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

CHARLESTON DIVISION

JO HUSKEY, et al.,

Plaintiffs,

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

ETHICON, INC., et al.,

Defendants.

MEMORANDUM OPINION AND ORDER
(Motions for Summary Judgment)

Pending before the court are the defendants' Motion for Partial Summary Judgment [Docket 161], Motion for Partial Summary Judgment Based on Preemption of Certain Claims [Docket 178], Motion for Partial Summary Judgment on Punitive Damages [Docket 187], and Plaintiffs Jo and Allen Huskey's Motion for Partial Summary Judgment on Defendant Ethicon Inc.'s Separate Defenses [Docket 163]. For the reasons stated below, the Motion for Partial Summary Judgment [Docket 161] is **GRANTED in part** and **DENIED in part**, the Motion for Partial Summary Judgment Based on Preemption of Certain Claims [Docket 178] is **DENIED**, the Motion for Partial Summary Judgment on Punitive Damages [Docket 187] is **DENIED**, and Plaintiffs Jo and Allen Huskey's Motion for Partial Summary Judgment on Defendant Ethicon Inc.'s Separate Defenses [Docket 163] is **GRANTED**.

I. Background

This case is one of more than 60,000 that have been assigned to me by the Judicial Panel on Multidistrict Litigation in seven MDLs involving pelvic mesh products. Approximately 19,000 of these cases reside in the *In re Ethicon, Inc.* MDL, MDL No. 2327.

The device at issue in this case is the Gynecare TVT Obturator ("TVT-O"), manufactured by the defendants, Ethicon, Inc. and Johnson & Johnson, Inc. (collectively, "Ethicon"). The TVT-O is a medical device that includes a mechanism used to place a mesh tape, or sling, under the urethra to provide support to the urethra to treat stress urinary incontinence. (Mem. in Supp. of Mot. for Partial Summ. J. [Docket 162], at 1).

Before being implanted with the TVT-O, Ms. Huskey suffered from stress urinary incontinence which caused her to leak urine when she laughed, coughed, sneezed, exercised, or experienced abdominal pressure. (*See* Byrkit Dep. [Docket 161-3], at 187:21-23; 189:3-6). Ms. Huskey initially utilized pelvic floor strengthening exercises to alleviate her symptoms. (*See* Huskey Dep. [Docket 161-4], at 308:18-309:4; 309:22-310:4). When those exercises failed to fully remedy her stress urinary incontinence, she sought surgical treatment. (*See id.* at 312:22-313:1).

Ms. Huskey's physician, Dr. Gretchen Byrkit, implanted the TVT-O device on February 23, 2011. (*See* Statement of Undisputed Facts Regarding Jo Huskey's Medical History and Condition [Docket 215], at 5). After the surgery, Ms. Huskey experienced several complications, including erosion of the mesh and dyspareunia. (*See id.* at 5-6). Ms. Huskey underwent a revision surgery with Dr. Sohail Siddique on November 18, 2011, which excised a portion of the TVT-O's mesh. (*See id.* at 6-7). After her revision, Ms. Huskey's stress urinary incontinence symptoms returned, and she experienced constant pelvic and vaginal pain. (*See id.* at 8).

Ms. Huskey and her husband, Allen Huskey, currently advance several claims against Ethicon, including negligence, strict liability for design defect, strict liability for failure to warn, strict liability for manufacturing defect, fraud, fraudulent concealment, constructive fraud, negligent misrepresentation, negligent infliction of emotional distress, breach of express and implied warranty, gross negligence, unjust enrichment, and violation of the Illinois Consumer Fraud Act, 815 Ill. Comp. Stat. 505/1 *et seq*. (*See* Short Form Compl. [Docket 1], at 4-5).

II. Legal Standards

A. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not "weigh the evidence and determine the truth of the matter." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587-88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some "concrete evidence from which a reasonable juror could return a verdict in his [or her] favor[.]" *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere "scintilla of evidence" in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise,

conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Felty v. Graves Humphreys Co.*, 818 F.2d 1126, 1128 (4th Cir. 1987); *Ross v. Comm'ns Satellite Corp.*, 759 F.2d 355, 365 (4th Cir. 1985), *abrogated on other grounds, Price Waterhouse v. Hopkins*, 490 U.S. 228 (1989).

B. Preemption

Federal preemption originates from the Constitution's Supremacy Clause. *See* U.S. Const. art. VI, cl. 2.[1] In addressing a preemption issue, the court's first task is to determine whether Congress intended to preempt. *See Cal. Fed. Savings & Loan Ass'n v. Guerra*, 479 U.S. 272, 280-81 (1978). Intent to preempt can manifest itself in three forms: field preemption, express preemption, and conflict preemption. *See H&R Block E. Enters. v. Raskin*, 591 F.3d 718, 722 (4th Cir. 2010). Field preemption occurs when the "federal scheme of regulation of a defined field is so pervasive that Congress must have intended to leave no room for the states to supplement it[.]" *City of Charleston, S.C. v. A Fisherman's Best, Inc.*, 310 F.3d 155, 169 (4th Cir. 2002). Express preemption arises when "Congress expressly declares its intent to preempt state law." *Pinney v. Nokia, Inc.*, 402 F.3d 430, 453 (4th Cir. 2005). Finally, conflict preemption occurs when "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985) (internal quotation omitted). Conflict preemption can also arise when "compliance with both federal and state regulations is a physical impossibility[.]" *Id.* (internal quotation omitted).

