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

CHARLESTON DIVISION

DIANNE M. BELLEW,

Plaintiff,

v. **CIVIL ACTION NO. 2:13-cv-22473**

ETHICON, INC., et al.,

Defendants.

MEMORANDUM OPINION AND ORDER
(Defendants' Motion for Partial Summary Judgment Based on Preemption)

Pending before the court is Defendants' Motion for Partial Summary Judgment Based on Preemption of Certain Claims ("Motion for Partial Summary Judgment") [Docket 124]. Responses and replies have been filed, and the motion is ripe for review. As set forth below, Defendant's Motion for Partial Summary Judgment [Docket 124] is **DENIED**.

I. Background

This bellwether case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 67,000 cases currently pending, approximately 22,000 of which are in the Ethicon, Inc. MDL, MDL 2327. In this particular case, the plaintiff was surgically implanted with the Prolift Anterior Pelvic Floor Repair System ("Prolift"), a mesh product manufactured by Ethicon and Johnson & Johnson (collectively, "Ethicon") to treat POP. (*See* Short Form Compl. [Docket 1],

at 2).[1] The plaintiff received her surgery in Arizona. (*Id.* at 3). The plaintiff claims that as a result of implantation of the Prolift, she has experienced multiple complications, including mesh erosion, mesh contraction, inflammation, dyspareunia (pain during sexual intercourse), urinary incontinence, chronic pain, and recurring prolapse of organs. (Master Compl. ¶ 49). In addition, she had four subsequent operations to remove and revise the implanted mesh. (Pl. Fact Sheet [Docket 206-1], at 7). The plaintiff alleges negligence, failure to warn, design defect, common law fraud, fraudulent concealment, negligent misrepresentation, breach of express warranty, violation of consumer protection laws, gross negligence, and punitive damages. (Short Form Compl. [Docket 1], at 4).[2]

In the instant motion, Ethicon moves for partial summary judgment on "any claim that the Prolene polypropylene filaments used in the [Prolift] mesh are a defective or negligently designed product or that the Defendants had any duty to warn about . . . any other risks from the filament material beyond the warnings that Ethicon actually gave." (Mot. for Partial Summ. J. Based on Preemption of Certain Claims [Docket 124], at 1). In making this argument, Ethicon turns again to the doctrine of federal preemption, and so, for the third time in the course of this MDL, I must consider whether the FDA's premarket clearance of the Prolift and Prolene sutures, both of which are composed of Prolene polypropylene mesh, results in the preemption of the plaintiff's state law claims.

[1] I have selected this case as a Prolift bellwether case in the Ethicon MDL. (*See* Pretrial Order # 98 [Docket 29], at 1).

[2] Since filing her short form complaint, the plaintiff has dropped several causes of action from her lawsuit. (*See* Pl.'s Opp. to Defs.' Mot. for Summ. J. [Docket 153], at 1 n.1 ("Ms. Bellew will not pursue any causes of action for manufacturing defect, breach of implied warranty, constructive fraud, unjust enrichment, negligent infliction of emotional distress, or 'strict liability—product defect' (except to the extent the latter encompasses design defect and failure to warn).")).

II. Legal Standard

Federal preemption originates from the Constitution's Supremacy Clause. *See* U.S. Const. art. VI, cl. 2.[3] 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 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*,

[3] "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.

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

In two previous cases, both brought against Ethicon, this court has examined the issue of whether the Federal Food, Drug, and Cosmetic Act ("FDCA") preempts the plaintiff's state law products liability claims arising from Ethicon's medical device. Ethicon argued that even though its medical device only went through the cursory 510(k) clearance process, the Prolene mesh component of the device received premarket approval from the FDA—meaning that after rigorous investigation, the FDA deemed the Prolene a "safe" and "effective" medical product, 21 U.S.C. § 360e(d)(2) (2012)—and as a result, the medical device itself cannot be challenged as defective under state law. Emphasizing the difference between the thorough premarket approval process and the less stringent 510(k) clearance process,[4] as well as the difference between the medical device at issue and its Prolene component, I rejected this preemption argument in both cases. *See Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 760–61 (S.D. W. Va. 2014) (finding that the plaintiffs' claims are not preempted by federal law); *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362287, at *14 (S.D. W. Va. July 8, 2014) (same).[5]

Here, Ethicon acknowledges this court's previous rulings against it on this issue but

[4] For a discussion on the difference between 510(k) clearance and premarket approval, see *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 751–52 (S.D. W. Va. 2014).

[5] As evidenced by the discussion below, the Supreme Court's holdings regarding the FDCA's preemption provision have carried significant weight in my analysis on this matter. Notably, the express difference in 510(k) review and premarket approval review, with the latter focused on safety and the former focused on equivalency, has led the Supreme Court to separate applications of FDA preemption. The Court has held that while the FDCA preempts state claims arising from medical devices cleared through the premarket approval process, *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322–23 (2008), it does not preempt state claims arising from medical devices cleared through the 510(k) clearance process, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501–02 (1996). Therefore, the fact that the Prolift has received 510(k) clearance does not trigger federal preemption in this case.

nevertheless attempts to offer "decisive" arguments and evidence that "differ from what the Court has already seen and considered." (Mem. in Supp. of Defs.' Mot. for Partial Summ. J. Based on Preemption of Certain Claims ("Mem. in Supp.") [Docket 125], at 1). In its briefing, Ethicon introduces the following:

> [1] [A]n additional expert declaration which addresses facts the Court has previously held to be important to preemption[,] establish[ing] that the potential for degradation of Prolene polypropylene filaments—or more specifically, the lack thereof—is independent of the number of Prolene polypropylene filaments present in a person's body . . . . [2] Additional evidence show[ing] that the FDA's interpretation of the 510(k) process as including a safety and effectiveness analysis is due deference. [3] [C]linical studies [submitted by Ethicon] with the Prolift 510(k) to support the safety and effectiveness of the device.

Id. at 2–3. For the benefit of the parties, I begin by restating my findings with respect to Ethicon's arguments that I have previously considered in *Lewis* and *Huskey*. I then turn to Ethicon's additional contentions and ultimately decline to deviate from my prior rulings.

A. Revisiting *Lewis* and *Huskey*

First, as I explained in *Lewis* and *Huskey*, Ethicon's reliance on the premarket approval of the Prolene suture "ignores the fact that the Prolene suture and the [Prolift] are two entirely different medical devices":

> 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 [Prolift] is a form of transvaginal mesh. The Prolene suture consists of a single filament of polypropylene; the [Prolift] is a mesh woven from knitted Prolene filaments. The average Prolene suture is a few inches long; the [Prolift] contains many times the amount of polypropylene material. The Prolene suture is not intended to adhere to human tissue; the [Prolift] is designed to adhere to human tissue. The Prolene suture is designed to be easily pulled out of the body; the [Prolift] cannot be removed without invasive surgery. . . .

Lewis v. Johnson & Johnson, 991 F. Supp. 2d 748, 757–58 (S.D. W. Va. 2014); *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362287, at *9 (S.D. W. Va. July 8, 2014) (quoting *Lewis*).

Furthermore, Ethicon's preemption argument ignores the limited nature of the FDA's approval of the Prolene suture.

> 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 [Prolift] 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.

Lewis, 991 F. Supp. 2d at 758; *Huskey*, 2014 WL 3362287, at *9 (quoting *Lewis*).

In another attempt to secure preemption, Ethicon next contends that because a component of the Prolift has surpassed the FDA's vigorous premarket approval process, the plaintiff's design defect claims tied to that component are preempted, even though the device as a whole has not received FDA approval. In *Lewis*, I rejected this argument on the basis that "[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." *Lewis*, 991 F. Supp. 2d at 759 (quoting *Gavin v. Medtronic, Inc.*, CIV.A. 12-0851, 2013 WL 3971612, at *11 (E.D. La. July 19, 2013)). Put simply,

> [t]o 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. [Quotation marks and citation omitted]. "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.

Lewis, 991 F. Supp. 2d at 760; *Huskey*, 2014 WL 3362287, at *10 (quoting *Lewis*). Considering FDCA preemption separately as to each component of a medical device "would create a doctrine that forces courts to dissect every medical device." *Lewis*, 991 F. Supp. 2d at 760. Such an approach "would only serve to create chaos in a field that is already difficult to navigate." *Id.* As I explained previously,

> bright line rules are important to create clarity for all parties involved. . . . 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 [Prolift] 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. . . . 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 760; *Huskey*, 2014 WL 3362287, at *10 (quoting *Lewis*). This piecemeal application of federal preemption doctrine is exactly what Ethicon asks the court to declare, (*see* Mem. in Supp. [Docket 125], at 17 (explaining that its "preemption motion is expressly limited to claims stemming from the use of Prolene polypropylene material in the body . . . *not* to other properties of the device or the device as a whole")), and for the above reasons, I refuse to employ FDCA preemption in this manner.

As in *Huskey*, Ethicon also points to two recent federal district court decisions that have found the plaintiff's design defect claims to be preempted in situations similar to the case at bar. *See Bertini v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 246, 255 (E.D.N.Y. 2014) (finding that because the FDA gave premarket approval to the "R3 metal liner component" of a hip implant system, the defect claims involving the R3 metal liner component of the system are preempted); *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 405 (S.D.N.Y. 2013) (finding that design defect claims regarding a premarket-approved device are "squarely preempted" and that "such preemption extends to a component" of a premarket-approved device). In *Huskey*, I found these cases to be unpersuasive, and I stand by my findings in this case as well.

First, the *Simon* court failed to give credence to the difference between premarket approval and 510(k) clearance, unduly relying on case law concerning devices that had received premarket approval when the medical device before the court had only received 510(k) clearance. *Huskey*, 2014 WL 3362287, at *12. Second, the *Bertini* court's fragmented application of the preemption doctrine to various components of the medical device at issue counters the authoritative law on preemption. *Id.* at *13. Specifically, Supreme Court precedent and federal regulations on preemption do not separately consider device components and instead speak only to the FDA's review of the *device*. *See, e.g.*, *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322 (2008) (preempting state requirements "only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a *particular device*" (quoting 21 C.F.R. § 808.1(d))) (emphasis added). As such, reference to *Simon* and *Bernini* is of no avail.

B. Addressing New Arguments

In addition to restating the arguments from *Huskey* and *Lewis*, Ethicon asserts three "new" arguments in favor of preemption. (Mem. in Supp. [Docket 125], at 1). First, Ethicon submits a revised version of the declaration of Dr. Thomas A. Barbolt to demonstrate that "[a]t no point in the process of creating the Prolift device is any change made to the surface characteristics of the Prolene polypropylene filaments that would cause degradation." (*Id.* at 3 (citing to Dr. Barbolt's declaration [Docket 124-1])). Aside from the addition of five short paragraphs about the process of integrating the Prolene polypropylene filaments into the Prolift, Dr. Barbolt's declaration is exactly the same as the one offered by Ethicon in *Huskey*. In *Huskey*, I concluded that this "additional declaration from an Ethicon employee" does not alter the legal reasoning applied in *Lewis*. *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362287, at *11 (S.D. W. Va. July 8, 2014). Here, the insertion of five bullet points into that declaration is likewise unpersuasive.

Next, Ethicon maintains that the FDA interprets its 510(k) process as a safety and effectiveness analysis. To this end, Ethicon provides a 100-page expert report by Mr. Timothy A. Ulatowski, an "expert consultant on matters concerning medical device regulations, policies, and [FDA] procedures." (Ulatowski Report [Docket 124-16], at 4). Except for one document, the sources that Mr. Ulatowski relies on to reach his conclusions existed at the time I ruled on this issue in *Huskey*. The outlier document is the FDA's most recent guidance on the 510(k) process. *See generally* FDA, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]: Guidance for Industry and Food and Drug Administration Staff* ("Guidance Document") (July 29, 2014), *available at* http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm282952.htm (last visited Nov. 20, 2014). Mr.

Ulatowski cites to several statements in the Guidance Document suggesting that the FDA considers the 510(k) process to be an analysis of safety and effectiveness. For example, the Guidance Document notes that despite the different standards of review in the 510(k) process and the premarket approval process, "the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review." (Ulatowski Report [Docket 124-16, at 4 (quoting Guidance Document, *supra*, at 6)). In Ethicon's view, this "interpretation" by the FDA deserves "deference." (Mem. in Supp. [Docket 125], at 17–18).

As an initial matter, the Guidance Document is not an FDA "interpretation" of the FDCA as Ethicon suggests. The FDA explains that the Guidance Document "is not intended to implement significant policy changes to the current 510(k) review process." Guidance Document, *supra*, at 1. The Guidance Document simply serves as a description of the FDA's "current thinking on a topic" that "should be viewed only as recommendations." *Id.*; *see also Devon Energy Corp. v. Kempthorne*, 551 F.3d 1030, 1039 (D.C. Cir. 2008) (concluding that guidance documents do not constitute "authoritative and binding interpretations" unless they "mark the consummation of the agency's decisionmaking process" and either "determine 'rights or obligations' or result in discernible 'legal consequences' for regulated parties" (quoting *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997))). Therefore, while cognizant of the recommendations in the Guidance Document, I must defer to the current Code of Federal Regulations and Supreme Court precedent, both of which consistently maintain that 510(k) clearance does not concern product safety. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996) ("[T]he 510(k) process is focused on equivalence, not safety."); *id.* at 493 (explaining that devices deemed "substantially equivalent" through the 510(k) process have "never been formally reviewed . . . for safety or efficacy"); 21 C.F.R. § 807.97 (2012) (providing that 510(k) clearance

"does not in any way denote official approval of the device" and "[a]nd 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").

In any event, the information provided in the Guidance Document is not inconsistent with the authoritative sources on 510(k) clearance. While the FDA certainly considers safety and effectiveness of a product in a 510(k) review, the Guidance Document stresses that the "evidentiary standard" is more lax in the 510(k) process than in the premarket approval process. Guidance Document, *supra*, at 7. For premarket approval, the medical device must independently demonstrate safety and effectiveness. *Id.* at 6. In contrast, for 510(k) review, the FDA considers safety and effectiveness comparatively, "generally rel[ying], in part, on FDA's prior determination that a reasonable assurance of safety and effectiveness exists for the predicate device." *Id.* at 7. The analysis is predominantly relative, and the FDA does not engage in an independent investigation of the medical device's safety and effectiveness. *Id.* ("FDA generally evaluates differences between the new device and the predicate device to determine their effect on safety and effectiveness."). Because the language of the Guidance Document does not indicate that the FDA's approach to 510(k) review has shifted since I last reviewed this issue—indeed, the FDA directs the industry not to view the Guidance Document as such—the Guidance Document and Mr. Ulatowski's discussion of it do not change my position on the application of preemption to this case.

Ethicon's final argument focuses on the clinical data that Ethicon submitted to the FDA in its 510(k) application for the Prolift. In accordance with the FDA's *Guidance for the Preparation of a Premarket Notification Application for Surgical Mesh*, which encourages manufacturers to submit a "[s]ummary of information regarding safety and effectiveness upon

which an equivalence determination can be made," ([Docket 124-10], at 1), Ethicon submitted clinical and scientific reports regarding the Prolift to aid the FDA in its 510(k) evaluation. In Ethicon's view, the FDA's "analy[sis of] this data supporting the safety and effectiveness of Prolift before clearing the device" implies that the 510(k) process concerns safety and effectiveness such that the plaintiff's claims regarding the Prolift are preempted. (Mem. in Supp. [Docket 125] at 19). I disagree. As the Supreme Court explains in *Lohr*,

> even though the FDA may well examine § 510(k) applications for Class III devices (as it examines the entire medical device industry) with a concern for the safety and effectiveness of the device . . . [510(k) clearance] simply allow[s a product], as a device substantially equivalent to one that existed before 1976, to be marketed without running the gauntlet of the [premarket approval] process.

Lohr, 518 U.S. at 493–94. The FDA considers safety and effectiveness information submitted by the manufacturer for the narrow purpose of "ascertain[ing] whether the later device is no more dangerous and no less effective than the earlier device." *Id.* at 493. Consequently, the 510(k) process, even if it partially involves the review of clinical studies or data, does not constitute a "formal[]" review of the device for safety or effectiveness. *Id.* For these reasons, the fact that Ethicon submitted clinical data with its 510(k) application is not compelling.

My judgment in *Lewis* and *Huskey* remains the law in this case. Bound by Supreme Court precedent, I cannot conclude that 510(k) clearance speaks to the safety or effectiveness of the Prolift. Moreover, in light of the practical difficulties explained above, I decline to find that the premarket approval of the Prolene suture results in the preemption of the plaintiff's state law claims arising from the Prolift. Ethicon's modified arguments do not persuade me to deviate from this position, which I have adhered to in not just Ethicon's MDL but in all of the pelvic mesh MDLs. That is, preemption is not warranted in these cases. I therefore **DENY** Ethicon's Motion for Partial Summary Judgment.

C. Motion *in Limine*

In the last paragraph of its Motion for Partial Summary Judgment, Ethicon moves *in limine* to preclude evidence and argument that the Prolene polypropylene is defective or that the Prolift required different labeling related to the use of Prolene polypropylene in that device. (Mem. in Supp. [Docket 125], at 19–20). As I have repeatedly explained, preemption is warranted only when a medical device as a whole has received FDA premarket approval. FDA review of the device's component parts is irrelevant to the application of preemption doctrine. Accordingly, I **DENY** Ethicon's motion on this point.

IV. Conclusion

For the reasons stated above, Ethicon's Motion for Partial Summary Judgment [Docket 124] is **DENIED**. The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: November 24, 2014

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE