IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

PATRICIA HOSBROOK, Plaintiff, v. ETHICON, INC., et al., Defendants.	:	Case No. 3:20-cv-88 JUDGE WALTER H. RICE

AMENDED DECISION AND ENTRY[1] OVERRULING IN PART AND SUSTAINING IN PART DEFENDANTS' MOTION TO DISMISS THE CASE-SPECIFIC OPINIONS OF BRUCE ROSENZWEIG, M.D. (DOC. #86) AND SUSTAINING DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT (DOC. #39)

Before the Court are two motions filed by Defendants, Ethicon, Inc., Ethicon LLC and Johnson and Johnson ("Defendants" or "Ethicon"). The first motion filed by Defendants is a Motion to Limit the Case-Specific Opinions of Bruce Rosenzweig, M.D. ("Motion to Limit"), Doc. #86. Plaintiff, Patricia Hosbrook, ("Plaintiff"), has filed a Response in Opposition to the Motion to Limit, Doc. #93, and Defendants filed a Reply. Doc. #95.

Defendants' second motion is a Motion for Partial Summary Judgment, Doc. #39. Plaintiff has filed a Response in Opposition, Doc. #46. Defendants have

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[1] The only amendments are on page 11: page 11, line three, now reads "Defendants' motion" instead of "Plaintiff's motion" and line 8, last word, reads "was" rather than "were."

filed a Reply, Doc. #47 and a Notice of Supplemental Authority, Doc. #82.[2] The motions are now ripe for decision.

I. Background

On March 27, 2007, Plaintiff underwent surgery and had implanted a pelvic mesh product manufactured by Ethicon known as "Prolift." Doc. #34-1, PAGEID#131. The surgery was performed by Silas Terry, Jr., M.D.[3] at Livingston Regional Hospital, located in Livingston, Tennessee. *Id*. Prolift contained a synthetic mesh made of a polypropylene material and was used to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI").

Following the surgery, Plaintiff experienced a number of physical problems and underwent surgery on May 14, 2012, for the removal of extruded vaginal mesh as well as a rectocele repair. Doc. #34-1, PAGEID#133. On November 16, 2012, she filed a "Short Form Complaint" ("SFC"), incorporating the First Amended Master Complaint, against Defendants in Multidistrict Litigation (MDL) proceedings in the United States District Court, Southern District, West Virginia. *In re: Am. Med. Sys., Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, 844 F. Supp. 2d 1359 (U.S. Jud. Pan. Mult. Lit. 2012). Plaintiff has alleged numerous causes of action

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[2] *See*, "Defendants Ethicon, Inc. and Johnson & Johnson's Notice of Refiling Briefing Related to Motion for Partial Summary Judgment," Doc. #94.

[3] Dr. Terry died on December 4, 2012. He was not deposed prior to his death.

against Defendants including strict liability, negligence, fraud and consumer law violations. Doc. #1, PAGEID##1, 3-5; Doc. #66-1.

Pretrial matters in this case were handled in the MDL proceeding in the Southern District of West Virginia against Defendants and other manufacturers of the pelvic surgical mesh products. This case was then transferred to this district for trial.

II. Motion to Limit, Doc. #86

A. Introduction.

Defendants' Motion to Limit seeks an order precluding Dr. Rosenzweig from testifying

> (1)that Plaintiff would not have been injured if she had undergone a traditional surgical procedure instead of Prolift implantation because comparison to these alternatives is irrelevant; (2) about mesh degradation and other alleged mesh deformations because there is no evidence to link those opinions to Plaintiff's case; (3) about lack of informed consent based on insufficient product warnings because such testimony is irrelevant, unreliable, and risks prejudice and confusing the jury; and (4) about purported limitations on Plaintiff's current activity level, "poor" prognosis, and the need for future surgery.

Doc. #86, PAGEID#17816

Defendants argue that the opinions of Plaintiff's case-specific expert are "speculative and unsupported by any evidence." Plaintiff's response to the Motion to Limit is that the motion should be overruled because the MDL Court "has repeatedly" held Dr. Rosenzweig's general and case specific opinions on the

subjects raised by Plaintiff to be relevant and reliable. Doc. #93, PAGEID#17915. Before addressing these subjects, the Court will first review the law concerning Defendants' motion.