Once Congress's intent to preempt is determined, the focus turns to the scope of that preemption. *See Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324, 328 (4th Cir. 1996). Two

[1] "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

presumptions guide this inquiry. *See id.* First, "'the purpose of Congress is the ultimate touchstone' in every pre-emption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)). Second, a court starts "with the basic assumption that Congress did not intend to displace state law." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). "This presumption is strongest when Congress legislates 'in a field which the States have traditionally occupied.'" *S. Blasting Servs., Inc. v. Wilkes Cnty., N.C.*, 288 F.3d 584, 590 (4th Cir. 2002) (quoting *Lohr*, 518 U.S. at 485).

C. Choice of Law

The parties agree that Illinois's choice-of-law rules apply in this case. Illinois has adopted the most-significant-relationship test as enumerated in Restatement (Second) of Conflict of Laws. *See Townsend v. Sears, Roebuck & Co.*, 879 N.E.2d 893, 901 (Ill. 2007); *Gregory v. Beazer E.*, 892 N.E.2d 563, 578 (Ill. Ct. App. 2008). Under that test, courts should consider the following factors: (1) the place where the injury occurred, (2) the place where the conduct causing the injury occurred, (3) the domicile, residence, nationality, place of incorporation and business of the parties, and (4) the place where the relationship, if any, between the parties is centered. *See Townsend*, 879 N.E.2d at 901 (citing Restatement (Second) of Conflict of Laws § 145(2), at 414 (1971)). This choice of law analysis applies to each individual *issue* in a case. *See Townsend*, 879 N.E.2d at 901; *Gregory*, 892 N.E.2d at 578. Here, the surgery to implant the device and any alleged injuries to the plaintiffs occurred in Illinois. Therefore, for the plaintiffs' substantive claims, I apply the law of Illinois.

The analysis is different for punitive damages. Illinois courts permit dépeçage, or a separate choice-of-law analysis for each individual issue. *See Townsend*, 879 N.E.2d at 901-02 (explaining that Illinois follows the Restatement, which uses dépeçage). Ethicon urges the court to

apply New Jersey law to the punitive damages claim because the alleged conduct that gives rise to the punitive damages claim occurred there. Ethicon's argument is in line with the Restatement, which states that "when the primary purpose of the tort rule involved is to deter or punish misconduct, the place where the conduct occurred has peculiar significance." Restatement (Second) of Conflict of Laws § 145 cmt. e. The plaintiffs, appearing to agree with Ethicon, likewise brief punitive damages in relation to New Jersey law. The focus of the punitive damages inquiry is Ethicon's corporate conduct, and that conduct allegedly occurred in New Jersey. Therefore, New Jersey law applies to the plaintiffs' punitive damages claim.

III. Failure to Warn

Ethicon first challenges the plaintiffs' failure-to-warn claim. To recover on a failure-to-warn claim, a plaintiff must establish that inadequate warnings rendered a product unreasonably dangerous and caused the plaintiff's injuries. *Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 345 (Ill. 2008). In the case of medical devices, the duty to warn is to the prescribing physician, not the patient. *Giles v. Wyeth, Inc.*, 500 F. Supp. 2d 1063, 1065 (S.D. Ill. 2007); *Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d 35, 42 (Ill. 2002). Ethicon advances two arguments against the plaintiffs' failure-to-warn claim: (1) that the TVT-O's warnings were adequate because Dr. Byrkit was aware of the TVT-O risks, and (2) that the plaintiffs failed to present evidence that the allegedly inadequate warnings caused the plaintiffs' injuries. Ethicon's arguments fail on both counts.

A. Adequacy of Warnings

Ethicon contends that the TVT-O's warnings were adequate because the implanting physician, Dr. Byrkit, was independently aware of the TVT-O's potential complications and risks. In Illinois, "there is no duty to warn of a risk that is already known by those to be warned." *Proctor*

v. Davis, 682 N.E.2d 1203, 1211 (Ill. App. Ct. 1997); *see also Hansen*, 764 N.E.2d at 42 ("[A] prescription medical device manufacturer need not provide a warning of risks already known to the medical community."). A duty to warn arises only when there is "unequal knowledge and the defendant, possessed of such knowledge, knows or should know that harm might occur if no warning is given." *Proctor*, 682 N.E.2d at 1211 (quotation marks omitted).

The plaintiffs argue that there is a dispute of fact as to whether the TVT-O's warnings were adequate because Dr. Byrkit was not warned about the TVT-O's alleged potential to rope and curl after implantation, polypropylene mesh's propensity to degrade in vivo, or the risks associated with small pore, heavy-weight mesh. Ethicon attempts to construe these risks as "mechanisms and design defects" about which there is no duty to warn. (*See* Reply in Supp. of Mot. for Partial Summ. J. [Docket 228], at 10). Ethicon cites no support for this proposition, and Illinois law appears to make no such formalistic distinction. Illinois law requires that manufacturers warn of "dangerous condition[s]," not merely the potential injuries that might result from use of the product. *Happel v. Wal-Mart Stores, Inc.*, 766 N.E.2d 1118, 1123 (Ill. 2002); *Kennedy v. Medtronic, Inc.*, 851 N.E.2d 778, 783 (Ill. App. Ct. 2006); *see also Hansen*, 764 N.E.2d at 42 ("dangerous propensities"). For instance, in *Hansen*, the Illinois Supreme Court found a dispute of fact over the adequacy of warnings where a medical device manufacturer allegedly failed to warn about the proper use of the device's mechanisms. The defendant manufactured IV tubes and failed to warn about the need to use particular tubes—those with threaded connections—with IVs inserted into patients' jugular veins. *See Hansen*, 764 N.E.2d at 43.

Here, the TVT-O's potential to rope and fray, polypropylene's propensity to degrade, and complications associated with small pore mesh are all potential dangerous conditions about the

TVT-O of which Dr. Byrkit allegedly was not warned. Therefore, there is a dispute of fact about whether the TVT-O's warnings were adequate.

B. Causation

Ethicon also argues that the plaintiffs have failed to present evidence that the allegedly inadequate warnings caused the plaintiffs' harm. Ethicon argues that Dr. Byrkit did not rely on the product's IFU and that Dr. Byrkit would not have changed her decision to prescribe the device if she had received a better warning.

In Illinois, causation under a products liability theory is the same as under a negligence theory. *See Smith v. Eli Lilly & Co.*, 560 N.E.2d 324, 328 (Ill. 1990). Therefore, a plaintiff must prove that the defendant's conduct was both the cause-in-fact and the legal cause of her injuries. *See Rodriguez v. Glock, Inc.*, 28 F. Supp. 2d 1064, 1070 (N.D. Ill. 1998). Illinois courts have utilized two tests to determine whether a defendant's conduct was a cause-in-fact: the "substantial factor" test and the "but-for" test. *Rodriguez*, 28 F. Supp. 2d at 1070; *Kerns v. Engelke*, 369 N.E.2d 1284, 1292 (Ill. App. Ct. 1977), *aff'd in part*, 390 N.E.2d 859 (Ill. 1979). The "substantial factor" test asks whether the defendant's conduct is a "material element" and a "substantial factor" in bringing about the plaintiff's injury. *Wehmeier v. UNR Indus., Inc.*, 572 N.E.2d 320, 335 (Ill. App. Ct. 1991). Under the "but-for" test, "the defendant's conduct is not a cause of an event if the event would have occurred without it." *Kerns*, 369 N.E.2d at 1292.

First, Ethicon argues that the allegedly inadequate warnings did not cause the plaintiffs' injuries because Dr. Byrkit did not rely on the TVT-O's Instructions for Use ("IFU") in making her decision. But there is no such testimony in the record. Dr. Byrkit read the IFU before implanting the TVT-O, although she could not "recall the last time" she reviewed it. (*See* Byrkit Dep. [Docket 213-1], at 31:15-18; 67:7-11; 206:2-9). Dr. Byrkit also stated that she uses "the same" implantation

procedure described in the IFU on every patient. (*See id.* at 90:3-15; 102:1-9). There is, therefore, sufficient evidence that Dr. Byrkit relied on the IFU in prescribing the TVT-O.[2]

Second, Ethicon argues that Dr. Byrkit would not have changed her decision to prescribe the TVT-O if she had received a better warning.[3] Dr. Byrkit's testimony is inconsistent. On the one hand, she testified that she would have changed her decision had she received a better warning:

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

(Byrkit Dep. [Docket 161-3], at 96:2-7). However, when asked whether she would again prescribe the TVT-O to a patient "with the same signs and symptoms" as the plaintiff, Dr. Byrkit responded that she "would use the TVT-O again." (*Id.* at 279:1-10). She also testified that she continues to use the TVT-O in her practice today. (*Id.* at 58:10-20). This conflicting testimony demonstrates the existence of a genuine dispute of fact over whether Dr. Byrkit would have prescribed the TVT-O to Ms. Huskey had she received a better warning. Therefore, under either the "substantial factor" or the "but-for" test, the plaintiffs have set forth evidence creating a genuine dispute of fact on the issue of causation.

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[2] Contrary to Ethicon's suggestion, this case is readily distinguishable from *Lewis v. Johnson & Johnson* on this issue. In *Lewis*, I dismissed the failure-to-warn claim in part because the treating physician affirmatively testified that she *did not rely* on the IFU when prescribing the device. She also testified that she relied on a number of other factors, including Ms. Lewis's "symptoms, her voiding diary, her urodynamics, and physical exam." *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, No. 2:12-cv-2327, 2014 WL 186869, at *4 (S.D. W. Va. Jan. 15, 2014). In this case, however, there is no such testimony by Dr. Byrkit.

[3] The parties disagree whether the plaintiffs are required to prove that Dr. Byrkit would have acted differently if she received a better warning. The cases cited by the parties conflict on this issue. *Compare Fisher v. Bristol-Myers Squibb Co.*, 181 F.R.D. 365, 370 (N.D. Ill. 1998) ("[S]tep two of the causation battle will require [the plaintiff] to show that his physician would not have prescribed Stadol if the defendants had provided adequate warnings."), *with Noyola v. Johnson & Johnson*, 85 C 2184, 1986 WL 14657, at *4 (N.D. Ill. Dec. 16, 1986) ("What a physician might or might not have done had he been adequately warned is not an element plaintiff must prove as a part of her case."). I need not resolve this issue here because the plaintiffs presented evidence demonstrating that Dr. Byrkit would have acted differently.

Accordingly, Ethicon's motion for summary judgment on the failure-to-warn claim is **DENIED**.

IV. Fraud-Based Claims and Warranty Claims

The plaintiffs bring several claims based on fraud: common law fraud, fraudulent concealment, constructive fraud, and negligent misrepresentation. I refer to these claims as the plaintiffs' "fraud-based claims." The plaintiffs also bring claims for breach of express and implied warranties. Ethicon argues that all of these claims are simply repackaged failure-to-warn claims, to which the learned intermediary doctrine applies and prevents recovery. I agree with Ethicon.

Under the learned intermediary doctrine, manufacturers of drugs and medical devices have a duty to warn prescribing physicians, not end-users, about the product's dangerous propensities. *Hansen*, 764 N.E.2d at 42; *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 N.E.2d 387, 393 (Ill. 1987). The prescribing physician functions as a learned intermediary between the manufacturer and the patient by deciding which product "best fits the patient's needs and choos[ing] which facts from the various warnings should be conveyed to the patient[.]" *Kirk*, 513 N.E.2d at 393. Ethicon argues that because Illinois's learned intermediary doctrine does not require medical device manufacturers to warn end-users, the doctrine should bar the fraud-based claims premised on representations made to Ms. Huskey. Otherwise, Ethicon contends, plaintiffs could simply plead around the learned intermediary doctrine by characterizing failure-to-warn claims as fraud claims.

Illinois courts have not directly addressed this issue. However, courts around the country have extended the learned intermediary doctrine to all claims based on a manufacturer's failure to warn, including claims for fraud, misrepresentation, and breach of warranty. *See, e.g.*, *Talley v. Danek Med., Inc.*, 179 F.3d 154, 163-64 (4th Cir. 1999) (barring breach of warranty and fraud claims); *Lee v. Mylan, Inc.*, 806 F. Supp. 2d 1320, 1325 (M.D. Ga. 2011) (negligent

misrepresentation and breach of warranty claims); *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1372 (S.D. Fla. 2007) (negligent misrepresentation); *Southern v. Pfizer, Inc.*, 471 F. Supp. 2d 1207, 1218 (N.D. Ala. 2006) (fraudulent misrepresentation); *In re Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. 700, 709 (E.D. Tex. 1997) (misrepresentation and implied warranty); *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 169 (Tex. 2012) (fraud by omission).

Here, the plaintiffs' fraud-based claims and warranty claims are simply repackaged failure-to-warn claims. The plaintiffs appear to concede that their fraud-based claims are based solely on representations made by Ethicon to Ms. Huskey. They state that these claims "in no way rely on anything that Ethicon communicated to Dr. Byrkit, or anything that Dr. Byrkit told to Mrs. Huskey," (Pls.' Mem. in Opp. to Ethicon's Mot. for Summ. J. [Docket 213], at 15). But Ms. Huskey was unable to identify any particular statements *by Ethicon* upon which she relied:

> Q: What information did you rely on that you received from Johnson & Johnson and Ethicon to inform your decision about whether or not to have the mesh surgery? You personally, not your doctor.
>
> A: There was no information as far as I'm aware of. It was not provided.
>
> Q: So what information from Johnson & Johnson and Ethicon about possible risks and benefits associated with mesh or with the TVT mesh product did you rely upon in making your decision to have the surgery?
>
> A: Once again, there was no information available on what I looked at.
>
> Q: There was no information available on what? On risks and benefits?
>
> A: Well, when I opened the brochure I looked through it, and what I saw and then having the discussion with Dr. Byrkit, after what she had explained to me and reading through the information that I did see, there wasn't any big warnings as far as, you know, if you look at a brochure and you look at cautionary measures, normally they stand out on a brochure because that's one of the things where they want you to make sure you read that. And there was nothing in that brochure that jumped out for, okay, there's a FDA warning, there was nothing that drew my attention to it as being something highlighted as risks involved with mesh.

(Huskey Dep. [Docket 161-4], at 474:20-476:3). This inability to identify any particular fraudulent statements upon which Ms. Huskey relied indicates that the gravamen of these claims is Ethicon's failure to warn Ms. Huskey about particular risks or dangers associated with the TVT-O. If the learned intermediary doctrine "could be avoided by casting what is essentially a failure to warn claim under a different cause of action . . . then the doctrine would be rendered meaningless." *In re Norplant Contraceptive Products Liab. Litig.*, 955 F. Supp. 700, 709 (E.D. Tex. 1997). Accordingly, I predict with confidence that, if confronted with this issue, the Illinois Supreme Court would hold that the learned intermediary doctrine applies to all claims based on a medical device manufacturer's failure to warn, including fraud, fraudulent concealment, constructive fraud, negligent misrepresentation, and breach of warranty.[4] Therefore, Ethicon's motion for summary judgment on fraud-based claims and warranty claims is **GRANTED**.

V. Unjust Enrichment, Manufacturing Defect Claims, Illinois Consumer Fraud Act

Ethicon moves for summary judgment on the plaintiffs' claims for unjust enrichment, manufacturing defect, and violation of the Illinois Consumer Fraud Act, 815 Ill. Comp. Stat. 505/1 *et seq*. The plaintiffs do not oppose summary judgment and withdraw these claims. (*See* Pls.' Mem. in Opp. to Def. Ethicon's Mot. for Partial Summ. J. [Docket 213], at 15, 20). Therefore, Ethicon's motion for summary judgment on claims for unjust enrichment, manufacturing defect, and violation of the Illinois Consumer Fraud Act, 815 Ill. Comp. Stat. 505/1 *et seq.*, is **GRANTED as unopposed**.

[4] I note that Ethicon did not expressly argue in its opening brief that the learned intermediary doctrine applies to the warranty claims. "[T]he ordinary rule in federal courts is that an argument raised for the first time in a reply brief or memorandum will not be considered." *Mew Sporting Goods, LLC v. Johansen*, --- F. Supp. 2d ---, No. 1:13-cv-10, 2014 WL 222114, at *3 n.2 (N.D. W. Va. Jan. 21, 2014). However, Ethicon did assert that "[r]egardless of how [the plaintiffs' claims] are denominated, such claims can only succeed if the manufacturer gave defective warnings to the learned intermediary." (Mem. in Supp. of Mot. for Partial Summ. J. [Docket 162], at 13). This argument clearly applies with equal force to the warranty claims, allowing me to consider it here.

VI. Punitive Damages

Ethicon moves for summary judgment on the issue of punitive damages [Docket 187]. As previously stated, the law of New Jersey applies to the plaintiffs' claim for punitive damages. Ethicon argues that the New Jersey Product Liability Act ("NJPLA"), N.J. Stat. Ann. § 2A:58C-1 *et seq.*, precludes an award of punitive damages in this case. The NJPLA provides that manufacturers of medical devices are immune from punitive damages awards where their products have been approved, licensed, or generally recognized as safe and effective by the FDA. The relevant statute reads, in pertinent part,

> Punitive damages shall not be awarded if a drug or device or food or food additive which caused the claimant's harm *was subject to premarket approval or licensure by the federal Food and Drug Administration* under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq. *and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations*, including packaging and labeling regulations. . . . For purposes of this subsection, the terms "drug", "device", "food", and "food additive" have the meanings defined in the "Federal Food, Drug, and Cosmetic Act."

N.J. Stat. Ann. § 2A:58C-5 (emphasis added).[5] Ethicon contends that the FDA has endorsed and recognized the safety and effectiveness of the TVT-O in its 510(k) clearance. I decided this exact issue in relation to *Lewis v. Johnson & Johnson*. *See In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-cv-4301, 2014 WL 186869, at *10 (S.D. W. Va. Jan. 15, 2014). As I explained there, and in a separate opinion in that case, *Lewis v. Johnson & Johnson*, --- F. Supp. 2d ---, No. 2:12-cv-04301, 2014 WL 152374, at *4-6 (S.D. W. Va. Jan. 15, 2014), the FDA has not "approved or licensed" or "generally recognized" the TVT-O as "safe and effective." N.J. Stat. Ann. § 2A:58C-5.

[5] A portion of this statute, which I have omitted and which is not applicable here, was stricken by a New Jersey appellate court as preempted by federal law. *See McDarby v. Merck & Co.*, 949 A.2d 223 (N.J. Super. Ct. App. Div. 2008).

Ethicon states, without explanation, that this case is distinguishable from my holding in *Lewis*. (Mem. in Supp. of Mot. for Partial Summ. J. on Punitive Damages [Docket 188], at 11). Ethicon simply rehashes old arguments and, yet again, essentially asks that I reconsider an earlier decision. As Ethicon is well aware, it is improper to ask the court "to rethink what the Court ha[s] already thought through—rightly or wrongly." *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 649 (S.D. W. Va. 2013) (quotations omitted). Therefore, Ethicon's motion for summary judgment on the issue of punitive damages [Docket 187] is **DENIED**.

VII. Preemption

Ethicon moves for partial summary judgment based on preemption [Docket 178]. Ethicon argues that the plaintiffs' claims should be preempted to the extent that any claim contends "that PROLENE* in mesh degrades and that degradation leads to other consequences, such as infection." (Mot. for Partial Summ. J. Based on Preemption of Certain Claims ("Preemption Mot.") [Docket 178], at 2). Ethicon bases this argument on the fact that the Prolene suture, which they argue is a component part of the TVT-O, went through the FDA's rigorous premarket approval process, rather than the less stringent 510(k) clearance process. The Prolene suture is a different medical device and, like the mesh contained in the TVT-O, is made of polypropylene. This court examined that exact issue in *Lewis v. Johnson & Johnson* and found that the plaintiffs' claims were not preempted. *See* --- F. Supp. 2d ---, No. 2:12-cv-04301, 2014 U.S. Dist. LEXIS 4985, at *32 (S.D. W. Va. Jan. 15, 2014); *see also id.* at *4-5 for a discussion of the differences between 510(k) clearance and premarket approval. As noted in *Lewis*, the Supreme Court has determined that claims related to devices approved through the FDA's premarket approval process are preempted while claims related to medical devices cleared through the FDA's 510(k) clearance

process are not. *See id.* at *18-19; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322-23 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501-02 (1996).

Ethicon attempts to distinguish the instant case from *Lewis* and argues that the court has not yet addressed the following issues:

> (1) the fact that the FDA-approval of PROLENE* polypropylene for use in the body is the "status quo" for that material and, whatever the Court's views of the safety and efficacy considerations of the 510(k) process, the approval of that component is not stripped away because the device as a whole was later cleared through the 510(k) process; (2) that Plaintiffs' claims regarding degradation and resulting inflammation and infection stem from the PROLENE* polypropylene-based filaments, not the other parts of the kit; and (3) evidence that the quantity of PROLENE* used does not have any effect on whether the PROLENE* degrades when placed in the human body.

(Preemption Mot. [Docket 178], at 1-2). Ethicon's arguments are without merit. As I explained in *Lewis*,

> Ethicon's argument ignores the fact that the Prolene suture and the TVT are two entirely different medical devices that went through different FDA processes. Although Ethicon represents that the products are primarily composed of the same material, it does not automatically follow that the material is safe in both devices. The Prolene suture is a nonabsorbable surgical suture; the TVT is a form of transvaginal mesh. The Prolene suture consists of a single filament of polypropylene; the TVT is a mesh woven from knitted Prolene filaments. The average Prolene suture is a few inches long; the TVT measures one-half inches by sixteen inches, and contains many times the amount of polypropylene material. The Prolene suture is not intended to adhere to human tissue; the TVT is designed to adhere to human tissue. The Prolene suture is designed to be easily pulled out of the body; the TVT cannot be removed without invasive surgery. . . .
>
> The FDA's approval of the Prolene suture necessarily related to its use as a suture; it did not categorically approve Prolene filament for use in medical devices. When the FDA approved the Prolene suture, it stated that it had concluded the Prolene suture was "safe and effective *for use as recommended in the submitted labeling*." The FDA did not examine whether that same material was safe when woven together to create a transvaginal mesh product. Ethicon would like the court to determine that because the FDA found polypropylene is safe to use as a suture, it is automatically safe to use in transvaginal mesh. Although purportedly constructed of the same material, it is a different product, used in a different manner, for a different purpose. The plaintiffs have presented evidence demonstrating the

> difference in risk profiles between the Prolene suture and TVT, and evidence that the process of weaving the filaments creates different surface characteristics in the mesh. If a specific type of metal were approved for use in a bone screw via the premarket approval process, it would not follow that that same type of metal was safe in all medical devices, no matter what their function in the human body. The same is true for Prolene filament. It does not follow that the same Prolene filament that is safe for use as a suture is automatically safe for use in transvaginal mesh.

2014 U.S. Dist. LEXIS 4985, at *24-25 (internal citations omitted).

Additionally,

> "[p]ersuasive authority from other district courts . . . indicates that the preemption analysis is not applied differently to the component parts of a medical device and the medical device itself[.]" *Gavin v. Medtronic, Inc.*, CIV.A. 12-0851, 2013 WL 3791612, at *11 (E.D. La. July 19, 2013). Interestingly, the shoe is normally on the other foot—the defendant is arguing that a cause of action is preempted because a device underwent premarket approval, while the plaintiff is arguing there is no preemption because a component part of the device underwent 510(k) clearance. Courts addressing this issue have determined that a device should not be broken into its component parts in order to apply a preemption analysis . . . . The same reasoning used in those cases is applicable here: analyzing the component parts of a device separately from the device itself simply does not make sense.
>
> "To require that a distinction be drawn between the approval process of the individual components of a system and the system itself, would, it seems, add a level of complication to the medical device approval process not anticipated by Congress, the FDA, or medical device manufacturers." *Lewkut*, 724 F. Supp. 2d at 656. "It makes no sense—indeed, it would probably be impossible—to pick apart the components of a medical device and apply different preemption analyses to different components." *Riley*, 625 F. Supp. 2d at 780. Determining preemption based upon the component parts of a device, rather than the device as a whole, would create a legal quagmire whereby tort claims against one part of a device are preempted while tort claims against another part of a device are not. Indeed, this is exactly what Ethicon would like the court to declare—as Ethicon noted, its "motion addresses only the use of PROLENE filaments and does not address other alleged defects, such as mesh pore size." (Defs.' Mot. for Summ. J. [Docket 128], at 1).
>
> Analyzing each component of a medical device separately to determine whether claims are preempted would create a doctrine that forces courts to dissect every medical device. In that world, a different preemption analysis would apply to each part of the device, rather than the device as a whole. *See Phillips*, 2010 WL 2270683, at *5 n.4 (noting the "serious practical difficulties" with separating the device from its component parts to determine preemption). Particularly in complex litigation such as this, bright line rules are important to create clarity for all parties

> involved. The doctrine Ethicon asks this court to accept would only serve to create chaos in a field that is already difficult to navigate. Each involved party should be able to determine whether tort claims regarding a medical device are preempted based upon the review process the device actually went through. If the TVT had gone through the premarket approval process while the polypropylene filament had gone through the 510(k) process, I cannot imagine that Ethicon would think the component parts of a device should be analyzed separately from the device itself. As discussed above, Ethicon itself has recognized the importance of viewing the TVT as a whole, rather than just its component parts. Just as "a device receiving premarket approval cannot be separated into its component parts to avoid application of express preemption," *Gross*, 858 F. Supp. 2d at 487, a device receiving 510(k) approval cannot be separated into its component parts to create express preemption.

Id. at *27-32. None of Ethicon's arguments demonstrate that I should deviate from this reasoning. Although Ethicon may have rephrased some of its arguments and has submitted an additional declaration from an Ethicon employee, the legal reasoning here is the same as in *Lewis*.

Ethicon also argues that I should reconsider my ruling in *Lewis* based on the reasoning in two other cases: *Bertini v. Smith & Nephew, Inc.*, No. 13 Civ. 79, 2014 U.S. Dist. LEXIS 35837 (E.D.N.Y. Mar. 17, 2014) and *Simon v. Smith & Nephew, Inc.*, No. 13 CIV. 1909 PAE, 2013 WL 6244525 (S.D.N.Y. Dec. 3, 2013). These cases concern the same allegedly defective hip replacement system, the R3 Acetabular System, developed by Smith & Nephew. *See Bertini*, 2014 U.S. Dist. LEXIS 35837, at *2; *Simon*, 2013 WL 6244525, at *4. The R3 System "is a hip implant system used in total hip replacement procedures." *Bertini*, 2014 U.S. Dist. LEXIS 35837, at *2. "The R3 System is made up of the Acetabular Cup (shell) . . . and one of several possible liners." *Id.* The purpose of the liner is "to prevent the loosening of the hip components, which is a defect in total hip replacement systems that often results in pain and a decrease in the hip implant's stability." *Id.* The R3 System received 510(k) clearance from the FDA. *Id.* at *2-3. Later, Smith & Nephew developed a new hip replacement system, the Birmingham Hip Resurfacing ("BHR") System. *Id.* at 3. The BHR System was approved through the premarket approval process. *Id.*

Thereafter, the FDA granted supplemental premarket approval to the BHR System using the R3 acetabular metal hip liner. *Id.* at 3-4. Essentially, the premarket approval of the BHR System was amended to include one of the same components as the R3 System—the R3 acetabular metal hip liner. *See id.* Importantly, in both *Bertini* and *Simon*, the plaintiff was implanted with an R3 System (which received 510(k) clearance rather than premarket approval), not the BHR System. *See Bertini*, 2014 U.S. Dist. LEXIS 35837, at *12; *Simon*, 2013 WL 6244525, at *4.

In *Simon*, the plaintiff argued that the R3 System was defectively designed. *See* 2013 WL 6244525, at *4. The plaintiff argued that the design defect claims were not preempted because the R3 system was not approved through the premarket approval process. *See id.* at *4. The defendant argued that each of the plaintiff's claims "challenge[d] the safety and effectiveness of the optional metal liner; and the R3 metal liner was indeed [premarket]-approved." (*Id.*). The court's actual holding in *Simon* was that the plaintiff's Amended Complaint failed to state a claim for strict liability, negligence, and breach of implied warranty. *See id.* at *6, 7, 8. However, the court also found that even if the complaint had stated claims, those claims would have been preempted. *See id.* In relevant part, the court stated:

> [E]ven if the Amended Complaint were fairly read to assert a claim of design defect based solely on the optional metal liner, any such claim would be preempted. That is because the optional metal liner received supplemental [premarket] approval in conjunction with the BHR System. As noted, design defect claims regarding a [premarket]-approved device are squarely preempted by the [Medical Device Amendments to the Food, Drug and Cosmetic Act]. Such preemption extends to a component of a [premarket]-approved device.

Id. at *7. To support this proposition, the court cited to *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 656 (S.D. Tex. 2010), which stated: "To require that a distinction be drawn between the approval process of the individual components of a system and the system itself, would, it seems, add a level of complication to the medical device approval process not anticipated by Congress,

the FDA, or medical device manufacturers." *Id.* It also cited to *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 780 (D. Minn. 2009), for the proposition that "separating components of [premarket]-approved device to apply different preemption analysis 'makes no sense.'" *Id.*

I respectfully disagree with the *Simon* court's analysis. First, neither *Lewkut* nor *Riley* held that premarket approval of a component part of a device meant that all claims against a 510(k) cleared device were preempted. Notably, *Lewkut* dealt with a device that was, as a whole, approved through the premarket approval process. *See* 724 F. Supp. 2d at 652. That device contained a component that, prior to the device's premarket approval, was cleared through the 510(k) process. *See id.* The court in *Lewkut* found the fact that the component part "was previously approved through only the § 510(k) process, and was commercially available when" the medical device received premarket approval did "not change the fact that it was later subject to the more rigorous scrutiny of the [premarket approval] process as a component of" the full medical device. *Id.* at 657. The court ultimately held that because the entire device had gone through the premarket approval process, the plaintiff's claims were preempted. *See id.* at 658. The *Simon* court's reliance on *Lewkut* is misplaced; in *Lewkut*, the entire device had received premarket approval.

The other case relied upon by the *Simon* court, *Riley*, also dealt with a device that had received premarket approval. *See* 625 F. Supp. 2d at 774-75. The plaintiff there argued that because the approved device was coated with a drug, the preemption analysis of *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322-23 (2008), should not apply. *See id.* at 779. The *Riley* court noted that the device at issue was "not merely a drug or merely a drug-delivery system; it [was] instead a compound of mechanical and chemical parts that work together as a single medical device. In approving the [device], the FDA exercised its authority to regulate medical devices, not its authority to regulate drugs." *Id.* It also noted that the plaintiff's claims were "manifestly claims

against the device as a whole." *Id.* at 780. The court found that because the FDA had approved and regulated the completed product as a medical device, the court should apply the express preemption analysis set forth in *Riegel*. *See id.*

As the above discussion reveals, the *Simon* court's reliance on *Lewkut* and *Riley* as support for applying total preemption to a medical device that only received 510(k) clearance was misguided. Both *Lewkut* and *Riley* dealt with whether product liability claims regarding a device that received premarket approval were preempted; the Supreme Court has been clear that they are. *See Riegel*, 552 U.S. at 330 ("State requirements are pre-empted under the [Medical Device Amendments] . . . to the extent that they are 'different from, or in addition to' the requirements imposed by federal law."). The Supreme Court has been equally clear that product liability claims regarding a device that received 510(k) clearance are *not* preempted. *See Medtronic v. Lohr*, 518 U.S. 470, 494 (1996). The courts in *Lewkut* and *Riley* followed the Supreme Court precedent that claims against a device that receives premarket approval are generally preempted.[6] The court in *Simon*, on the other hand, deviated from Supreme Court precedent which found that claims against a device receiving 510(k) approval are *not* preempted. Read in their entirety, the cases cited in *Simon* do not suggest that premarket approval of a component part of a device means that claims against the entire device should be preempted.

The *Bertini* court's analysis likewise seems to confuse the preemption analysis. The court repeatedly notes that preemption applies to a device as a whole rather than component parts but then finds that the plaintiffs' claims are preempted because of the premarket approval of a component part, ignoring the status of the device as a whole:

[6] Claims against a device that received premarket approval are not preempted to the extent that they assert that the device manufacturer failed to obey FDA requirements. *See Riegel*, 552 U.S. at 330 (stating that the Federal Food, Drug and Cosmetic Act "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations"). However, this exception is irrelevant to the instant case.

> While the R3 metal liner is just one part of the hip replacement system, it is the main focus of plaintiffs' Complaint. Plaintiff[]s attribute Mr. Bertini's injuries to two separate but interrelated defects: "the loosening of the R3 metal liner and the failure of the locking mechanism in the R3 System to hold the R3 metal liner in place." The liner's purpose is to prevent the other hip components, including the R3 acetabular shell and its locking mechanism, from loosening. Similarly, the locking mechanism feature is supposed to ensure that the liner stays connected to the R3 acetabular shell; essentially, it assists the liner in performing the liner's function. Although plaintiffs describe these device failures as two separate defects, they are in large part describing the same phenomena—the R3 metal liner's inability to attach to the R3 acetabular shell, which resulted in plaintiffs' injuries.
>
> Because plaintiff's injuries are alleged to have been caused by the failure of multiple components, I must apply a preemption analysis for the hip replacement system as one unit, and not examine each individual component. Assuming that I did apply a preemption analysis to each individual component, I would find that plaintiff's claims with respect to the R3 metal liner, which received PMA approval, would be preempted, whereas the claims related to the R3 System, including the R3 acetabular shell and locking mechanism, would not be preempted. But, left solely with their claims with respect to the R3 System, plaintiffs would be unable to show that the R3 acetabular shell and its locking mechanism alone proximately caused plaintiffs' injuries, because plaintiffs have plead that the R3 System and the R3 metal liner together were the cause of plaintiff's injuries. Plaintiffs would have to prove that the R3 acetabular shell did not stay attached to the R3 metal liner, without being able to argue, as they have repeatedly throughout this litigation, that this failure to attach was due in large part to the R3 metal liner improperly loosening from the R3 acetabular shell. Therefore, if a claim involving the R3 metal liner's alleged defect is preempted, the entire claim should be dismissed because plaintiffs will be unable to sufficiently plead the remainder of that claim.

2014 U.S. Dist. LEXIS 35837, at *12-14. I disagree with this reasoning. In approving the BHR system with the liner from the R3 System, the FDA did not examine the R3 liner's safety and efficacy with regard to other hip replacement systems—the FDA was instead looking at whether the BHR System, as a whole, was safe and effective. It is difficult to understand why the *Bertini* court found that premarket approval of one medical device meant that claims against an entirely different medical device were preempted. While these cases from other district courts outside of the Fourth Circuit may be cited to as persuasive authority, I do not find either of them persuasive in light of existing Supreme Court precedent and federal regulations.

Preemption is based on FDA premarket approval of a medical device, not its component parts. Supreme Court precedent speaks to whether a specific *device* underwent premarket approval or 510(k) clearance. *See generally Riegel,* 552 U.S. 312; *Lohr*, 518 U.S. 470. The relevant federal statute speaks to the approval or clearance of *devices*. *See generally* 21 U.S.C. § 360, *et seq*. The regulations interpreting the preemption provision of that federal statute discuss *devices*. *See* 21 C.F.R. 808.1. As I stated in *Lewis,* "[j]ust as a device receiving premarket approval cannot be separated into its component parts to avoid application of express preemption, a device receiving 510(k) approval cannot be separated into its component parts to create express preemption." 2014 U.S. Dist. LEXIS 4985, at *32 (internal quotation omitted). The Supreme Court and federal regulations instruct that state requirements are preempted "only when the Food and Drug Administration has established specific counterpart regulations or there are *other specific requirements applicable to a particular device*." *Riegel*, 552 U.S. at 322 (quoting 21 C.F.R. § 808.1(d) (emphasis added). The fact that the Prolene suture underwent premarket approval is irrelevant to whether the 510(k) process sets forth specific requirements applicable to the TVT-O. The law is clear that it does not.

For the reasons set forth above, Ethicon's motion for partial summary judgment based on preemption [Docket 178] is **DENIED**.

VIII. Separate Defenses

The plaintiffs move for summary judgment on several of Ethicon's separate defenses [Docket 163]. Ethicon listed its separate defenses in its Master Answer and Jury Demand of Defendant Ethicon, Inc. to First Amended Master Complaint [Docket 2-2]. In response to the plaintiffs' motion, Ethicon now withdraws most of these defenses. Accordingly, for the following defenses, the plaintiffs' motion for summary judgment is **GRANTED as unopposed**: 1, 3, 4, 5, 6,

7, 8, 9, 11, 13, 14, 25, 30, 32, 33, 35, 42, 45, 49, 50, 51, 52, 55, 57, 58, 60, 62, 67, 68, 76, 77, 78, and 79.

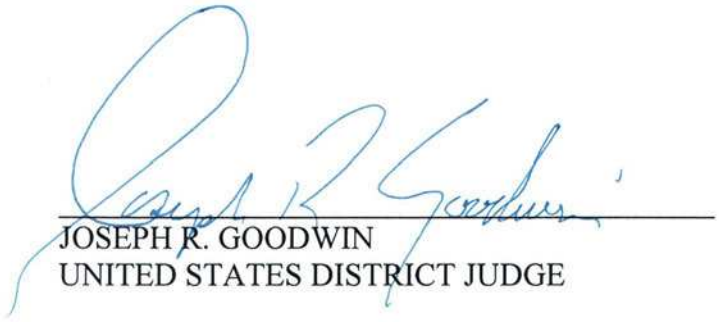
Ethicon opposes summary judgment on the remaining separate defenses, which relate to punitive damages, preemption, and federal regulations. Ethicon refers the court to the arguments contained in its Motion for Partial Summary Judgment on Punitive Damages [Docket 187] and Motion for Partial Summary Judgment Based on Preemption of Certain Claims [Docket 178]. I have already addressed and rejected Ethicon's arguments contained in those motions and supporting memoranda. Therefore, for the following defenses, which relate to punitive damages, preemption, and federal regulations, the plaintiffs' motion for summary judgment is **GRANTED**: 10, 15, 16, 17, 18, 19, 20, 22, 23, 24, 39, 59, 74, and 75.

IX. Conclusion

For the reasons stated above, Ethicon's Motion for Partial Summary Judgment [Docket 161] is **GRANTED in part** and **DENIED in part**, Ethicon's Motion for Partial Summary Judgment Based on Preemption of Certain Claims [Docket 178] is **DENIED**, Ethicon's Motion for Partial Summary Judgment on Punitive Damages [Docket 187] is **DENIED**, and Plaintiffs Jo and Allen Huskey's Motion for Partial Summary Judgment on Defendant Ethicon Inc.'s Separate Defenses [Docket 163] is **GRANTED**.

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

ENTER: July 8, 2014



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE