huskey*, 29 F. Supp. 3d at 704 and *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *8 (S.D. W. Va. July 8, 2014) Courts found, Dr. Rosenzweig is sufficiently qualified to offer his opinion on this topic. Specifically, Dr. Rosenzweig, a urogynecologist, is qualified to opine about the risks of the TVT-Exact and its implantation and whether he believes Ethicon's IFU adequately warned Plaintiff about those risks. Ethicon's Motion [DE 34] will be denied in part, insofar as it pertains to Dr. Rosenzweig's opinions regarding the adequacy of Ethicon's warnings.

3. COMPLICATIONS

Ethicon requests the Court exclude Dr. Rosenzweig's testimony regarding Plaintiff's complications caused by the biomaterial properties of her mesh implant because Dr. Rosenzweig is allegedly unqualified. [DE 35, at 4]. Simply put, there is nothing about Dr. Rosenzweig's background that leads the Court to believe he is not qualified to opine on complications that are caused by mesh implants and similar materials. This issue was previously addressed in *Wilkerson v. Boston Scientific Corp.*, which held, "Dr. Rosenzweig's established background and skill in pelvic surgery, polypropylene, and the complications associated with degradation qualify him to opine on the degradation process, even though his knowledge about the precise biochemical interactions involved might not be as extensive as that of others." No. 2:13-cv-04505, 2015 WL 2087048, at *5 (S.D. W. Va. May 5, 2015). This Court agrees and will deny Ethicon's Motion [DE 34] in part, insofar as it seeks to exclude Dr. Rosenzweig's testimony regarding complications caused by the material used in Plaintiff's mesh implant. The Court will discuss Dr. Rosenzweig's opinions regarding references to the physical characteristics of Plaintiff's specific implant further herein, as Ethicon curiously split up its argument on this issue.

4. SAFER ALTERNATIVES

Ethicon makes the related arguments that Dr. Rosenzweig should not be allowed to opine on the availability of safer alternative designs and procedures or that they would have prevented Plaintiff's injuries. [DE 35, at 5, 8]. As the Court previously found herein, Dr. Rosenzweig may express his opinion about whether products with less polypropylene, such as Ultrapro, and those using PVDF material would have prevented or lessened Plaintiff's injuries. Plaintiff need only show there was a *safer* alternative not one that eliminated all risks, as Ethicon claims, *see* [DE 35, at 8]. Dr. Rosenzweig's opinions are both relevant and supported by his experience and reliable materials, including various publications. To the extent Ethicon disagrees with Dr. Rosenzweig's opinions or the materials he relied on, Ethicon is free to cross-examine him and introduce evidence contesting his opinions, but his opinions will not be excluded.

5. INFORMED CONSENT PROCESS

Ethicon argues Dr. Rosenzweig's opinions about the adequacy of the implanting physicians informed consent process should be excluded because "Dr. Rosenzweig is effectively opining as to Dr. Voss's personal knowledge (or lack thereof) at the time of Ms. Sexton's surgery." [DE 35, at 5]. However, Plaintiff insists she has no intention of offering testimony as to Dr. Voss's state of mind. [DE 37, at 9]. Instead, Dr. Rosenzweig merely opines that

Plaintiff could not make a well-informed decision to have the TVT-Exact implanted due to Ethicon's allegedly inadequate warnings found in the IFU. *Id.* Therefore, Ethicon's Motion [DE 34] will be granted in part, insofar as it pertains to Dr. Rosenzweig opining on Dr. Voss's state of mind or Dr. Voss's role in the informed consent process.

This limitation does not prevent Dr. Rosenzweig from testifying to what he sees as inadequacies in Ethicon's warnings, and the Court trusts that Plaintiff's counsel can tailor their evidence to argue the alleged inadequacies in Ethicon's warnings without inferring what Dr. Voss's state of mind was or what he knew when he consulted with Plaintiff. If Plaintiff wishes to address alleged flaws or a lack of knowledge in Dr. Voss's informed consent process, those questions are better suited for Dr. Voss than Dr. Rosenzweig.

6. PHYSICAL CHARACTERISTICS OF PLAINTIFF'S MESH IMPLANT

Ethicon requests that the Court exclude Dr. Rosenzweig's opinions about degradation, rigidity, roping, stiffening, curling, cording, and other alleged complications concerning the physical state of the mesh used in Plaintiff's implant as "unreliable because they are based on pure speculation" and not on Dr. Rosenzweig's examination, analysis, or testing of Plaintiff's implant for signs of such issues. [DE 35, at 6-7].

In *Huskey*, the plaintiff sought to introduce Dr. Rosenzweig's specific causation opinions, and Ethicon argued his opinions were unreliable because he did not test the plaintiff's mesh after it was explanted. *Huskey*, 29 F. Supp. 3d at 707. In fact, Dr. Rosenzweig was incapable of testing the mesh because it was discarded by the hospital when it was removed. *Id*. Accordingly, Dr. Rosenzweig's opinion regarding degradation of the plaintiff's mesh was not based on any testing of the actual mesh removed from the plaintiff. Instead, it was based on his examination of the plaintiff, in which he found that she exhibited tenderness near her vagina, and his opinion, based on experience with mesh degradation, that the tenderness could have been caused by mesh degradation and that her remaining mesh was likely degrading. *Id*. at 703. The *Huskey* Court found Dr. Rosenzweig's testimony on degradation, fraying, and particle loss was not reliable under Rule 702 because it was based solely on his experience with other explanted mesh and his theories about the plaintiff's mesh implant's possible degradation. *Id*. at 702.

Unlike *Huskey*, in the present case, Dr. Rosenzweig's opinions regarding the physical characteristics are not solely based on experience and theories about Plaintiff's symptoms. Instead, Dr. Rosenzweig's report discusses another doctor's findings. [DE 37, at 10]. Specifically, Dr. Rosenzweig references Dr. Caballero's examination and states the following:

> Dr. Caballero surmised that her sling could have contracted or migrated, or was a little bit tight and hypersuspended. He recommended a sling revision, and she consented. He performed a surgery under general anesthesia. He was able to palpate the sling after making a vertical vaginal incision, and he placed a right angle clamp around the sling, which was around the level of the proximal urethra. Dr. Caballero observed that the sling had curled on itself into a bunch, and was slightly hypersuspended. Once he divided the sling, the sling arms retracted laterally about 2 cm on each side. He proceeded to retract about 1 cm of sling from each side, any that was exposed so it would not erode through the closure of the incision. Noting that the urethra was a little bit thin after this maneuver, he proceeded to mobilize a flap of fascia from the anterior vaginal wall to reinforce the defect. He closed the vaginal incision and did a cystoscopy to confirm no bladder or urethral injury with bilateral efflux of clear urine. The pathology showed vaginal mesh, vaginal biopsy with fibrotic submucosal tissue, mild vaginal congestion with focal lymphocytic infiltrate.

[DE 34-1, at 8]. During Dr. Rosenzweig's deposition, basing his opinion on Plaintiff's medical records, he testified, "For deformation and contraction, we *know* that that there was a chronic foreign body reaction because the focal lymphocyctic infiltration of the pathology specimen." [DE 37-1, at 4 (emphasis added)].

Whereas Dr. Rosenzweig's testimony in *Huskey* regarding the cause of the plaintiff's tenderness was more theoretical and worded as a possible explanation, Dr. Rosenzweig's opinion here is more certain with less room for other potential causes, as exhibited in the above testimony regarding deformation and contraction. *See* [DE 37-1, at 4]. Nevertheless, the Court will not go so far as to give Dr. Rosenzweig free rein to opine on the physical characteristics

of mesh he did not examine himself. Instead, the Court will only allow Dr. Rosenzweig to offer his opinion on the alleged evidence of degradation or similar changes in the physical state of the mesh implant that are found in Plaintiff's medical records. Any opinions about the cause of Plaintiff's injuries related to degradation of the mesh implant or similar changes that Dr. Rosenzweig cannot support with citation to an examining doctor's records or documented tests of Plaintiff's mesh implant shall be excluded as unreliable. This decision does not prevent Dr. Rosenzweig from opining that Plaintiff's injuries were caused by the material of the mesh implant, its alleged incompatibility with the human body and the natural occurrences within said body, and the degradation process of mesh in general.

7. FUTURE SURGICAL INTERVENTION AND PROGNOSIS

Ethicon asks the Court to preclude Dr. Rosenzweig from opining on Plaintiff's need for future surgery and her future prognosis, arguing such opinions are speculative, unreliable, and irrelevant. [DE 35, at 9]. As Plaintiff correctly asserts, Kentucky law recognizes that future medical expenses are to some extent inherently speculative. *See* [DE 37, at 13 (citing *Boland-Maloney Lumber Co., Inc. v. Burnett*, 302 S.W.3d 680, 691-92 (Ky. Ct. App. 2009))]. Moreover, Kentucky law allows medical experts to testify as to whether a person with similar injuries to the plaintiff's injuries will need future surgeries. *See Cincinnati Ins. Co. v.*

Samples, 192 S.W.3d 311, 317-18 (Ky. 2006). Therefore, Dr. Rosenzweig's opinions that Plaintiff will likely require more surgeries and will suffer future damages is permitted under Kentucky law, relevant to questions about Plaintiff's damages, and reliable if Dr. Rosenzweig's opinions are supported by his experience and knowledge as to how many people with injuries like Plaintiff's require future surgeries and continue to suffer from their injuries. For the forgoing reasons, Ethicon's Motion [DE 34] will be denied in part, insofar as it pertains to excluding Dr. Rosenzweig's opinions about Plaintiff's future surgeries and prognosis.

8. DEFECTS

Ethicon's request for the Court to preclude Dr. Rosenzweig from stating that Plaintiff's TVT-Exact implant contained "defects" or was "defective" will be granted, as such terms are legal terms of art. *See Sederholm v. Bos. Sci. Corp.*, No. 2:13-cv-12510, 2016 WL 3282587 (S.D. W. Va. June 14, 2016) (citation omitted).

III. CONCLUSION

Having considered the matter fully, and being otherwise sufficiently advised,

IT IS ORDERED as follows:

(1) Ethicon's Motion for Partial Summary Judgment [DE 32] is **GRANTED IN PART**, insofar as it pertains to strict liability-

manufacturing defect (Count II), strict liability-defective product (Count IV), common law fraud (Count VI), fraudulent concealment (Count VII), constructive fraud (Count VIII), negligent misrepresentation (Count IX), breach of express warranty (Count XI), breach of implied warranty (Count XII), violation of consumer protection laws (Count XIII), punitive damages (Count XVII), and discovery rule and tolling (Count XVIII), and **DENIED IN PART**, insofar as it pertains to negligence (to the extent it is based on negligent failure to warn or negligent manufacturing defect)(Count I), strict liability-failure to warn (Count III); gross negligence (to the extent based on negligent failure to warn or negligent manufacturing defect) (Count XIV); unjust enrichment (Count XV).

(2) Ethicon's Supplemental Motion for Summary Judgment [DE 69] is **GRANTED IN PART**, insofar as it pertains to Plaintiff's claims for design defects involving biologic slings as a feasible, safer alternative and negligent infliction of emotional distress (Count X), and **DENIED IN PART**, insofar as it pertains to claims for design defects involving products with less polypropylene, such as Ultrapro, and those using PVDF material being feasible, safer alternatives;

(3) Ethicon's Motion to Limit the Case-Specific Opinions and Testimony of Bruce Rosenzweig, M.D [DE 34] is **GRANTED IN PART**, insofar as it pertains to Ethicon's state of mind, knowledge, and

conduct, Dr. Voss's state of mind, Dr. Voss's role in the informed consent process, the cause of Plaintiff's injuries related to degradation of the mesh implant or similar changes that Dr. Rosenzweig cannot support with citation to an examining doctor's records or documented tests of Plaintiff's mesh implant, and Plaintiff's TVT-Exact implant containing "defects" or being "defective", and **DENIED IN PART**, insofar as it pertains to the adequacy of Ethicon's warnings, complications caused by the material used in Plaintiff's mesh implant, safer alternatives that have not been otherwise dismissed herein, and Plaintiff's future surgeries and prognosis.

This 10th day of September, 2021.

Signed By:
Joseph M. Hood
Senior U.S. District Judge