B. Legal Analysis of Motion to Limit

A motion to limit testimony, or motion *in limine*, is not addressed in the Federal Rules of Evidence or the Federal Rules of Civil Procedure. The practice of ruling on such motions has instead developed "pursuant to the district court's inherent authority to manage the course of trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). The purpose of a motion *in limine* is to allow the Court to rule on issues pertaining to evidence in advance of trial in order to both avoid delay and ensure an evenhanded and expeditious trial. See *Indiana Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp.2d 844, 846 (N.D. Ohio 2004) (citing *Jonasson v. Lutheran Child & Family Servs.*, 115 F.3d 436, 440 (7th Cir. 1997)). Pretrial orders also often save the parties time and cost in preparing for trial and presenting their cases.

Courts are generally reluctant to grant broad exclusions of evidence in *limine*, however, because "a court is almost always better situated during the actual trial to assess the value and utility of evidence." *Koch v. Koch Indus., Inc.*, 2 F. Supp.2d 1385, 1388 (D. Kan. 1998); accord *Sperberg v. Goodyear Tire & Rubber* Co., 519 F.2d 708, 712 (6th Cir. 1975). A court should not make a ruling *in limine* unless the moving party meets its burden of showing that the evidence in question is clearly inadmissible. *Indiana Ins. Co.*, 326 F. Supp.2d at 846; *Koch,* 2 F. Supp.2d at 1388. If this high standard is not met, evidentiary rulings should be

deferred so that the issues may be resolved in the context of the trial. *Indiana Ins. Co.*, 326 F. Supp.2d at 846.

C. Opinions of Expert Witnesses

Regarding expert witnesses, Fed. R. Evid. 702, provides as follows:

> 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 if:
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> (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;
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> (b) the testimony is based on sufficient facts or data;
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> (c) the testimony is the product of reliable principles and methods; and
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> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the Supreme Court announced the standard for the admission of expert scientific testimony in a case involving the prescription anti-nausea drug, Benedectin. It held that the trial judge is to act as the gatekeeper and exclude expert witness testimony if is it not both relevant and reliable. *Daubert* provided four non-exclusive factors to assist in determining the reliability of the expert's methodology:

> (1) whether the theory or technique has been tested;
> (2) whether the theory or technique has been subjected to peer review and publication;

> (3) the known or potential rate of error of the method used and the existence and maintenance of standards controlling the technique's operation; and
> (4) whether the theory or method has been generally accepted by the scientific community.

Daubert, 509 U.S. at 593-94, 113 S.Ct. 2786. In *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 148, 119 S.Ct. 1167 (1999), the Court clarified *Daubert* by applying Rule 702 to expert testimony based on technical or other specialized knowledge. *Kumho Tire*, however, made clear that reliability is "flexible" and that the four *Daubert* factors are not a "definitive checklist or test" and must be tailored to the facts of the particular case. *Id.*, (quoting *Daubert*, 509 U.S. at 593, 113 S.Ct. 2786.) Accordingly, although the court has the ability to exclude expert witnesses if the requirements of Rule 702 are not satisfied, it cannot weigh the facts or evaluate the correctness of the expert witness's conclusions. These tasks are for the jury. *Stollings v. Ryobi Techs., Inc.*, 725 F.3d 765 ((7th Cir. 2013)

1. Opinions about Alternative, Traditional Surgical Procedures

Defendants argue that the opinions of Dr. Rosenzweig concerning alternative traditional surgical procedures are irrelevant to Plaintiff's claims. They assert that although Plaintiff is not required to do so, she can present proof of an alternative product design for the Prolift. In this case, however, Plaintiff's expert offers proof of alternative traditional surgical *procedures* when her claim is for an allegedly defective or unreasonably dangerous *product* under the Tennessee Product Liability Act ("TPLA"), Tennessee Product Liability Act ("TPLA") Tenn.

Code Ann §§ 29-28-101 through 29-28-108.[4] Defendants assert that their position is supported by *King v. Danek Medical, Inc.*, 37 S.W. 3d 429 (Tenn. Ct. App. 2000)[5] as well as the TPLA statute, the relevant portion of which reads as follows:

> A manufacturer or seller of a product shall not be liable for any injury to a person or property caused by the product unless the product is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Tenn. Code Ann. § 29-28-105(a).

