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

CHARLESTON DIVISION

CAROLYN LEWIS, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:12-cv-04301

JOHNSON & JOHNSON, et al.,

Defendants.

MEMORANDUM OPINION AND ORDER
(Motion in Limine No. 1, Summary Judgment Motions on 510(k) Issue)

Pending are Plaintiffs' Motion in Limine No. 1 – 510(k) Clearance of the Ethicon Mesh Products by the United State Food and Drug Administration ("FDA"), or Lack of FDA Enforcement Action [Docket 124], Defendants' Motion for Partial Summary Judgment Based on Preemption of Certain Claims [Docket 128], and Plaintiffs' Motion for Partial Summary Judgment [Docket 150]. The motions are ripe for review. For the reasons set forth below, Plaintiffs' Motion in Limine No. 1 [Docket 124] is **GRANTED**, Defendants' Motion for Partial Summary Judgment Based on Preemption of Certain Claims [Docket 128] is **DENIED**, and Plaintiffs' Motion for Partial Summary Judgment [Docket 150] is **GRANTED**.

I. Background

A. Factual and Procedural History

This multidistrict litigation involves surgical mesh products manufactured and sold by the defendants, Ethicon, Inc. and Johnson & Johnson, Inc. (collectively "Ethicon") to treat pelvic organ prolapse and stress urinary incontinence. One of the devices produced by Ethicon is the

Gynecare TVT ("TVT"), which was implanted in the plaintiff, Ms. Lewis. The instant case is the first bellwether trial scheduled in this MDL, and trial is set to begin on February 10, 2014.

There are three motions currently before the court. The first is Plaintiffs' Motion in Limine No. 1 – 510(k) Clearance of the Ethicon Mesh Products by the United State Food and Drug Administration, or Lack of FDA Enforcement Action [Docket 124]. In it, the plaintiffs argue that evidence related to FDA clearance and regulation of the TVT should be excluded under Federal Rules of Evidence 402 and 403. The plaintiffs contend that because the FDA's 510(k) clearance process is not related to safety and efficacy, evidence of the clearance is irrelevant and misleading to the jury. The defendants respond that compliance with FDA regulations is relevant and admissible, that the TVT's clearance is relevant to its safety and effectiveness, and that post-clearance FDA regulation also relates to safety and effectiveness.

The second motion is Defendants' Motion for Partial Summary Judgment Based on Preemption of Certain Claims ("Defs.' Mot. for Summ. J.") [Docket 128]. The defendants primarily argue that because the TVT is made with the same material that is in another device approved through the FDA's premarket approval process, state law tort claims related to the TVT are preempted. The plaintiffs contend that Ethicon's discussion of the premarket approval of other medical devices is irrelevant to the TVT and the case at hand.

The third motion is Plaintiffs' Motion for Partial Summary Judgment [Docket 150]. In it, the plaintiffs argue that three affirmative defenses provided for by Texas law do not apply to Ethicon. The plaintiffs state that two of the defenses fail because they speak only to products that have been approved by the FDA, and the TVT was not approved by the FDA. They also argue that

a third affirmative defense does not apply because it relates only to mandatory safety regulations, and no such regulations exist in this case.

B. The FDA 510(k) Approval Process

The TVT is a Class II medical device regulated by the FDA. In order to market and sell the TVT, Ethicon went through the FDA's 510(k) clearance process. *See* 21 C.F.R. § 807.87, 807.92, 807.93 (2012) (describing the requirements for 510(k) clearance). The 510(k) clearance process "imposes a limited form of review" on manufacturers of qualifying devices. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996). "If the FDA concludes on the basis of the § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis[.]" *Id.* This is an easier bar to pass than the FDA's rigorous premarket approval process, under which "[m]anufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." *Id.* at 477; *see also id.* at 478-79 ("The § 510(k) notification process is by no means comparable to the [premarket approval] process; in contrast to the 1,200 hours necessary to complete a [premarket approval] review, the § 510(k) review is completed in an average of only 20 hours. As one commentator noted: 'The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly.'") (internal citations omitted); *Horn v. Thoratec Corp.*, 376 F.3d 163, 167 (3d Cir. 2004) ("A manufacturer can obtain an FDA finding of 'substantial equivalence' by submitting a pre-market notification to the agency in accordance with Section 510(k) of the [Federal Food, Drug and Cosmetic] Act. A device found to be 'substantially equivalent' to a predicate device is said to be 'cleared' by FDA (as opposed to

'approved' by the agency under a [premarket approval]). *A pre-market notification submitted under Section 510(k) is thus entirely different from a [premarket approval], which must include data sufficient to demonstrate to FDA that the device is safe and effective*.") (quoting Amicus Curiae Letter Brief to the Court, filed by the FDA) (internal citations omitted) (emphasis in original).

The Supreme Court has determined that the 510(k) process is focused on equivalence with a preexisting device rather than safety, while the premarket approval process is focused on safety and efficacy. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008); *Lohr*, 518 U.S. at 478-79, 493. Because of the differences in these processes, tort claims regarding medical devices cleared through the 510(k) process are not preempted by federal law, while tort claims regarding medical devices approved through the premarket approval process generally are preempted. *Riegel*, 552 U.S. at 321-23; *Lohr*, 552 U.S. at 501-02.[1]

II. Legal Standards

A. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pre-trial motions. In multidistrict litigation cases such as this, the choice-of-law for these pre-trial motions depends on whether they involve federal or state law. "When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located." *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted); *see also* 15 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 3866 (3d

[1] Not all tort claims regarding medical devices that have gone through premarket approval are preempted. However, "because of the congressional balance reflected in the [Medical Device Amendments to the Federal Food, Drug and Cosmetic Act], a plaintiff's state law cause of action based on injuries caused by a Class III medical device could only survive if the alleged malfunction also violated a federal requirement." *Walker v. Medtronic, Inc.*, 670 F.3d 569, 579 (4th Cir. 2012).

ed. 2009). This is in accordance with the law in this circuit. *See Bradley v. United States*, 161 F.3d 777, 782 n.4 (4th Cir. 1998) ("[T]his court cannot and does not apply the law of another circuit simply because the case was transferred from the other circuit.").

The Honorable Shira A. Scheindlin has made a similar observation that the law of the transferee circuit applies:

> [C]ourts have held that the law of the transferee circuit controls pretrial issues such as whether the court has subject matter or personal jurisdiction over the action, or whether the cases should be remanded to state court because the cases were not properly removed.

In re Methyl Tertiary Butyl Ether ("MTBE") Prods. Liab. Litig., 241 F.R.D. 435, 439 (S.D.N.Y. 2007) (footnote omitted). Judge Scheindlin's observation, as noted in her opinion, reflects the general approach. *See, e.g.*, *In re Linerboard Antitrust Litig.*, No. 04 Civ. 4001, MDL 1261, 2005 WL 1625040, at *4 (E.D. Pa. July 11, 2005) (applying the law of the Third Circuit on a motion to dismiss for lack of subject matter jurisdiction); *In re Bridgestone/Firestone, Inc., Tires Prods. Liab. Litig.*, 256 F. Supp. 2d 884, 888 (S.D. Ind. 2003) (applying the law of the Seventh Circuit on a motion for remand to state court). Pursuant to this doctrine and this court's Order on summary judgment motions, Texas substantive law will apply to the plaintiffs' tort claims, New Jersey law will apply to the plaintiffs' punitive damages claims, and the law of the Fourth Circuit will apply to issues of federal law.

B. 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., Ltd. 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).

C. Preemption

Federal preemption originates from the Constitution's Supremacy Clause. *See* U.S. Const. art. VI, cl. 2.[2] In addressing a preemption issue, the court's first task is to determine whether Congress intended to preempt. *See California 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

[2] "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.

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 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).

III. Discussion

A. Plaintiffs' Motion in Limine No. 1 – 510(k) Clearance of the Ethicon Mesh Products by the FDA, or Lack of FDA Enforcement Action

The plaintiffs argue that any evidence of FDA clearance of Ethicon's mesh products or FDA enforcement actions should be excluded because the 510(k) process does not relate to the safety or efficacy of the product. Therefore, evidence of FDA clearance should be excluded as irrelevant under Federal Rule of Evidence 402 and misleading under Rule 403. Ethicon argues that such evidence is relevant and admissible. I **FIND** that evidence of FDA clearance and enforcement should be excluded under Federal Rules of Evidence 402 and 403.

Rule 403 provides that even relevant evidence may be excluded "if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Evidence regarding the 510(k) process poses a substantial risk of misleading the jury and confusing the issues. That a device has been given clearance through the FDA's 510(k) process is not relevant to state tort law. Admission of any evidence regarding the 510(k) process runs the risk of misleading the jury to believe that FDA 510(k) clearance might be dispositive of the plaintiffs' state law claims.. The prejudicial value of evidence regarding the 510(k) process far outweighs its probative value.

Both parties cite to the Third Restatement of Torts to support their position. The Restatement states that "a product's compliance with an applicable *product safety statute or administrative regulation* is properly considered in determining whether the product is defective[.]" (emphasis added). Restatement (Third) of Torts: Products Liability § 4 (1998). The comments to this section specifically explain that the phrase "safety statute or administrative

regulation" is meant to encompass regulations "that establish binding safety standards for the design and marketing of products." *Id.* § 4 cmt. a. Similarly, "the safety statute or administrative regulation must be such that compliance reduces the risk that caused the plaintiff's harm." *Id.* § 4 cmt. c.

The 510(k) process is not a safety statute or administrative regulation. The Supreme Court has determined that "the 510(k) process is focused on equivalence, not safety." *Lohr,* 518 U.S. at 493 (internal quotation omitted); *see also Riegel,* 552 U.S. at 323 ("While § 510(k) is focused on equivalence, not safety, premarket approval is focused on safety, not equivalence.") (internal quotation omitted).[3] FDA regulations also note that 510(k) clearance "does not in any way denote official approval of the device." 21 C.F.R. § 807.97 (2012). The FDA thus prohibits manufacturers of devices cleared through the 510(k) process from making any representations that their devices have been approved by the FDA. *See id.* ("Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding."). Because the FDA's 510(k) clearance of the TVT does not speak to its safety or efficacy, it is irrelevant to this case and inadmissible under Rule 402.

Ethicon argues that even if 510(k) clearance does not relate to safety and efficacy, the subsequent FDA regulation of a Class II medical device *does* relate to its safety and efficacy. However, admission of evidence regarding FDA enforcement actions against Ethicon (or the lack thereof) runs the same risk of misleading the jury as the 510(k) clearance process. Jurors are likely

[3] Other courts interpreted *Lohr* as holding that the 510(k) process does not go to whether a product is safe and effective, and that the 510(k) process does not impose any requirements on its own. *See, e.g., Martin v. Am. Med. Sys., Inc.*, 116 F.3d 102, 104 (4th Cir. 1997); *Bass v. Stryker Corp.*, 669 F.3d 501, 507 (5th Cir. 2012); *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 794 (8th Cir. 2001); *Mack v. Stryker Corp.*, 893 F. Supp. 2d 976, 985 (D. Minn. 2012); *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 747 n.6 (E.D. Pa. 2007); *Nicoll v. I-Flow, LLC*, No. 12-1593, 2013 WL 2477032, at *3 (E.D. La. June 7, 2013).

