IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

BRENDA J. DAVIS, **Plaintiff,** **v.** **JOHNSON & JOHNSON, et al.,** **Defendants.**	**Case No. 2:20-cv-02635-HLT**

MEMORANDUM AND ORDER

This is a product-liability action. Plaintiff Brenda J. Davis seeks damages from Defendants Johnson & Johnson and Ethicon, Inc. for injuries arising out of the use of Prolift+M pelvic mesh. This case was part of multidistrict litigation known as *In re: Ethicon, Inc., Pelvic Repair System Products Liability Litigation*, MDL No. 2327, and was transferred back to the District of Kansas following consolidated pretrial proceedings. The matter is currently before the Court on Defendants' motion for summary judgment (Doc. 107) and motion to strike (Doc. 105).[1] For the reasons stated below, the Court denies Defendants' summary-judgment motion on the statute-of-limitations issue, grants it as to the failure-to-warn theory, and denies the motion to strike.

I. BACKGROUND[2]

Prolift+M is a medical device used in the treatment of pelvic organ prolapse. It is manufactured by Ethicon, Inc. Doc. 108 at 1. On June 21, 2010, Dr. Errick Arroyo implanted Plaintiff with Prolift+M in Overland Park, Kansas. *Id.* On that same day, Plaintiff also had a

[1] There are currently also eleven pending *Daubert* motions. Docs. 99, 100, 101, 102, 103, 104, 109, 111, 113, 115, and 117. Trial is set for October 3, 2022. Because at least of some of Plaintiff's claims survive summary judgment, the Court will endeavor to rule on the pending *Daubert* motions in advance of trial. However, given the excessive number of motions filed in this case, the Court cannot offer a definitive timeline and the parties should therefore prepare for trial accordingly.

[2] The Court considers the following uncontroverted facts for purposes of summary judgment.

laparoscopic hysterectomy and a left salpingo-oophorectomy. Doc. 128 at 2. Plaintiff relied solely on Dr. Arroyo's recommendation to have the pelvic mesh surgery in 2010. Doc. 108 at 3. Putting himself back to the time of Plaintiff's surgery in 2010, Dr. Arroyo testified that he stands by his decision to use Prolift+M. *Id.* at 4.

On July 7, 2010, Plaintiff saw Dr. Arroyo for a post-operative visit. Doc. 128 at 4. According to Dr. Arroyo, the pain Plaintiff was experiencing at that time was unrelated to mesh erosion. *Id.* At another follow-up on July 22, 2010, Dr. Arroyo noted that Plaintiff was doing better, and her status was improving. *Id.*

On August 11, 2010, Dr. Arroyo saw Plaintiff and told her she was "doing excellent at this time" and had "no significant pain." *Id.* Although Dr. Arroyo believed Plaintiff was "well-healed" and did not have any major concerns, he did note a small area of a permanent suture and mesh erosion and told Plaintiff that it may cause her dyspareunia (pain with intercourse). Doc. 108 at 2; Doc. 128 at 3. Plaintiff had a follow-up appointment with Dr. Arroyo on August 16, 2011, but she did not show up for that appointment. Doc. 108 at 2. However, Plaintiff did have an annual physical exam in August 2011, which included a normal pelvic exam. Doc. 128 at 3.

On June 7, 2013, Plaintiff saw her gynecologist, who noted that Plaintiff's mesh had become exposed. *Id.* at 5. At that time, they discussed possible mesh removal. *Id.* On June 18, 2013, Plaintiff saw Dr. Arroyo. Dr. Arroyo's notes from the appointment noted a small area of mesh erosion that had "not bothered the patient until recently." *Id.*; *see also* Doc. 128-10 at 2.

On July 23, 2013, Plaintiff saw Dr. Ebenezer Babalola with "suspected mesh erosion." Doc. 128 at 5; Doc. 128-11 at 2. Dr. Babalola noted that she had increased pain since 2012, that Dr. Arroyo did not find any abnormalities in 2013, that Plaintiff's primary care physician suggested a possible cervical cyst, and that another Ob/Gyn observed mesh erosion. Doc. 128 at

5. Dr. Babalola also noted that Plaintiff "[n]eeds mesh excision." *Id.* Plaintiff underwent a mesh removal by Dr. Babalola in Kansas City on September 11, 2013. Doc. 108 at 2.

Plaintiff's Amended Fact Sheet states that she began experiencing symptoms of the injuries at issue in this case "[s]hortly after implant for follow up appointments. Beginning July or August 2010." Doc. 108-1 at 7. Plaintiff also testified that her injuries started in July or August 2010, shortly after the pelvic mesh surgery. Doc. 108 at 2. However, Plaintiff's Amended Fact Sheet also says that she did not attribute these issues to the pelvic mesh until 2013, when her doctor suggested revision surgery. Doc. 108-1 at 8; Doc. 128 at 5-6. Plaintiff testified at her deposition that she attributed her dyspareunia to the pelvic mesh because she did not have it until after the mesh surgery. Doc. 108 at 2.

On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that reported over 1,000 adverse events in a three-year period related to pelvic mesh products, though the complications being reported were described as rare. *Id.*; Doc. 128 at 3. On July 13, 2011, the FDA issued a Safety Communication that provided an update about complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse. Doc. 108 at 2-3. The FDA advised that the use of surgical mesh was a "continuing serious concern" and that serious complications were "not rare," and many required surgical treatment and hospitalization. *Id.* The 2011 FDA Safety Communication also stated that "mesh contraction" leading to vaginal pain was a "previously unidentified risk." Doc. 128 at 3. Dr. Arroyo was not aware of this complication at the time of Plaintiff's surgery. *Id.* Both of these notices were referenced in Plaintiff's petition. *See* Doc. 1-1 at 11-13. Plaintiff's petition also referenced a December 2011 Joint Committee Opinion by the American College of Obstetricians and

Gynecologists and the American Urogynecologic Society that identified changes to pelvic mesh inside the body. Doc. 108 at 3; *see also* Doc. 1-1 at 13.

Plaintiff's expert, Dr. Bruce Rosenzweig, believes Plaintiff sustained "pelvic and vaginal pain, dyspareunia and hispareunia, mesh erosion, revision surgery, urinary tract infections, urinary incontinence, frequency, urgency, [and] dysuria" as a result of Prolift+M. Doc. 108 at 3. He also believes Plaintiff sustained additional complications of "chronic inflammation, foreign body reaction, scarring, contraction, shrinkage, deformation and degradation of the mesh." Doc. 128 at 3-4. According to Plaintiff, Prolift+M has caused her significant problems and she seeks compensatory damages of $20 million and punitive damages of $50 million. Doc. 98 at 35-36.

II. STANDARD

Summary judgment is appropriate if there is "no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the initial burden of establishing the absence of a genuine issue of fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The burden then shifts to the nonmovant to demonstrate that genuine issues remain for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986). In applying this standard, courts view the facts and any reasonable inferences in a light most favorable to the non-moving party. *Henderson v. Inter-Chem Coal Co.*, 41 F.3d 567, 569 (10th Cir. 1994). "An issue of material fact is genuine if a reasonable jury could return a verdict for the nonmoving party." *Id.* (internal quotation and citation omitted).

III. ANALYSIS

In the Pretrial Order, Plaintiff asserts claims for (1) negligence (but not on a manufacturing-defect theory); (2) strict liability for failure to warn; (3) strict liability for defective design; (4) negligent infliction of emotional distress; (5) gross negligence; (6) loss of consortium; and (7)

punitive damages. Doc. 98 at 26-30. However, in response to summary judgment, Plaintiff has dropped her claims for negligent infliction of emotional distress, gross negligence, and loss of consortium. Doc. 128 at 19-20. Plaintiff's claim for punitive damages is the subject of a pending motion to strike (Doc. 105) and will be addressed separately below.

Thus, the only claims at issue for purposes of summary judgment are Plaintiff's allegations of negligence, strict liability/failure to warn, and strict liability/defective design. Under Kansas law, these claims all merge into one product-liability claim, despite the alternative theories. *Pedro v. Armour Swift-Eckrich*, 118 F. Supp. 2d 1155, 1158-59 (D. Kan. 2000); *Roeder v. Am. Med. Sys., Inc.*, 2021 WL 4819442, at *4 (D. Kan. 2021); *see also* K.S.A. § 60-3302(c).

Here, Defendants challenge Plaintiff's merged claim—under all theories—as falling outside the statute of limitations. They separately seek summary judgment on Plaintiff's strict liability/failure-to-warn theory for lack of proximate cause.

A. Statute of Limitations – All Theories

The parties don't dispute that Plaintiff's claims for negligence and strict liability all are governed by the two-year statute of limitations in K.S.A. § 60-513(a). *See Pedro*, 118 F. Supp. 2d at 1158-59. That statute incorporates a discovery rule. K.S.A. § 60-513(b) states that causes of action under subsection (a) do not accrue "until the act giving rise to the cause of action first causes substantial injury, or, if the fact of injury is not reasonably ascertainable until some time after the initial act, then the period of limitation shall not commence until the fact of injury becomes reasonably ascertainable to the injured party." This provision "postpones the running of the limitations period until the time the plaintiff is able to determine that her injury may be caused by some act of the defendant." *Benne v. Int'l Bus. Machines Corp.*, 87 F.3d 419, 427 (10th Cir. 1996).

The term "substantial injury" is interpreted to mean "actionable injury." *Michaelis v. Farrell*, 296 P.3d 439, 444 (Kan. Ct. App. 2013). But this does not require knowledge of the full extent of a plaintiff's injuries. *Id.* Rather, a "substantial injury" is one that justifies a legal action for damages. *See Roeder*, 2021 WL 4819442, at *4; *Moss v. Mamalis*, 138 P.3d 380, 384 (Kan. Ct. App. 2006) ("It is knowledge of the fact of an actionable injury, not the extent, which triggers the statute of limitations.").

The term "reasonably ascertainable" confers some obligation to investigate. *See Michaelis*, 296 P.3d at 444. It is an "objective standard based on an examination of the surrounding circumstances." *See Davidson v. Denning*, 914 P.2d 936, 943 (Kan. 1996). It also confers an obligation on a plaintiff to reasonably investigate the cause of the harm once she has sufficient notice of an injury. *Burton v. R.J. Reynolds Tobacco Co.*, 397 F.3d 906, 915 (10th Cir. 2005).

"If examining the surrounding circumstances shows that the plaintiff clearly had knowledge of his or her injury and that the defendant was the likely cause, the trial court can make the legal determination that the injury was reasonably ascertainable at that point." *Michaelis*, 296 P.3d at 445. If there are conflicting facts about when a substantial injury occurred or was reasonably ascertainable, it is a question of fact for the jury. *Id.*; *see also Burton*, 397 F.3d at 914; *Roeder*, 2021 WL 4819442, at *4.

Plaintiff's original petition was filed on January 31, 2014. Doc. 1-1 at 5. The issue, therefore, is whether her injuries were reasonably ascertainable before or after January 31, 2012. If they were reasonably ascertainable before, her claim is untimely. If they were not reasonably ascertainable until after, her claim is timely. In this case, the Court finds that there is a genuine question of fact regarding when Plaintiff's injuries were reasonably ascertainable.

On one hand, Plaintiff's Amended Fact Sheet states that her symptoms began shortly after her surgery, beginning in July or August in 2010. She also testified at her deposition that her injuries began around that time, and that she attributes many of her symptoms to the pelvic mesh because they were not present before the mesh surgery. Dr. Arroyo also noted a small area of exposed suture and mesh erosion, which he linked to Plaintiff's dyspareunia in 2010. Also, by 2011, the FDA had issued two public health notices about complications associated with pelvic mesh. *See Timothy v. Bos. Sci. Corp.*, 665 F. App'x 295, 298 (4th Cir. 2016) ("Because the FDA had issued an official notification about the link between the product Mrs. Timothy used and the injuries she suffered, we have no trouble concluding Mrs. Timothy had notice that the mesh was the cause-in-fact of her injuries . . . .").

On the other hand, Plaintiff's Amended Fact Sheet states that she did not attribute her issues to the pelvic mesh until 2013, when her doctor suggested revision surgery. At her initial post-operative follow-up appointments with Dr. Arroyo, he told her she was doing excellent, was healing well, and there were no major concerns. Although she missed an appointment with Dr. Arroyo a year after surgery, she had an annual physical in 2011 that included a normal pelvic exam. But in June 2013, she saw a gynecologist, who noted the mesh had become exposed and discussed mesh removal with Plaintiff. Dr. Arroyo also noted mesh erosion at that time that had "not bothered the patient until recently." Around that time, other causes of Plaintiff's symptoms were suggested, such as a possible cervical cyst. Plaintiff subsequently saw Dr. Babalola in July 2013 for "suspected mesh erosion" and increased pain since 2012. Dr. Babalola then performed a mesh removal on Plaintiff in September 2013.

Some of this evidence suggests Plaintiff was suffering injuries shortly after the surgery in 2010, and she attributed them to the mesh, or else could have made the connection with

investigation. *See Benne*, 87 F.3d at 427 (noting that the statute of limitations started running when the plaintiff knew her injury was associated with the defendant's product). But other evidence suggests that Plaintiff's substantial injuries did not start until 2012 or 2013 or were initially attributable to other possible causes. *See Stark v. Johnson & Johnson*, 10 F.4th 823, 830 (7th Cir. 2021) ("A jury might reasonably find that Ms. Stark believed that her mesh-related complications were caused by [Ehlers-Danlos Syndrome] and had no reason to look further for an explanation."). Further, her initial follow-ups with Dr. Arroyo did not necessarily give her reasons to be concerned. *See Cutter v. Ethicon, Inc.*, 2021 WL 3754245, at *6 (6th Cir. 2021) ("If a doctor advises a patient that everything looks good even though portions of the implant remain in her body, a reasonable patient could interpret that to mean that her pain was not caused by defects in the implant itself."). Based on this conflicting evidence, the Court cannot make a legal determination that Plaintiff's injuries were reasonably ascertainable at a specific point in time. *Michaelis*, 296 P.3d at 445.

The Court acknowledges that many other courts have addressed similar issues and reached differing results. *Compare Mecham v. C.R. Bard, Inc.*, 2020 WL 2768997, at *6-9 (D. Utah 2020) (finding claim untimely where the plaintiff began experiencing symptoms outside the limitations period, attributed them to the pelvic mesh, but failed to undertake further investigation) *and Mallow v. Ethicon, Inc.*, 2022 WL 844196, at *4 (W.D. Okla. 2022) ("Given this documented medical knowledge and the conditions Ms. Mallow complained of in 2011 and 2014, Ms. Mallow did possess 'sufficient information which, if pursued, would lead' her to the conclusion that the Prosima mesh caused her injuries much earlier than her claimed realization in March of 2016.") *with Roeder*, 2021 WL 4819442, at *5 (finding conflicting evidence where the plaintiff suspected issues with her mesh but was told by her doctor that she was healing properly, had good support, and there were no signs of erosion) *and Stark*, 10 F.4th at 829-30 (noting facts supporting both

positions). But based on the facts presented here, the question of when Plaintiff's claim accrued is best left for a jury. Defendants' motion on this point is denied.

B. Proximate Cause – Strict Liability/Failure to Warn

To prevail under a failure-to-warn theory, a plaintiff must establish that the failure to warn proximately caused her injuries. *Roeder*, 2021 WL 4819442, at *6. In cases such as this, the learned-intermediary doctrine applies to the question of causation. "The 'learned intermediary doctrine' states that once a manufacturer warns a doctor about a drug's inherent dangers, it has fulfilled its legal duty to provide a warning." *Wright v. Abbott Laboratories, Inc.*, 259 F.3d 1226, 1233 (10th Cir. 2001).[3] In other words, if Defendants adequately warned Dr. Arroyo—as opposed to Plaintiff directly—about the risks of pelvic mesh, they satisfied the duty to warn. *See Hall v. Merck, Sharp & Dohme*, 774 F. Supp. 604, 606 (D. Kan. 1991).

If the warning to the doctor was inadequate, there is a rebuttable presumption of causation. *Roeder*, 2021 WL 4819442, at *6; *Burton*, 397 F.3d at 918. This is because the law presumes that a doctor would have properly warned a plaintiff had an adequate warning been given, and the plaintiff could have avoided the injury. *Roeder*, 2021 WL 4819442, at *6. But a "[d]efendant may rebut this presumption by establishing that the prescribing physician would not have changed his course of treatment after reading and heeding the additional information in the warning." *Id.* In such a case, the burden then shifts back to the plaintiff to prove causation. *Id.*; *see also Miller v. Pfizer Inc.*, 196 F. Supp. 2d 1095, 1127 (D. Kan. 2002) ("If Pfizer provides credible evidence to rebut the presumption, the presumption disappears and the burden shifts back to plaintiffs to affirmatively prove causation."); *Eck v. Parke, Davis & Co.*, 256 F.3d 1013, 1019 (10th Cir. 2001)

[3] This applies to medical devices as well. *Samarah v. Danek Med., Inc.*, 70 F. Supp. 2d 1196, 1204 (D. Kan. 1999) (stating that "Kansas courts have interpreted the exception to protect manufacturers of medical devices as well as prescription drugs").

("Assuming the defendants successfully rebut this presumption, the burden shifts rather heavily back upon the [plaintiffs]."). Once the presumption is rebutted by the defendant, a plaintiff must show that a proper warning would have altered the doctor's behavior. *See Miller*, 196 F. Supp. 2d at 1127.

As a preliminary matter, Defendants' arguments are prefaced on the assumption that there is a disputed question of fact regarding the adequacy of the warnings for Prolift+M. Doc. 108 at 14.[4] The effect of this assumption is that there is a rebuttable presumption of causation. *Roeder*, 2021 WL 4819442, at *6. It then becomes Defendants' burden to rebut the presumption by showing that the doctor would have made the same decision even if he had been additionally warned.

Defendants argue that Dr. Arroyo was aware that all of Plaintiff's injuries were risks of Prolift+M, and that he testified that those risks would not have changed his recommendation to use Prolift+M. Doc. 108 at 14-16.[5] Dr. Arroyo testified that he stood by his decision to offer Prolift+M to Plaintiff. Doc. 108-3 at 42 ("Q. Yes. Putting yourself back at the time that you counseled the plaintiff, do you stand by your decision to offer the Prolift+M as a surgical alternative to fix her prolapse? A. Yes, I do."). This testimony effectively rebuts the presumption

[4] Despite this assumption, Plaintiff argues in her brief that the warning was inadequate. Doc. 128 at 12-15. Given Defendants' assumption that the warnings were inadequate, the Court will likewise assume without deciding that the warnings were inadequate.

[5] Defendants also argue that Dr. Arroyo did not rely on the Instructions for Use ("IFU") for Prolift+M and instead relied on other sources to learn the pertinent risks, including his experience, discussions with colleagues and instructors, and information learned at medical conferences. Doc. 108 at 14-15. But this information was not included in the statement of facts. To the extent these facts are undisputed, they may alternatively support summary judgment in favor of Defendants on this issue. *Breen v. Ethicon, Inc.*, 2021 WL 673485, at *6 (W.D. Wash. 2021) ("Even assuming that Defendants' warnings were inadequate, Breen cannot establish proximate cause because Dr. Mitchell did not rely on any of Defendants' representations."); *Ellis v. Ethicon, Inc.*, 2021 WL 2949779, at *4 (W.D. Wash. 2021) ("Plaintiffs cannot establish proximate cause because of Dr. Mitchell's prior knowledge of the risks of injuries."); *Pierre v. Intuitive Surgical, Inc.*, 476 F. Supp. 3d 1260, 1279 (S.D. Fla. 2020) (stating that a manufacture cannot be liable for inadequate warnings where the treating physician independently knew of relevant risks and did not tell the patient). However, because of the unclear factual record, the Court proceeds under the learned-intermediary burden-shifting framework.

of causation and shifts the burden back to Plaintiff to show that additional warnings would have altered Dr. Arroyo's recommendation. *See Miller*, 196 F. Supp. 2d at 1127-28.

Plaintiff contends there were additional precautions and warning that Dr. Arroyo did not know about, and which could have affected his decision to use Prolift+M in treating Plaintiff. Doc. 128 at 15-16. First, Plaintiff argues that Dr. Arroyo was not aware that mesh contraction was a possible complication and that this information could have impacted his decision. *Id.* at 4, 6, 16. Second, Plaintiff argues that Ethicon's medical director had previously recommended a warning about the use of Prolift+M in sexually active patients or in conjunction with a hysterectomy, and that Dr. Arroyo testified that this knowledge could have impacted his decision. *Id.* at 6, 15-16.

Regarding mesh contraction, Dr. Arroyo testified he was not aware that was a potential complication at the time of Plaintiff's surgery. *See* Doc. 108-3 at 32. Plaintiff contends this "information could have affected his decision to implant the product." Doc. 128 at 6. But that's not what Dr. Arroyo testified. When asked, "Would the knowledge of mesh contraction have altered your decision to offer the mesh to her as a potential option," Dr. Arroyo responded, "No, not necessarily," and then said he would have discussed it with Plaintiff, but if they both felt it was still the best course of action, "I would still proceed the same." Doc. 108-3 at 32. More problematic to Plaintiff's claim, however, is that "contracture" was included in the IFU for Prolift+M. *See id.* at 45 (listing "contracture" as a potential adverse reaction for Prolift+M). Obviously, regardless of whether Dr. Arroyo was aware of this potential risk, there can be no failure to warn by Defendants where they did warn of that risk. *See Wright*, 259 F.3d at 1233 ("Under Kansas law, a plaintiff cannot prevail against a prescription drug manufacturer in a failure to warn case where the manufacturer warned the 'learned intermediary' of the drug's inherent risks.").[6]

[6] Defendants also dispute whether mesh contraction is an injury versus a mechanism by which an injury occurs, and whether Plaintiff actually had mesh contraction. *See Dye v. Covidien LP*, 470 F. Supp. 3d 1329, 1340 (S.D. Fla.

Regarding the claim that Ethicon's medical director wanted a warning to be added that the device should not be used in sexually active patients or when performing a concurrent hysterectomy,[7] Plaintiff contends that Dr. Arroyo testified this information "could have affected his decision to implant the device." Doc. 128 at 6. Again, this is not an entirely accurate reflection of Dr. Arroyo's testimony. Dr. Arroyo was asked whether the fact "that the manufacturer believed that the Prolift mesh should not be placed in sexually active patients" would have altered Dr. Arroyo's decision to offer it to Plaintiff. Dr. Arroyo answered, "Possibly." Doc. 108-3 at 36. When told that the manufacturer's medical affairs director wanted a warning that Prolift should not be used if also performing a concurrent hysterectomy, Dr. Arroyo testified that he "would like to know if there was any contraindication as such," that he didn't know if it would have impacted his decision to offer Prolift+M to Plaintiff, but it "is possible it could have." *Id.* But this is not evidence that a different warning would have altered Dr. Arroyo's behavior, especially in light of his testimony that he stands by his decision. *See Ellis*, 2021 WL 2949779, at *4 ("Plaintiffs have not presented any non-speculative evidence that Dr. Mitchell would have taken a different course of action if additional warnings were given to him."); *Sharp v. Ethicon, Inc.*, 2020 WL 1434566, at *4 (W.D. Ark. 2020) ("Even after he was presented with Ms. Sharp's criticism of the product warnings, he still testified that he would have taken the same course of action then as he would now . . . ."); *Plott v. Ethicon, Inc.*, 2020 WL 12948625, at *2 (N.D. Ga. 2020) ("The Plotts point to Dr. Denton's testimony that she would have wanted to know certain information; that

2020). Because there's no genuine dispute about whether Defendants warned of contraction, the Court does not reach those issues.

[7] Plaintiff also states that "Dr. Arroyo did not know that the French doctors who helped develop the Prolift procedure had been telling Ethicon as early as 2003 that they were concerned about erosion and contraction associated with the Prolift mesh." Doc. 128 at 15. But Plaintiff did not include this in her statement of facts. Further, the IFU for Prolift+M does include warnings about both contracture and mesh erosion. Doc. 108-3 at 45. As stated above, there can be no failure to warn where there was a warning.

information might have been a factor in her decision to recommend the Prolift; or that she would have passed certain information along. However, at the conclusion of her deposition, she confirmed that she stood by her decision to recommend and use Prolift for Mrs. Plott and that nothing she had heard in her (Dr. Denton's) deposition changed her mind."); *Labiche v. Johnson & Johnson*, 2021 WL 3719554, at *1 (S.D. Tex. 2021) ("Nisbet's testimony that she refers to only shows that, had Nisbet been told of the risks or issues at the time, it would have merely affected her decision or made her investigate other possible treatments. This is different than saying that it would have changed her ultimate decision.").

Further, there's no evidence that Ethicon's medical director actually called for a warning that Prolift[8] mesh "should not be used" in sexually active patients or concurrently with a hysterectomy, as the questions were presented to Dr. Arroyo. Plaintiff cites to an excerpt from an expert report to support this factual contention. Doc. 128 at 6 (citing Ex. M., Dr. Garley Report, at 17).[9] But that report did not suggest a warning that Prolift+M "should not be used" in sexually active patients or patients receiving a hysterectomy. It said that Ethicon's European medical director sought a warning that the potential for certain complications should be "taken in consideration" when using mesh in sexually active patients and concurrently with a hysterectomy. Doc. 128-13 at 18. The factually unsupported hypotheticals asked by counsel during Dr. Arroyo's deposition does not establish causation. *Miller*, 196 F. Supp. 2d at 1130 (noting that an equivocal answer about a hypothetical warning is not sufficient to defeat summary judgment); *Conway*, 2021

[8] Defendants additionally argue that reference to "Prolift" in this context is a different product than Prolift+M, which was used in Plaintiff's procedure. Doc. 144 at 3-4; *see also Conway v. Am. Med. Sys., Inc.*, 2021 WL 6126293, at *5 (D. Md. 2021). But they have not presented any facts from which the Court could make this determination.

[9] Defendants also argue that this raises hearsay issues. But because of the ruling in this order, the Court will assume that this evidence could be presented in a way that does not implicate hearsay.

WL 6126293, at *11 (finding that "hypothetical contraindications not otherwise supported by the evidence" could not support fraud claim).

Plaintiff cites several cases that she says denied summary judgment on the learned-intermediary doctrine and proximate-cause issue, including in cases where the treating doctor testified that they stood by their decision. Doc. 128 at 17-18. The Court notes that several of these cases did not actually discuss any of the facts of the case, which make them unhelpful to the analysis here. *See id.* (*Tyree*, *Williams*, *Jimenez*, *Nava*, *Allen*, *Wolford*, and *Waltman*). The others are distinguishable. *See, e.g.*, *Sluis v. Ethicon, Inc.*, 529 F. Supp. 3d 1004, 1018 (D.S.D. 2021) ("Contrary to Ethicon's argument, Dr. Benson never said that he would have offered the Prolift +M to Mrs. Sluis even if he knew of these problems. Rather, Dr. Benson told defense counsel that he still believed that the Prolift +M was a reasonable option 'in the right patient;' he did not say that Mrs. Sluis was such a patient and was not asked whether he would still offer her the Prolift +M if he had substantially the same information as an allegedly adequate warning from Ethicon would have provided."); *Aldridge v. Ethicon, Inc.*, 2020 WL 1308335, at *4 (S.D. Ala. 2020) (noting that a question of fact remained despite an "isolated snippet" of the doctor's testimony based on an "imprecise question" about whether the doctor would have altered his decision).

Plaintiff also relies on *Roeder*. But that case is also distinguishable. There, the defendant did not meet its burden to show that the treating doctor would have made the same decision had an adequate warning been given. *Roeder*, 2021 WL 4819442, at *6. Further, the doctor "also testified that he did not know that Total Petrochemicals wrote a letter stating that its products are not suitable for human implants," "that he would want to know if there were detrimental effects to implanting mesh in the vagina and, if there was, he would not use those products." *Id.* Based on this, the court in *Roeder* concluded that the defendant had "not established that Dr. Werth would

not have changed his course of treatment if he had been provided an adequate warning." *Id.* As discussed above, the facts here are distinguishable.

Finally, Plaintiff argues that, had additional risks been told to her by Dr. Arroyo, Plaintiff would have not elected to follow through with the surgery. Doc. 128 at 16. But "[w]hat the plaintiffs would or would not have done had they received certain warnings is irrelevant to the learned intermediary doctrine." *Fox v. Ethicon, Inc.*, 2016 WL 3748509, at *4 (S.D.W. Va. 2016). Plaintiff also argues that Dr. Arroyo's knowledge of the risks associated with Prolift+M increased over time. Doc. 128 at 16-17. But this doesn't establish that a failure to warn on the part of Defendants caused Plaintiff's injuries.

Accordingly, Defendants are entitled to summary judgment on Plaintiff's failure-to-warn theory.

C. Motion to Strike – Punitive-Damages Claim[10]

In the Pretrial Order, Plaintiff states she is seeking punitive damages. Doc. 98 at 30. Defendants move to strike that claim. Doc. 105.[11] According to Defendants, Plaintiff did not seek punitive damages in her original state-court petition. Defendants further objected to including the claim in the Pretrial Order, but that objection was overruled by the magistrate judge. Doc. 98 at 30 n.7. According to Defendants, the magistrate judge was "under the misimpression" that the operative complaint was the MDL Master Complaint, which included punitive damages, versus the original state-court petition, which did not. Doc. 106 at 2. According to Defendants, the MDL

[10] Defendants argue that Plaintiff failed to timely respond to this motion. Plaintiff's response brief was filed one week late, presumably based on a miscalculation of the two-week response deadline given the other pending motions, which all carried a three-week response deadline. While the Court does not condone late responses and cautions the parties to be mindful of all deadlines going forward, the Court declines to strike a claim solely because of the late response.

[11] This motion also seeks to strike Plaintiff's claim for loss of consortium. But as noted above, Plaintiff is no longer pursuing that claim. Doc. 128 at 19-20.

Master Complaint was not adopted in this case because Plaintiff did not file a short-form complaint that incorporated the MDL Master Complaint. *Id.* at 3. Plaintiff contends, however, that the MDL Master Complaint is the operative complaint, that she could not initially plead punitive damages in her state-court petition under state law,[12] and that the magistrate judge has already ruled on Defendants' objection by including the punitive-damages claim in the Pretrial Order. Doc. 127 at 1-3.

The Court denies Defendants' motion to strike for three reasons. First, the Pretrial Order supersedes all other pleadings in this case and controls going forward. *See Zapata v. IBP, Inc.*, 19 F. Supp. 2d 1215, 1217 (D. Kan. 1998). It includes a claim for punitive damages. Thus, regardless of what any other pleadings included, the Pretrial Order, which governs now, includes the claim.

Second, although Defendants argue that the claim was included only because of a "misimpression" about what pleading controlled, it is unclear why Defendants did not correct the record at the time. Based on the arguments presented in the briefing on the motion to strike, there appears to be some confusion among the parties as to what pleading previously governed this case. But the time to litigate the scope of the case was during the drafting of the Pretrial Order, not now.

Third, and most importantly, Defendants do not argue that the inclusion of the punitive-damages claim prejudices them, other than a vague statement that "Defendants have defended this case based on the assertions Plaintiff has made in her Petition and other court-required submissions." Doc. 106 at 5-6. But punitive damages have long been an issue in the MDL. *See* Doc. 50-1 at 57-60. Defendants offer no specific explanation as to how the inclusion of the punitive-damages claim in the Pretrial Order leaves them unprepared for trial. To the extent

[12] *See* K.S.A. § 60-3703 ("No tort claim or reference to a tort claim for punitive damages shall be included in a petition or other pleading unless the court enters an order allowing an amended pleading that includes a claim for punitive damages to be filed.").

Defendants believe they are unprepared for trial because of the Pretrial Order, they may promptly file an appropriate motion for additional discovery.[13] Defendants may also make any appropriate motion at trial that the question of punitive damages should not be submitted to the jury, should Plaintiff fail to put on sufficient evidence on this issue. But the Court otherwise denies the motion to strike.

IV. CONCLUSION

In sum, there is a genuine issue of fact regarding when Plaintiff's injuries were reasonably ascertainable. However, Plaintiff has not shown a genuine issue of fact as to whether additional warnings would have altered Dr. Arroyo's recommendation regarding the use of Prolift+M. Defendants' request to strike Plaintiff's claim for punitive damages is denied.

THE COURT THEREFORE ORDERS that Defendants' Renewed Motion for Summary Judgment (Doc. 107) is GRANTED IN PART and DENIED IN PART. The motion is granted as to Plaintiff's failure-to-warn theory. But it is denied as to Defendants' argument that Plaintiff's product-liability claim is barred by the statute of limitations.[14]

THE COURT FURTHER ORDERS that Defendants' Motion to Strike Plaintiff's Claims for Loss of Consortium[15] and Punitive Damages (Doc. 105) is DENIED.

IT IS SO ORDERED.

Dated: May 18, 2022

/s/ *Holly L. Teeter*
HOLLY L. TEETER
UNITED STATES DISTRICT JUDGE

[13] Given the approaching trial date, any such motion should be filed within ten days of this order.

[14] To the extent Plaintiff has abandoned or withdrawn claims addressed in the motion, the Court denies the motion as moot.

[15] *See supra* note 14.