In response to Defendants' argument, Plaintiff asserts that Dr. Rosenzweig "simply informs the jury of what is now common knowledge to the medical community: that a native tissue prolapse repair using biologic grafts rather than synthetic mesh are safer surgical interventions than transvaginal mesh kits like the Prolift." Doc. #93, PAGEID#17915. Plaintiff also argues that the Prolift is both a procedure and a product. "The Prolift is itself a vaginal procedure that uses a polypropylene product as a support mechanism to treat POP." *Id.* PAGEID#17916.

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[4] The alternative surgical procedures offered by Dr. Rosenzweig consist of the following: (1) the use of sutures, including delayed absorbable sutures like PDS, in a uterosacral ligament suspension and a sacrospinous fixation; an anterior and posterior colporrhaphy; a sacrocolpopexy and a sacrohysteropexy; (2) autologous fascia lata; (3) repliform cadaveric fascia. Doc. #44-1, PAGEID204.

[5]The Court does not find *King* to be persuasive to Defendants' position. The state appellate court in *King* involved claims regarding the design and manufacture by the defendants of spinal system devices utilizing pedicle screws implanted in the plaintiffs. The plaintiffs argued that summary judgment should not have been granted. The state appellate court, however, specifically found that plaintiffs' expert was not qualified "to give expert opinions which clearly require medical expertise that he does not possess." As such, "his opinions, set out as bullet points, are not admissible pursuant to Tennessee Rules of Evidence 702" and the motion for summary judgment was sustained, since no evidence existed that the spinal system devices manufactured and implanted in the plaintiffs were defective. *Id.* at 444.

According to Plaintiff, "Ethicon's 'Surgical Technique' Guide for the 'Prolift Pelvic Floor Repair System' clearly characterizes Prolift as a procedure." *Id*.

Although Plaintiff may be correct that Dr. Rosenzweig's four procedures are intended to merely inform the jury that biologic grafts are safer than Prolift, the fact remains that Prolift is a product and Plaintiff must establish under the TPLA that it was "in a defective condition" or "unreasonably dangerous" at the time it left the control of the manufacturer or seller. To introduce evidence of alternative surgical procedures in a product liability case is irrelevant and would create confusion for the jury. As to Plaintiff's argument that the Prolift is both a product and a procedure, thus making Dr. Rosenzweig's testimony of alternative surgical procedures relevant, the Court is not convinced since every medical product intended to be implanted requires a surgical procedure. As stated by the MDL Court, "alternative procedures/surgeries do not inform the issue of whether an alternative design for a product exists." In re *Ethicon, Inc. Pelvic Repair Sys Prod. Liab. Litig.*, 2017 WL 1264620, at *3 (S.D. W. Va. Mar. 29, 2017). Accordingly, Defendants' motion to exclude testimony from Dr. Rosenzweig regarding alternative procedures is sustained.

2. Opinions Concerning Mesh Degradation and Other Alleged Deformation

Defendants next argue that the opinions of Dr. Rosenzweig concerning mesh degradation and other alleged deformation should be excluded since there are no facts in support of these opinions. They argue that Plaintiff's expert did not

conduct a medical examination of her, examine the explant mesh and that nothing in the medical records support his opinions of degradation or deformation. Because causation cannot be established as required by Tennessee law, Defendants argue Rosenzweig's opinions are "speculative, irrelevant[,]and prejudicial," Doc. #87, PAGEID#17826. To establish causation under Tennessee law, Defendants cite to case law and assert that Plaintiff is required to "trace the injury to some specific error in the construction or design of the [product].' *Fulton v. Pfizer Prods. Grp.*, 872 S.W.2d 908, 912 (Tenn. Ct. App. 1993) (quoting *Browder v. Pettigrew*, 541 S.W.2d 402, 404 (Tenn. 1976)). *Kilpatrick v. Bryan*t, 868 S.W.2d 594 (Tenn. 1993) ("mere possibility of such causation is not enough") *Id.*

Defendants also rely on *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 707-08 (S.D.W. Va. 2014). In *Huskey*, the MDL Court excluded Dr. Rosenzweig's opinions since he had not tested the plaintiff's mesh yet opined, based on his background and work, that degradation had occurred.