to believe that FDA enforcement relates to the validity of the plaintiffs' state law tort claims, which it does not. As the plaintiffs note, Ethicon itself has argued in at least one other case that evidence related to FDA regulation is misleading and irrelevant. (*See* Pls.' Reply in Supp. of Mot. in Limine No. 1 – 510(k) Clearance of the Ethicon Mesh Prods. by the FDA, or Lack of FDA Enforcement Action ("Pls.' Reply") [Docket 167], at 1-2; Pls.' Reply Ex. 1 [Docket 167-1]). In that case, Ethicon argued that "the jury may attach undue significance" to an FDA determination, and that "alleged shortcomings in FDA procedures are not probative to a state law products liability claim[.]" (Pls.' Reply Ex. 1 [Docket 167-1], at 6). I agree with this reasoning.

Ethicon also contends that the TVT's clearance is relevant to its safety and efficacy, because the TVT was cleared "with reference" to a product that had gone through the premarket approval process. This, too, is irrelevant to the case at hand. The product that went through the premarket approval process is not the TVT. It is a different medical device that was approved for a different purpose. I will discuss the differences between these devices further in the preemption section, below.

In sum, the parties may not present evidence regarding the 510(k) clearance process or subsequent FDA enforcement actions. This is consistent with prior rulings by this court. *See, e.g.*, *Cisson v. C.R. Bard, Inc.*, No. 2:11-cv-00195, 2013 U.S. Dist. LEXIS 102699, at *22 (S.D. W. Va. July 23, 2013) ("The FDA 510(k) process does not go to safety and effectiveness and does not provide any requirements on its own. Basically, it has no operative interaction with state tort laws.") (internal reference omitted); Order, *Cisson v. C.R. Bard, Inc.*, No. 2:11-cv-00195 (S.D. W. Va. July 1, 2013), [Docket 309], at 3-4 ("Under United States Supreme Court precedent, the FDA 510(k) process does not go to whether the product is safe and effective . . . . Because the FDA

510(k) process does not go to whether the [mesh] products are safe and effective and the 510(k) process does not impose any requirements on its own, the 510(k) process is inapplicable to this case. This evidence is excluded under Federal Rule of Evidence 402 as irrelevant, and under Rule 403 for the reasons previously stated, including the very substantial dangers of misleading the jury and confusing the issues."); Mem. Op. & Order, *Cisson v. C.R. Bard, Inc.*, No. 2:11-cv-00195 (S.D. W. Va. June 27, 2013) [Docket 302], at 3-4 (holding that evidence regarding the 510(k) process and enforcement should be excluded under Rule 403).

B. Defendants' Motion for Partial Summary Judgment Based on Preemption of Certain Claims

The Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA") contain an express preemption provision. The provision provides that, with respect to medical devices, state law may not impose any requirement "which is different from, or in addition to" the requirements of the FDCA, or any requirement "which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the FDCA]." 21 U.S.C. § 360k(a) (2012).

The Supreme Court has determined that the FDCA's preemption provision does not apply to products liability claims regarding medical devices that underwent 510(k) clearance rather than the premarket approval process. *Lohr*, 518 U.S. at 501-02. In *Lohr*, the Court found that because the 510(k) requirements did not relate to the safety or efficacy of the device, they did not preempt state tort claims. *Id.* As the Court noted,

> The generality of [the 510(k)] requirements make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or

> producers. Rather, the federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements.

Id. at 501. Because of this, the Court reasoned, the FDCA's preemption provision does not apply to products that received clearance through the 510(k) process.

The FDCA's preemption provision does apply, however, to medical devices approved through the premarket approval process. *Riegel*, 552 U.S. at 322-23. The Supreme Court explained this distinction:

> While § 510(k) is focused on equivalence, not safety, premarket approval is focused on safety, not equivalence. While devices that enter the market through § 510(k) have never been formally reviewed under the MDA for safety or efficacy, the FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness. And while the FDA does not require that a device allowed to enter the market as a substantial equivalent take any particular form for any particular reason, the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness.

Id. at 323. "In sum, the Supreme Court held that the terms of a . . . device's premarket approval constitute federal requirements and that a common law tort claim premised on different or additional requirements is preempted by the MDA." *Walker v. Medtronic, Inc.*, 670 F.3d 569, 577 (4th Cir. 2012).

Ethicon argues that the plaintiffs' claims are preempted to the extent that they relate to the use of Prolene polypropylene filaments in the TVT. This argument is related to the components of the TVT mesh rather than the 510(k) clearance process that the TVT went through. Ethicon represents that the "TVT is made of PROLENE mesh . . . . PROLENE mesh in turn consists of knitted PROLENE filaments, which are composed of the same material as PROLENE suture. That

material is polypropylene to which proprietary ingredients have been added." (Mem. in Supp. of Mot. for Partial Summ. J. Based on Preemption of Certain Claims ("Mem. in Supp.") [Docket 129], at 2). Unlike the TVT, which went through the 510(k) clearance process, the Prolene suture went through the more rigorous premarket approval process.[4] Thus, Ethicon argues, any argument by the plaintiffs that the Prolene filaments are defective is preempted by federal law.

Ethicon's argument in support of preemption is premised on the FDA's premarket approval of the Prolene suture, not the 510(k) clearance of the TVT. Essentially, Ethicon argues that because the FDA confirmed the safety and effectiveness of the Prolene suture, and the TVT is composed of the same material as the Prolene suture, the plaintiffs should be barred from arguing that the Prolene material is defective. At first glance, this argument appears to have some merit—after all, the FDA gave the Prolene suture its stamp of approval and confirmed its safety and efficacy. However, 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.[5] 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

[4] The Prolene suture went through the FDA's new drug approval process rather than today's medical device premarket approval process because it was produced prior to the 1976 MDA. However, after the MDA was passed, Prolene was subject to premarket approval, supplemented its premarket approval application several times, and was regulated as a Class III medical device. It has since been reclassified as a Class II medical device. (*See generally* Decl. of Reynaldo Librojo in Supp. of Mot. for Summ. J [Docket 128-1]).

[5] Notably, the TVT did not even gain its 510(k) clearance due to its equivalence to the Prolene suture—it gained its clearance due to its equivalence to the Boston Scientific Protegen. (Pls.' Resp. Ex.1 (Cecchini Dep.) [Docket 174-1], at 4).

sixteen inches, and contains many times the amount of polypropylene material.[6] The Prolene suture is not intended to adhere to human tissue; the TVT is designed to adhere to human tissue.[7] The Prolene suture is designed to be easily pulled out of the body; the TVT cannot be removed without invasive surgery.[8]

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*." (Defs.' Mot. for Summ. J. Ex. 4 (FDA Approval Letter) [Docket 128-5], at 1) (emphasis added)). 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, (*see* Pls.' Resp. in Opp'n Ex. 5 (Dep. of Ethicon Vice President of Clinical Development and Medical Affairs Jim Hart) [Docket 174-5], at 3-4), and evidence that the process of weaving the filaments creates different surface characteristics in the mesh (*see* Pls.' Resp. in Opp'n Ex. 6 (Report Investigating Mesh Erosion in Pelvic Floor) [Docket 174-6], at 37 ("The knitting process produces a mesh with a 'technical front' and 'technical back'; these have different surface

[6] Defs.' Mot. for Summ. J. Ex. 18 (TVT 510(k) Notification) [Docket 128-19], at 11; Pls.' Resp. in Opp'n [Docket 174], at 5 (quoting Ethicon's description of the suture at http://www.ecatalog.ethicon.com/sutures-non-absorbable/view/prolene-suture).

[7] Pls.' Resp. in Opp'n [Docket 174], at 5 (quoting Ethicon's website).

[8] *Id.*

characteristics ('roughness') owing to the mesh construction.")). 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.

Furthermore, the TVT is a Class II medical device consisting of several components. Prolene filament is merely one component of the TVT. Although Ethicon focuses on the Prolene filament for the purposes of this motion, even they admit that the filament is not the only part of the TVT. (*See* Mem. in Supp. [Docket 129], at 9 (stating that the Prolene polypropylene is the "principal component" of the TVT)). The TVT—that is, the regulated medical device at issue in this case—consists of more than just Prolene filament. The TVT is "a sterile single-use device consisting of one piece of undyed PROLENE* polypropylene Mesh (tape) approximately ½ by 16 inches (1.1 x 40 cm), covered by a plastic sheath cut in the middle, and held between two stainless steel needles bonded to the mesh and sheath with plastic collars." (Defs.' Mot. for Summ. J. Ex. 18 (TVT 510(k) Notification) [Docket 128-19], at 11). Ethicon has pointed out the difference between the mesh itself and the final medical device in another case in this MDL:

> Plaintiffs' Motion to Remand rests in its entirety on the erroneous proposition that "the mesh is the device." This erroneous assertion is made with a total disregard for the FDA's classification and regulation of the Ethicon Products as Class II Medical Devices governed by the Federal Food and Drug Cosmetic Act, 21 U.S.C. § 301 *et seq*., and 21 C.F.R. §§ 800-98 . . . To accept Plaintiffs' argument that "the mesh is the device" would require the Court to ignore what the FDA classifies as the Class II medical device that is the subject of its regulatory authority and to accept that the individually cut mesh pieces, . . . which are only a part of the kit that makes up each Class II medical device, are somehow the same as the rolls of mesh that leave [the control of Ethicon's mesh producer].

(Defs. Ethicon, Inc., Gynecare, and Johnson & Johnson's Opp'n to Pls.' Mot. to Remand, *Musewicz v. Ethicon, Inc.*, No. 2:13-cv-26024 [Docket 16], at 4-5). Ethicon noted in that case that "the FDA does not classify or regulate the rolls of mesh; it classifies and regulates the final product manufactured by Ethicon, Inc., as a Class II medical device." (*Id.* at 4-5). Ethicon also described the process it goes through after it receives the woven rolls of mesh, stating it must "convert the knitted rolls of mesh into the finished . . . Ethicon Products, which includes cutting the large mesh rolls into individual units of implantable mesh, assembling these units with other component parts, such as the surgical tools, which are part of the Class II medical device, and sterilizing these different items." (*Id.* at 5).

"Persuasive 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. *See Smith v. Depuy Orthopaedics, Inc.*, CIV.A. 11-4139 JAP, 2013 WL 1108555, at *12 (D.N.J. Mar. 18, 2013) (finding plaintiff's claim was preempted where component parts of a device went through the 510(k) process but the device itself went through the premarket approval process); *Duggan v. Medtronic, Inc.*, 840 F. Supp. 2d 466, 471 (D. Mass. 2012) ("Many courts have held that once premarket approval is granted, all claims relating to all components of the device are preempted . . . . This analysis applies even

where a component of a [premarket]-approved device had previously been approved through the § 510(k) process."); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 487 (W.D. Pa. 2012) ("[A] device receiving premarket approval cannot be separated into its component parts to avoid application of express preemption."); *Bentzley v. Medtronic, Inc.*, 827 F. Supp. 2d 443, 452 (E.D. Pa. 2011) ("Plaintiff's contention that, in considering a preemption issue, the Court must break a medical device into its component parts, is without legal support. In fact, courts that have dealt with this issue have done just the opposite."); *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 656 (S.D. Tex. 2010) (stating other courts have "found, in the context of other medical devices, that attempting to separate the component parts of a medical device for purposes of preemption is not appropriate"); *Phillips v. Stryker Corp.*, 3:09-CV-488, 2010 WL 2270683 at *5, n.4 (E.D. Tenn. June 3, 2010) ("The Court notes the serious practical difficulties associated with plaintiff's divisibility argument, even were the Court inclined to accept it."); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 780 (D. Minn. 2009) (refusing to "pick apart the components of a medical device and apply different preemption analyses to different components"). 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.

Based upon the foregoing, I **FIND** that the plaintiffs' claims regarding the use of polypropylene are not preempted by federal law.

C. Plaintiffs' Motion for Partial Summary Judgment

In their motion for partial summary judgment, the plaintiffs argue that three affirmative defenses Ethicon plans to assert are inapplicable to this case. These affirmative defenses, found in Sections 82.007 and 82.008 of the Texas Civil Practice and Remedies Code, provide products liability defendants with rebuttable presumptions of adequate warnings and non-liability in certain situations.

1. Section 82.007

Section 82.007 of the Texas Civil Practice and Remedies Code ("Section 82.007") is only applicable to "products liability action[s] alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product." Tex. Civ. Prac. & Rem. Code § 82.007(a) (2013). The failure to warn and breach of express and implied warranty claims have been dismissed from this action. Therefore, I **FIND** that Section 82.007 does not apply to this case.

2. Section 80.008(a)

Section 82.008(a) of the Texas Civil Practice and Remedies Code ("Section 82.008(a)") states that:

> In a products liability action brought against a product manufacturer or seller, there is a rebuttable presumption that the product manufacturer or seller is not liable for any injury to a claimant caused by some aspect of the formulation, labeling, or design of a product if the product manufacturer or seller establishes that the

> product's formula, labeling, or design *complied with mandatory safety standards or regulations* adopted and promulgated by the federal government, or an agency of the federal government, that were applicable to the product at the time of manufacture and that governed the product risk that allegedly caused harm.

Tex. Civ. Prac. & Rem. Code § 82.008(a) (2013) (emphasis added). As discussed above, the TVT's 510(k) clearance does not relate to its safety or efficacy. Furthermore, Ethicon has not provided the court with any mandatory safety standards or regulations with which the TVT complied. Therefore, I **FIND** that Section 82.008(a) in inapplicable in this case.

3. Section 82.008(c)

Section 82.008(c) of the Texas Civil Practice and Remedies Code ("Section 82.008(c)") provides as follows:

> In a products liability action brought against a product manufacturer or seller, there is a rebuttable presumption that the product manufacturer or seller is not liable for any injury to a claimant allegedly caused by some aspect of the formulation, labeling, or design of a product if the product manufacturer or seller establishes that the product was subject to pre-market licensing or approval by the federal government, or an agency of the federal government, that the manufacturer complied with all of the government's or agency's procedures and requirements with respect to pre-market licensing or approval, and that *after full consideration of the product's risks and benefits the product was approved or licensed* for sale by the government or agency.

Tex. Civ. Prac. & Rem. Code § 82.008(c) (2013) (emphasis added). The FDA conducts a full analysis of the product's risks and benefits when a product goes through the premarket approval process, not the 510(k) clearance process. As discussed above, the 510(k) process relates to a medical device's equivalence to a pre-existing device; it does not require "full consideration of the product's risks and benefits[.]" Clearance through 510(k) notification also does not constitute FDA "approval" of the device. Therefore, I **FIND** that Section 82.008(c) does not apply to Ethicon in this case.

IV. Conclusion

Based upon the foregoing, Plaintiffs' Motion in Limine No. 1 [Docket 124] is **GRANTED**, Defendants' Motion for Partial Summary Judgment Based on Preemption of Certain Claims [Docket 128] is **DENIED**, and Plaintiffs' Motion for Partial Summary Judgment [Docket 150] is **GRANTED**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party. The court further **DIRECTS** the Clerk to post a copy of this published opinion on the court's website, www.wvsd.uscourts.gov.

ENTER: January 15, 2014

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE