IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

REGINA M. THOMPSON, et al.,	*	
Plaintiffs,	*	
v.	*	**Civil Case No. SAG-19-03159**
ETHICON, INC., et al.,	*	
Defendants.	*	

MEMORANDUM OPINION

Plaintiffs Regina M. Thompson and Gary Thompson (collectively, "Plaintiffs") filed suit against Ethicon, Inc. ("Ethicon") and Johnson & Johnson (collectively, "Defendants"), alleging products liability claims arising out of implantation of a transvaginal mesh manufactured and sold by Defendants. Plaintiffs' claims were filed directly into multi-district litigation ("MDL") proceedings in the United States District Court for the Southern District of West Virginia, In re: Ethicon, Inc. Pelvic Repair Systems Product Liability Litigation, MDL No. 2327. ECF 1 (Short Form Complaint, adopting by reference the Master Complaint in the MDL). Plaintiffs' case was transferred to this Court on October 31, 2019. ECF 49. Following the MDL proceedings, five of Plaintiffs' claims remain for disposition. Currently pending is Defendants' Supplemental Motion for Summary Judgment as to the remaining claims. ECF 70, 70-1 (collectively, "the Motion"). Plaintiffs opposed the Motion, ECF 71, and Defendants filed a Reply, ECF 72. No hearing is necessary. See Loc. R. 105.6 (D. Md. 2018). For the reasons that follow, Defendants' Motion will be granted in part and denied in part.

I. FACTUAL BACKGROUND

The facts described herein are viewed in the light most favorable to Plaintiffs as the non-moving parties. On February 10, 2005, Dr. Matthew Fagan performed surgery on Plaintiff Regina

Thompson ("Ms. Thompson") to insert an Ethicon Prolene Mesh implant, which is a prescription polypropylene mesh medical device, to treat pelvic organ prolapse and stress urinary incontinence. Ex. 71-5 at 6. Following the surgery, Ms. Thompson experienced pain, erosion, extrusion, infection, urinary problems, inflammation, recurrence, bleeding, dyspareunia, and vaginal scarring. Id. at 8. Two additional mesh revision surgeries resulted, on December 8, 2005, and December 8, 2011. Id. at 7.

In the MDL proceeding, on May 19, 2017, Dr. Donald R. Ostergard, M.D., issued an expert opinion on behalf of Ms. Thompson and the other MDL plaintiffs. ECF 71-13. Dr. Ostergard, a board-certified obstetrician and gynecologist, opined, in relevant part:

- "When complications develop from the defective Ethicon vaginal mesh devices, such as, vaginal mucosal dehiscence, mesh exposure, chronic pelvic, lower abdominal and vaginal pain along with urinary frequency, recurrent urinary tract infections, painful intercourse, vaginal/mesh tenderness, vaginal rigidity, the treatment is to remove the device . . . When pain or allergic reaction to the device develops or if the device erodes into adjacent organs, such as, the urethra, anal sphincter, rectum, or other bowel, the device must be removed." ECF 71-13, ¶ 5.

- "Complete removal generally is not possible due to the degradation of the polypropylene which weakens the mesh to the point that it literally falls apart during dissection. . . . When the device cannot be removed totally, a pelvic pain syndrome occurs which is very difficult to treat and narcotics may be required to control the pain. Acupuncture, tibial nerve stimulation, physical therapy and a lot of emotional support may be helpful, but will not treat the basic problem since mesh frequently remains in the body in varying amounts." Id.

- The polypropylene mesh used in the manufacture of Gynemesh is defective in thirteen ways, including its weave, its impurity, its degradation, its shrinkage, and its heavy weight. Id. ¶ 7.

- Studies, reports, and scientific articles have shown a long history of injuries to patients resulting from use of Gynemesh in patients. Id. ¶¶ 9, 10.

- Ethicon's own documents reflect knowledge of the deficiencies in the product. Id. ¶ 11.

- "The use of a safer product such as a cadaveric sub-urethral sling or a lighter weight, larger pore polypropylene mesh would have eliminated the risks associated with the defects inherent in this flawed device, including chronic inflammation, degradation, shrinkage, and infection." Id. ¶ 20.

In addition, on November 17, 2015, Prof. Dr. Med. Uwe Klinge, a surgeon with a focus on surgical research in the area of biomaterial science, also issued a general opinion as an expert witness for the MDL plaintiffs. ECF 71-14. In relevant part, Dr. Klinge opined:

- To a reasonable degree of medical and scientific certainty that Ethicon's "Prolift, Prosima and Gynemesh PS products are unreasonably dangerous and defectively designed to be placed in the pelvic tissues for prolapse repair." Id. at 30.

- To a reasonable degree of medical and scientific certainty that "Ethicon's line of products that were made with Gynemesh PS mesh to treat pelvic organ prolapse were not specifically designed to function in the pelvic floor; they are over engineered, will create an intensified and chronic foreign body reaction; they have pores that are too small to resist fibrotic bridging and scar plate formation; and they will curl, rope and fray leading to particle loss and sharp edge. All of these design failures will, to a reasonable degree of medical and scientific certainty, cause an unnecessary risk of patient complications and injuries that include, but are not limited to, chronic pain, nerve entrapment, chronic foreign body reaction, erosion, infection, dyspareunia, recurrence, mesh contraction, and exposure." Id.

- That safer alternative designs exist, including one new potential design, reflected in Ethicon internal documents, that out-performed "Gynemesh PS and Ultrapro in every design attribute except one-cost." Id. at 28.

Plaintiffs' case-specific expert, Dr. Phillip Agrusa, M.D., reviewed Ms. Thompson's medical records and submitted an expert report dated May 14, 2018. ECF 71-7. That report notes that following her February 2005 implant surgery, Ms. Thompson visited her doctor in July, 2005, November, 2005, and December, 2005, complaining of vaginal pain and dyspareunia. Id. at 2. In July, 2005, her doctor diagnosed mesh erosion in the vagina. Id. On December 8, 2005, Dr. Danita Akingba performed a mesh excision procedure. Id.; see ECF 71-9 at 2-5 (Dr. Akingba's operation report).

Dr. Agrusa also noted that Ms. Thompson was seen almost six years later, on October 4, 2011, for constant vaginal pain and inability to have intercourse since her first surgery in 2005. Id. ECF 71-7 at 2. Her examining physician found additional exposed mesh and significant vaginal tenderness. Id. Dr. Sylvester performed a second mesh excisional surgery, with cystoscopy, on December 8, 2011. Id.; see ECF 71-11 at 2-4 (Dr. Sylvester's operation report). Even after this second surgery, Ms. Thompson was seen by doctors numerous times for "complaints of vaginitis, bladder infections, pain, incontinence and voiding dysfunction." ECF 71-7 at 3. For instance, one doctor noted in a September, 2012 visit that Ms. Thompson showed signs of "significant fibrosis and vaginal atrophy." Id.

Dr. Agrusa's opinion concluded with the following statement: "The mesh clearly eroded quickly after her first surgery and again 6 years later. To a reasonable degree of medical certainty, there is no cause for the patient's current complaints other than the mesh device implanted in 2005 that required additional surgeries to remove mesh erosion." Id.

II. LEGAL STANDARD FOR SUMMARY JUDGMENT

Under Rule 56(a) of the Federal Rules of Civil Procedure, summary judgment is appropriate only "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." The moving party bears the burden of showing that there is no genuine dispute of material facts. See Casey v. Geek Squad, 823 F. Supp. 2d 334, 348 (D. Md. 2011) (citing Pulliam Inv. Co. v. Cameo Props., 810 F.2d 1282, 1286 (4th Cir. 1987)). If the moving party establishes that there is no evidence to support the non-moving party's case, the burden then shifts to the non-moving party to proffer specific facts to show a genuine issue exists for trial. Id. The non-moving party must provide enough admissible evidence to "carry the burden of proof in [its] claim at trial." Id. at 349 (quoting Mitchell v. Data Gen.

Corp., 12 F.3d 1310, 1315-16 (4th Cir. 1993)). The mere existence of a scintilla of evidence in support of the non-moving party's position will be insufficient; there must be evidence on which the jury could reasonably find in its favor. Id. at 348 (citing Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 251 (1986)). Moreover, a genuine issue of material fact cannot rest on "mere speculation, or building one inference upon another." Id. at 349 (quoting Miskin v. Baxter Healthcare Corp., 107 F. Supp. 2d 669, 671 (D. Md. 1999)).

Additionally, summary judgment shall be warranted if the non-moving party fails to provide evidence that establishes an essential element of the case. Id. at 352. The non-moving party "must produce competent evidence on each element of [its] claim." Id. at 348-49 (quoting Miskin, 107 F. Supp. 2d at 671). If the non-moving party fails to do so, "there can be no genuine issue as to any material fact," because the failure to prove an essential element of the case "necessarily renders all other facts immaterial." Id. at 352 (quoting Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986); Coleman v. United States, 369 F. App'x 459, 461 (4th Cir. 2010) (unpublished)). In ruling on a motion for summary judgment, a court must view all of the facts, including reasonable inferences to be drawn from them, "in the light most favorable to the party opposing the motion." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587-88 (1986) (quoting United States v. Diebold, Inc., 369 U.S. 654, 655 (1962)).

III. ANALYSIS

Defendants seek summary judgment on all five remaining counts of the Complaint: negligent design defect (Count I), strict liability design defect (Count V), loss of consortium (Count XVI), punitive damages (Count XVII), and discovery rule and tolling (Count XVIII). Each is addressed below.

A. Design Defect and Loss of Consortium Claims

The parties agree that the same three elements govern Plaintiffs' design defect claims, under both distinct theories of negligence and strict liability: "defect, attribution of defect to [Defendants], and a causal relationship between the defect and the injury." Parker v. Allentown, Inc., 891 F. Supp. 2d 773, 780 (D. Md. 2012) (quoting Laing v. Volkswagen of Am., Inc., 180 Md. App. 136, 159 (2008)); see also Watson v. Sunbeam Corp., 816 F. Supp. 384, 387 n.3 (D. Md. 1993) ("The elements of proof are the same whether the claim be characterized as one for strict liability or negligence."). The parties also agree that Mr. Thompson's loss of consortium claim is derivative, meaning it rises or falls on the viability of the design defect contentions. ECF 70-1 at 8-9; ECF 71-1 at 18; see Oaks v. Connors, 339 Md. 24, 34, 38 (1995). Finally, the parties, correctly, agree that Maryland law governs Plaintiffs' claims, because each of Ms. Thompson's surgeries, and Plaintiffs' resulting injuries, occurred in Maryland. ECF 70-1 at 4-5; ECF 71-1 at 6; see In re Ethicon, Inc., MDL No. 2327, 2014 WL 346717, at *8 (S.D.W. Va. Jan. 30, 2014) (concluding, in a suit directly filed into the Ethicon MDL, that "the choice of law that applies is the place where the plaintiff was implanted with the product"); Ben-Joseph v. Mt. Airy Auto Transporters, LLC, 529 F. Supp. 2d 604, 606-07 (D. Md. 2008) (explaining that Maryland courts apply the lex loci delicti rule to tort claims, which calls for application of the substantive law of the state in which the injury occurred).

While there are a host of elements necessary to establish liability under a negligence or strict liability theory, see Parker, 891 F. Supp. 2d at 780-81, 791 (listing the particular elements for each theory), Defendants argue that Plaintiffs do not have the expert testimony required to establish defect or causation under Maryland law, both of which are necessary elements of a negligence and strict liability claim, ECF 70-1 at 5-10. To establish defectiveness, Maryland

permits plaintiffs to invoke one of two tests: the consumer expectation test or the risk-utility test. Lloyd v. Gen. Motors Corp., 275 F.R.D. 224, 228 (D. Md. 2011). Under the consumer expectation test, a plaintiff must show that the product was sold in a condition "not contemplated by the ultimate consumer, which will be unreasonably dangerous to him." Id. (quoting Halliday v. Sturm, Ruger & Co., 368 Md. 186, 193 (2002)). "Unreasonably dangerous" is defined as "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it with the ordinary knowledge common to the community as to its characteristics." Halliday, 368 Md. at 193.

The parties dispute whether in this case, for purposes of the consumer expectation test, the "ultimate consumer" was Ms. Thompson, or her implanting physician. Defendants argue that the "learned intermediary" doctrine should apply, and that because the implanting pelvic surgeon, Dr. Fagan, was fully aware of the possible risks of implanting Prolene mesh, including erosion and the other symptoms Plaintiff experienced, her claims fail as a matter of law. ECF 70-1 at 6 (citing Fagan Dep., ECF 70-3 at 32-34, 38-40, 60-61). Plaintiffs counter that the "learned intermediary" doctrine has not been applied to a design defect case in Maryland, and is only used in the context of strict liability failure to warn claims. ECF 71-1 at 11-12 & n.2. As noted above, Plaintiffs' failure to warn claims were dismissed as part of the MDL. See ECF 63 (memorializing this dismissal).[1]

Ultimately, this Court need not reach the issue of whether the learned intermediary doctrine extends to the consumer expectation test for a design defect claim, because Plaintiffs' design defect counts survive summary judgment under the risk-utility test. That test applies when a product

[1] As the parties correctly note in their briefings, Count V of Plaintiffs' Complaint (Strict Liability – Design Defect) was inadvertently included in this Court's December 23, 2019 Order, ECF 63.

malfunctions in some way, Kelley v. R.G. Indus., Inc., 304 Md. 124, 138 (1985), and "asks 'whether a manufacturer, knowing the risks inherent in the product, acted reasonably in putting it on the market,'" Lloyd, 275 F.R.D. at 229 (quoting Ziegler v. Kawasaki Heavy Indus., Ltd., 74 Md. App. 613, 621 (1988). The risk-utility test, "therefore, shifts the focus from the consumer to the manufacturer of the product." Lloyd, 275 F.R.D. at 229. Under the risk-utility test, a product is deemed defective "when the foreseeable risk of harm could have been reduced or avoided by the adoption of a reasonable alternative design." Id.; see Ziegler, 74 Md. App. at 620-21. Specifically, the risk-utility test requires a seven-factor analysis:

> (1) The usefulness and desirability of the product—its utility to the user and to the public as a whole.
>
> (2) The safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury.
>
> (3) The availability of a substitute product which would meet the same need and not be as unsafe.
>
> (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
>
> (5) The user's ability to avoid danger by the exercise of care in the use of the product.
>
> (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or the existence of suitable warnings or instructions.
>
> (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

Parker, 891 F. Supp. 2d at 791 (citing Klein v. Sears, Roebuck & Co., 92 Md. App. 477, 486 (1992)).

Here, two of Plaintiffs' expert witnesses offer testimony about the existence of feasible alternative designs that would have reduced the foreseeable risk of harm. Specifically, both Dr. Ostergard and Dr. Klinge opine that alternative, safer mesh designs were available to the Defendants, without sacrificing utility. See, e.g., Ostergard Aff., ECF 71-13, ¶ 20 ("The use of a safer product such as a cadaveric sub-urethral sling or a lighter weight, larger pore polypropylene mesh would have eliminated the risks associated with the defects inherent in this flawed device, including chronic inflammation, degradation, shrinkage and infection."); Klinge Rep., ECF 71-14 at 17 ("The PVDF product, Dynamesh, is a safer design than Gynemesh PS for all of the reasons stated above as further established in Muehl's testing."). Dr. Klinge specifically discussed two alternatives that, in his expert opinion, were safer than Ethicon's TVT Prolene mesh: (1) a mesh device made of PVDF, product name "Dynamesh," which Ethicon itself observed outperformed its TVT Prolene mesh "in every design attribute" except cost, and (2) other meshes sold on the U.S. market since 1997 that utilized a sealed border, as opposed to Ethicon's TVT Prolene mesh, which utilized open, unsealed borders. ECF 71-15 at 37-40. Though Dr. Klinge does not discuss how much more costly Dynamesh would have been to produce, there is evidence that Ethicon saw Dynamesh as "easier to manufacture and sterilize," and called it "'the holy grail' of pelvic floor meshes." Id. at 38. This, taken in conjunction with the fact that alternative safer designs already existed on the market in 1997, is sufficient to create a genuine issue of material fact as to whether the Ethicon mesh device implanted in Ms. Thompson was defective under a risk-utility analysis.[2]

[2] In any event, it is worth noting that Defendants fail to meet their initial burden to provide sufficient evidence to show that these alternative designs were so costly that they were not feasible. Defendants' brief merely asserts that Dr. Agrusa "offered no . . . evidence of feasibility, availability of materials, costs of production, or acceptance in the marketplace." ECF 70-1 at 7. This alone, however, is insufficient for the Court to find, as Rule 56(a) requires, that no genuine issue of material fact exists, and that Defendants are entitled to judgment as a matter of law.

Defendants take further issue with the fact that the testimony about the safer alternative designs is not offered by Dr. Agrusa, who provides the required link in the chain between the alleged defect in the mesh and the injury to Plaintiffs. ECF 70-1 at 7. However, Defendants cite to no authority establishing that a single expert witness establish each element of a claim. In this case, the testimony of the general expert witnesses is sufficient to establish defect by meeting the requirements of the risk-utility test under Maryland law. *See Fireman's Fund Ins. Co. v. Tecumseh* Prods. Co., 767 F. Supp. 2d 549, 557 (D. Md. 2011) (noting that expert opinion testimony may be used to establish the existence of a design defect, as well as circumstantial evidence giving rise to an "inference" of a defect).

As to the third required element, causation, the general expert witnesses opine that the defective mesh can cause the type of injuries suffered by Ms. Thompson. See, e.g., Klinge Rep., ECF 71-14 at 31 ("All of these design failures will, to a reasonably degree of scientific certainty, cause an unnecessary risk of patient complications and injuries that include, but are not limited to, chronic pain, nerve entrapment, chronic foreign body reaction, erosion, infection, dyspareunia, recurrence, mesh contraction, and exposure."); Ostergard Aff., ECF 71-13, ¶ 5 ("When complications develop from the defective Ethicon vaginal mesh devices, such as, vaginal mucosal dehiscence, mesh exposure, chronic pelvic, lower abdominal and vaginal pain along with urinary frequency, recurrent urinary tract infections, painful intercourse, vaginal/mesh tenderness, vaginal rigidity, the treatment is to remove the device."). Dr. Agrusa then provides testimony that the mesh did cause Ms. Thompson's injuries, relying upon his differential diagnosis eliminating any other possible cause. While Defendants argue that his analysis is insufficient, their argument relies on a hypertechnical criticism of Dr. Agrusa's writing style. Dr. Agrusa concluded, "To a reasonable degree of medical certainty, there is not cause for the patient's current complaints other

than the mesh device implanted in 2005 that required additional surgeries to remove mesh erosion." ECF 71-7 at 3. Defendants' contention that Dr. Agrusa attributed the injury to the mesh device itself, and not to the defect/erosion, ECF 72 at 4, is unpersuasive. By his own description, the mesh device "required additional surgeries to remove mesh erosion." ECF 71-7 at 3. In other words, Dr. Agrusa has identified a design defect – mesh erosion, which is one of the defects noted by the general expert witnesses – and tied that to Ms. Thompson's "current complaints." Id. Accordingly, viewing the evidence in the light most favorable to Plaintiffs, it was the erosion of the device, not the device itself, that caused Plaintiffs' injury.

Further, in support of the negligence aspect of their claim, Plaintiffs adduced evidence from Dr. Klinge that Defendants had knowledge of the defects in their products at the time they were sold and that Defendants, in fact, funded a study into one of the same alternative designs that Dr. Klinge explains would have been much safer for consumers. See ECF 71-14 at 24-30; ECF 71-15 at 8-37 (describing the harms that Ethicon's TVT mesh devices can cause, and the knowledge that several Ethicon individuals had). Ultimately, taking the evidence in the light most favorable to Plaintiffs, there are genuine issues of material fact as to both defect and causation, which are the only elements disputed by Defendants at this stage. Summary judgment is therefore unwarranted as to Counts I, V, and XVI.

B. Claims alleging "Punitive Damages" and "Discovery and Tolling"

Plaintiffs concede that neither Count XVII (punitive damages) nor Count XVIII (discovery and tolling) states a cognizable independent claim under Maryland law. ECF 71-1 at 1. Accordingly, those counts will be dismissed with prejudice. Of course, to the extent punitive damages are recoverable under one of Plaintiffs' remaining claims, this ruling will not prevent Plaintiffs from seeking such damages as part of their recovery.

IV. CONCLUSION

For the reasons set forth above, Defendants' Supplemental Motion for Summary Judgment, ECF 70, will be GRANTED as to Counts XVII and XVIII, and DENIED as to Counts I, V, and XVI. A separate Order follows, which will also set a telephonic scheduling conference to discuss future proceedings.

Dated: July 10, 2020

/s/
Stephanie A. Gallagher
United States District Judge