Plaintiff does not specifically address Defendants' citations to Tennessee law and causation. Instead, she asserts that in a recent case similar to the one before this court, the district court correctly found that Dr. Rosenzweig's opinions were admissible regarding mesh degradation. In *Armstead v Colorplast Corp.*, 1:19-cv-1000, 2020 WL 353576, January 21, 2020 (M.D. N.C.), the defendant manufacturer sought to exclude Dr. Rosenzweig's opinions on mesh degradation since he had never physically examined the plaintiff or examined her mesh products. In overruling defendant's motion to exclude, the court noted that

plaintiff's expert "relied on Mrs. Armstead's medical records and testing results, as well as her medical history." *Id*. at *3. The court further found that "Dr. Rosenzweig employed a differential diagnosis methodology that involved ruling in possible causes for symptoms and conditions and then eliminating possible causes until reaching one that could not be ruled out or determining one is most likely." *Id*. at 3.

> Dr. Rosenzweig's methodology involved five steps: (1) reviewing Mrs. Armstead's records and test results; (2) reviewing her medical history; (3) reviewing and applying the scientific literature to determine possible causes of her symptoms; (4) applying clinical experience to determine possible causes; and (5) applying his experience and the literature to eliminate possible causes. Id. This is the same method that Dr. Rosenzweig uses in his practice to determine the cause or causes of his patients' medical conditions. Id. at 3–4. This methodology 'has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results.' (citation omitted)

Id.

The district court found that Dr. Rosenzweig could testify regarding his case specific opinions.

This Court agrees with *Armstead* and its holding that not conducting a physical examination of the plaintiff or the excised mesh is "relevant in considering whether to admit Dr. Rosenzweig's testimony" but "it is not determinative." *Id.* at *4. The reliability of an expert's opinion is "primarily a question of the validity of the expert's methodology, not the quality of the data used or the conclusions produced." *Manpower, Inc. v. Ins. Co. of Penn.*, 732 F.3d

796, 806 (7th Cir. 2013). At the very least, this fact of non-examination of Plaintiff is admissible for the weight to be given to the doctor's testimony.

Defendants' motion to exclude the opinions of Dr. Rosenzweig on the subjects of mesh degradation and "other alleged deformation" is overruled.

3. Opinion Regarding the Lack of Informed Consent

Dr. Rosenzweig has opined that the product label for the Prolift device did not sufficiently list certain risks. Because these risks were not on the product labeling, Plaintiff's expert asserts that neither Dr. Terry, nor Plaintiff was adequately informed, thus creating a "lack of informed consent." Defendants, however, argue that Dr. Terry (1) could have given warnings regarding the device to his patient and that it is speculative to assume that this did not occur; (2) under Tennessee law, a health care provider has a duty to disclose "appropriate information" to a patient to enable the patient to give informed consent to the treatment or the procedure, Tenn. Code Ann. § 29–26–118; and (3) medical device manufacturers are not required to warn of risks that are apparent to the physician who use it, Tenn. Code Ann § 29-28-105(d). In response, Plaintiff asserts that the MDL Court has found Dr. Rosenzweig competent to testify on the adequacy of the product warnings. *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 704 (S.D. W.Va. 2014) ("I therefore FIND that Dr. Rosenzweig is qualified to testify generally on the adequacy of the TVT-O's product warnings and marketing materials."); *Edwards v. Ethicon, Inc.*, 2014 WL 3361923, at *8 (S.D. W.Va. July 8, 2014) ("I therefore FIND

that Dr. Rosenzweig is qualified to testify generally on the adequacy of the TVT–O's product warnings and marketing materials.").

Any opinion that Dr. Rosenzweig states concerning what warnings that Defendants should have given will be subject to cross-examination and go to the weight and not the admissibility of the evidence. Although such evidence may not be compelling since Plaintiff's doctor is deceased and was not deposed, this is a determination for the jury and not the Court. Accordingly, Dr. Rosenzweig can testify on the subject of warnings.

4. Opinions about Plaintiff's Prognosis and the Need for Future Surgery are Unsupported by the Evidence

Defendants' final argument is that Dr. Rosenzweig's opinions about Plaintiff's prognosis are unsupported by the evidence. In support of this argument, Defendants cite to Plaintiff's deposition testimony taken in April of 2017. In this testimony, Plaintiff states that she had successful revision surgery in 2012 and, at least at that point in time, had no further complications or interference in her life. Dr. Rosenzweig has examined Plaintiff's medical records and has testified as an expert witness concerning other plaintiffs who have undergone these procedures. Based on these facts, Dr. Rosenzweig's testimony regarding Plaintiff's prognosis and the need for any further surgery goes to the weight of the evidence, a determination for the fact finder and not the Court. Accordingly, Defendants' motion to exclude testimony from Dr. Rosenzweig regarding Plaintiff's prognosis and future surgery is overruled.

III. Motion for Partial Summary Judgment, Doc. #39

A. Standard of Review

Summary judgment must be entered "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party=s case, and on which that party will bear the burden of proof at trial." *Celotex Corp.v. Catrett*, 477 U.S. 317, 322 (1986). The moving party always bears the initial responsibility of informing the court of the basis for its motion and identifying those portions of the record which it believes demonstrate the absence of a genuine issue of material fact. Id. at 323; see also *Boretti v. Wiscomb*, 930 F.2d 1150, 1156 (6th Cir. 1991).

"Once the moving party has met its initial burden, the nonmoving party must present evidence that creates a genuine issue of material fact making it necessary to resolve the difference at trial." *Talley v. Bravo Pitino Rest., Ltd.*, 61 F.3d 1241, 1245 (6th Cir. 1995); see also *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). Once the burden of production has so shifted, the party opposing summary judgment cannot rest on its pleadings or merely reassert its previous allegations. It is not sufficient to "simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Rule 56 "requires the nonmoving party to go beyond the [unverified] pleadings" and present some type of evidentiary material in support of its position. *Celotex*, 477 U.S. at 324. "The plaintiff must present more than a scintilla of evidence in support of his position; the evidence must be such that a

jury could reasonably find for the plaintiff." *Michigan Prot. & Advocacy Serv., Inc. v. Babin*, 18 F.3d 337, 341 (6th Cir. 1994).

Summary judgment shall be granted "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). "Summary judgment will not lie if the dispute about a material fact is 'genuine,' that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson*, 477 U.S. at 248. In determining whether a genuine dispute of material fact exists, a court must assume as true the evidence of the nonmoving party and draw all reasonable inferences in favor of that party. Id. at 255. If the parties present conflicting evidence, a court may not decide which evidence to believe. Credibility determinations must be left to the fact-finder. 10A Wright, Miller & Kane, Federal Practice and Procedure Civil 3d ' 2726 (1998). In determining whether a genuine dispute of material fact exists, a court need only consider the materials cited by the parties. Fed. R. Civ. P. 56(c)(3). "A district court is not . . . obligated to wade through and search the entire record for some specific facts that might support the nonmoving party=s claim." *InterRoyal Corp. v. Sponseller*, 889 F.2d 108, 111 (6th Cir. 1989), cert. denied, 494 U.S. 1091 (1990). If it so chooses, however, the Court may also consider other materials in the record. Fed. R. Civ. P. 56(c)(3).

B. Legal Analysis

1. Introduction

Under Ohio's choice-of-laws rules, the "law of the place of injury controls unless another jurisdiction has a more significant relationship to the lawsuit." *Pilgrim v. Universal Health Card, LLC*, 660 F.3d 943 (6th Cir. 2011) (citing *Morgan v. Biro Mfg. Co.*, 15 Ohio St. 3d 339, 474 N.E. 2d 286, 289 (1984)); 1 Restatement (Second) of Conflict of Laws, §§ 6, 145 and 146. Because the surgical implant of the pelvic mesh product occurred in Tennessee, and no other state has a more significant relationship to this claim, the substantive law of Tennessee applies.

Defendants assert in their Motion for Partial Summary Judgment that all of Plaintiff's claims, with the exception of strict liability for design defect, should be dismissed. Defendants contend that dismissal is appropriate because (1) the TPLA, Tenn. Code Ann §§ 29-28-101 through 29-28-108, subsumes all of Plaintiff's claims, other than those permitted by the statute; (2) Plaintiff has no evidence that she has a claim of strict liability for a manufacturing defect, "strict liability for defective product, or for strict liability for failure to warn; and (3) a claim under the Tennessee Consumer Protection Act, Tenn. Code Ann. §§ 47-18-109(a)(1), does not apply in this case and is also barred by the Act's five-year statute of repose.

Plaintiff's response does not address Defendants' argument that the TPLA subsumes all of her claims other than those permitted by the statute. Nor does she argue that she has any evidence of a manufacturing defect, strict liability for defective product, or that she has a claim under the Tennessee Consumer

Protection Act. Plaintiff does, however, argue that she has a valid cause of action against Defendants based on strict liability for failure to warn, Count III.

Defendants' Motion for Partial Summary Judgment is sustained. Specifically, the Court finds, pursuant to Rule 56 of the Federal Rules of Civil Procedure, that there is no genuine dispute of a material fact and that Defendants' Motion for Partial Summary Judgment should be sustained as a matter of law for Counts I, II, III, IV, VI, VII, VIII, IX, X, XI, XII, XIII, XIV and XV.

2. TLPA Claims

Defendants have filed a Motion for Partial Summary Judgment as to the following claims: negligence (Count I); 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 (Count X); breach of express warranty (Count XI); breach of implied warranty (Count XII); violation of consumer protection laws (Count XIII); gross negligence (Count XIV); and unjust enrichment (Count XV).[6]

[6] In addition to Count V, strict liability for design defect, Defendants have not moved for summary judgment on certain damages incorrectly designated as claims: Count XVI, loss of consortium, Count XVII, punitive damages and Count XVIII, discovery rule and tolling. Doc. #66-1.

Defendants argue, and Plaintiff does not contest, that Plaintiff's SFC is a product liability action governed by the TPLA. This state statute defines a product liability action as one which

> includes all actions brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging or labeling of any product. 'Product liability action' includes, but is not limited to, all actions based upon the following theories: strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent, or innocent; misrepresentation, concealment, or nondisclosure, whether negligent, or innocent; or under any other substantive legal theory in tort or contract whatsoever;

TPLA, §§ 29-28-102.

Defendants contend that because Plaintiff has alleged a product liability action as defined by the TPLA, the only potentially viable claims pled are her claims for strict liability for design defect, Count V, manufacturing defect, Count II and failure to warn, Count III.[7] All of Plaintiff's remaining claims are subsumed under the TPLA, the exclusive remedy for product liability claims. Accordingly,

> it makes no difference whether the complaint is couched in terms of negligence, strict liability or breach of warranty, it has generally been held in the State of Tennessee that in order for a plaintiff to recover under any theory of product liability, the plaintiff must establish that the product was defective and unreasonably dangerous at the time the product left the control of the manufacturer.

[7] Plaintiff has also pled a claim styled "strict-liability defective product," Count IV. The Court will address this claim, along with Count II, manufacturing defect, separately.

Higgs v. Gen. Motors Corp., 655 F. Supp. 22, 23 (E.D.Tenn.1985). *See also*, *McMillan v. Janssen Pharmaceutica*, Inc., 2011 WL 12088, at *1, *3 (E.D. Tenn. Jan. 4, 2011) (plaintiff's claims for negligence, strict liability, breach of express and implied warranties, negligent misrepresentation, fraud, and deceit were product liability actions under the TPLA and subject to its statute of repose); *Strayhorn v. Wyeth Pharmaceuticals, Inc.*, 737 F.3d 378 (6th Cir. 2013) (plaintiffs' attempts to characterize failure-to-warn claim as tort and contract causes of action "fall within the purview of the TPLA" and are barred against brand name drug manufacturers); *Johnson v Electrolux Home Prods, Inc.*, No. 2:09-CV-142, 2011 WL 4397494, at *4 (E.D. Tenn. Aug. 31, 2011) (the TPLA "was written to provide the exclusive remedy for injuries caused by products . . .").

In this case, Ethicon argues, and the Court agrees, that there is no genuine dispute of a material fact and that Defendants' Motion for Partial Summary Judgment should be granted as to the following claims of Plaintiff, since they are subsumed under the TPLA: (1) negligence based claims, Count I (negligence), Count X (negligent infliction of emotional distress) and Count XIV (gross negligence); (2) claims sounding in fraud, Count VI (common law fraud), Count VII (fraudulent concealment), Count VIII (constructive fraud), Count IX (negligent misrepresentation) and Count XIII (consumer protection); (3) warranty based

claims, Count IX (breach of express warranty) and Count XII (breach of implied warranty) and (4) unjust enrichment, Count XV.[8]

3. Lack of Proof of a Manufacturing Defect Claim and Plaintiff's Claim for "Strict Liability-Defective Product"

Plaintiff has pled a claim for "strict liability - manufacturing defect," Count II, and a claim styled "strict liability - defective product," Count IV. Although cognizable under the TPLA, no expert witness has opined that the implanted product deviated from any of Defendants' specifications. Tenn. Code Ann § 29-28-102(6). Also, Plaintiff's response does not address either of these two claims. Accordingly, the Court finds that there is no genuine dispute of a material fact as to Counts II and IV and that Defendants' motion for summary judgment as to these two claims is sustained.

4. Failure to Warn, Count III

Defendants also move for summary judgment on Count III, failure to warn. They contend that because Tennessee recognizes the learned intermediary

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[8]In addition to finding that certain of Plaintiff's claims are subsumed by the TPLA, the Court also finds that Plaintiff's claims for misrepresentation, unjust enrichment, consumer and warranty-based claims are barred because they are either inapposite to the facts as alleged in the SFC or barred by the applicable statute of limitations. Specifically, Plaintiff's negligent misrepresentation claim applies only to businesses or professionals supplying false information, *Hodge v. Craig*, 382 S.W. 325, 344-46 (Tenn. 2012), and her claim for unjust enrichment is legally irrelevant in a tort-based product liability suit. With respect to the statute of limitations, Plaintiff's consumer-based claim, § 47-18-109, Count XIII, is barred by a five-year statute of limitation from the date of the transaction, in this case March 27, 2007, the date of Plaintiff's surgery, to November 16, 2012, the filing of the SFC. Finally, Plaintiff's breach of warranty claim is barred by the four-year statute of limitations in Tenn. Code Ann. §§ 47-2-725(l), since the date is calculated from the date of Plaintiff's surgery, March 27, 2007, to the date of the filing of her SFC.

doctrine, the physician and not the patient is the user of the product and the one to be warned of any hazards. *Nye v. Bayer Cropscience, Inc.*, 347 S.W.3d 686, 701(Tenn. 2011); *Pittman v. The Upjohn Co.*, 890 S.W.2d 425, 430 (Tenn. 1994). As explained by the Tennessee Supreme Court in *Pittman*, a prescription drug case, the "makers of unavoidably unsafe products who have a duty to give warnings may reasonably rely on intermediaries to transmit their warnings and instructions." *Id.* at 429 (citations omitted). Plaintiffs, however, must still establish a causal connection between the warning given to the user and the injuries sustained.

In *Hurt v Coyne Cylinder Co.*, 956 F.2d 1319 (6th Cir. 1992), the Sixth Circuit reviewed Tennessee law in a case involving the alleged inadequacy of a warning label in a gas explosion. The Court held that summary judgment must be granted when a plaintiff fails to show proximate cause between the injury and the allegedly defective labels. The Court reiterated that under Tennessee law, a two-part test exists: "1) the plaintiff must establish the product is unreasonably dangerous by reason of defective warning and 2) the plaintiff must prove that the inadequate labelling proximately caused the claimed injury. (citations omitted) If either part is not met, the plaintiff fails to meet its burden." *Id.* at 1329.

Unfortunately for Plaintiff, the physician in this case, Plaintiff's doctor, is the intermediary. As noted above, Dr. Terry is deceased and was not deposed. Accordingly, there is no evidence before the Court that he read any warnings much less relied on them. Without this evidence of causation, the Court can only

conclude that the warnings given by Defendants were not a factor in the injuries sustained by Plaintiff. Accordingly, there is no genuine dispute of a material fact and Defendants' motion for summary judgment on Count III, failure to warn, is sustained.

IV. Conclusion

Accordingly, for the reasons stated above, Defendants' Motion to Dismiss the case-specific opinions of Bruce Rosenzweig, M.D., Doc. #86, is SUSTAINED in part and OVERRULED in part. Defendants' Motion for Partial Summary Judgment, Doc. #39, is SUSTAINED and Counts I, II, III, IV, VI, VII, VIII, IX, X, XI, XII, XIII, XIV and XV are dismissed.

Count V, design defect, remains for trial.

Date: April 23, 2021

Walter H. Rice

WALTER H. RICE
UNITED STATES DISTRICT JUDGE