

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

SUE ELLEN MAY, et al.,

Plaintiffs,

v.

ETHICON, INC.,
et al.,

Defendants.

CIVIL ACTION FILE
NO. 1:20-CV-322-TWT

OPINION AND ORDER

This is a products liability case. It is before the Court on Defendants Ethicon, Inc. and Johnson & Johnson's Motion for Partial Summary Judgment [Doc. 18]. For the reasons that follow, the Defendants Ethicon, Inc. and Johnson & Johnson's Motion for Partial Summary Judgment [Doc. 18] is GRANTED in part and DENIED in part.

I. Background

On December 10, 2003, Plaintiff Sue Ellen May underwent surgery at Northside Hospital in Atlanta, Georgia to treat her vaginal vault prolapse. *See* Pls.' Fact Sheet, at 4 [Doc. 18-1].¹ Her surgeon, Dr. John R. Miklos, implanted

¹ Plaintiff Gerald G. May is Mrs. May's husband and is suing the Defendants for loss of consortium.

a medical device known as a “Gynemesh GPSL” that is manufactured by Defendants Ethicon, Inc. and Johnson & Johnson. *Id.* The Plaintiffs allege that the mesh product implanted in Mrs. May caused numerous injuries, including chronic pain, narcotic dependence, dyspareunia, and other disabling conditions. *See* Pls.’ Resp. in Opp. to Defs.’ Mot. for Partial Summ. J., at 3 [Doc. 21]. The Plaintiffs’ expert, Dr. Nicholas Fogelson, opines that Mrs. May’s health problems resulted from an adverse reaction to a thermoplastic material used in the construction of the mesh product. *See* Ex. D to Pls.’ Resp. in Opp. to Defs.’ Mot. for Partial Summ. J., at 23 [Doc. 20-2]. Dr. Fogelson further opines that the mesh may never be successfully removed, and that Mrs. May is likely to experience health complications for the remainder of her life. *Id.*, at 29.

This case is one of thousands filed in federal court arising from injuries allegedly caused by the Defendants’ pelvic mesh products. The Plaintiffs’ case was previously pending in one of seven MDLs assigned to the Honorable Joseph R. Goodwin in the United States District Court for the Southern District of West Virginia. On January 9, 2020, Judge Goodwin transferred the Plaintiffs’ individual case to this jurisdiction for further proceedings. *See* Transfer Order [Doc. 25]. Discovery is complete and all dispositive motions have been filed. *Id.*

II. Legal Standard

Summary judgment is appropriate only when the pleadings, depositions, and affidavits submitted by the parties show no genuine issue of material fact exists and that the movant is entitled to judgment as a matter of law. FED. R. CIV. P. 56(a). The court should view the evidence and any inferences that may be drawn in the light most favorable to the nonmovant. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 158-59 (1970). The party seeking summary judgment must first identify grounds to show the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986). The burden then shifts to the nonmovant, who must go beyond the pleadings and present affirmative evidence to show that a genuine issue of material fact does exist. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 257 (1986). “A mere ‘scintilla’ of evidence supporting the opposing party’s position will not suffice; there must be a sufficient showing that the jury could reasonably find for that party.” *Walker v. Darby*, 911 F.2d 1573, 1577 (11th Cir. 1990).

III. Discussion

The Plaintiffs’ Short Form Complaint [Doc. 1] filed in the MDL states that they are bringing the following claims set forth in the Master Complaint [Doc. 26-1]:

Count I – negligence

Count II – strict liability – manufacturing defect

Count III – strict liability – failure to warn

Count IV – strict liability – defective product

Count V – strict liability – design defect

Count VI – common law fraud

Count VII – fraudulent concealment

Count VIII – constructive fraud

Count IX – negligent misrepresentation

Count X – negligent infliction of emotional distress

Count XI – breach of express warranty

Count XII – breach of implied warranty

Count XIII – violation of consumer protection laws

Count XIV – gross negligence

Count XV – unjust enrichment

Count XVI – loss of consortium

Count XVII – punitive damages

The parties agree that Georgia law applies to the Plaintiffs' claims. The Defendants have moved for summary judgment on Counts I, II, III, IV, VI, VII, VIII, IX, X, XI, XII, XIII, XIV, and XV of the Plaintiffs' Complaint. The Defendants do not presently seek summary judgment as to Counts V, XVI, and XVII of the Complaint.

In response to the Defendants' motion, the Plaintiffs have expressly abandoned Counts II, III, IV, VI, VII, VIII, IX, X, XI, XII, XIII, and XV of the Complaint. *See* Pls.' Br. in Opp. to Defs.' Mot. for Partial Summ. J., at 3. The Defendants' motion is granted as to those claims. The Plaintiffs oppose summary adjudication of their negligence and gross negligence claims set forth in Counts I and XIV of the Master Complaint.²

A. Count I – Negligence

The Defendants first argue that Count I alleging negligence should be dismissed or merged with the Counts alleging strict liability because “[g]eneral negligence is a theory of liability in a products liability claim” rather than “a stand-alone cause of action.” Defs.' Br. in Supp. of Mot. for Partial Summ. J., at 4 [Doc. 19] (quoting *Grieco v. Tecumseh Prods. Co.*, No. 4:12-cv-195, 2013 WL 5755436, at *5 (S.D. Ga. Oct. 23, 2013)). But Count I does not state a claim for “general negligence.” Rather, it states multiple claims sounding in negligence, including: (a) negligent design, (b) negligent manufacture, (c) negligent failure to test, (d) negligent failure to inspect, (e) negligent failure to

² The Plaintiffs also assert that their “discovery rule and tolling claim” survives because the Defendants declined to seek summary dismissal of that claim as set forth in Count XVIII of the Master Complaint. *See* Pls.' Resp. in Opp. to Defs.' Mot. for Partial Summ. J., at 3. But the Plaintiffs' Short Form Complaint does not list a “discovery rule and tolling claim” among the Plaintiffs' claims. Therefore, the Court concludes that the Plaintiffs have not stated a “discovery rule and tolling claim” in this case.

train, (f) negligent failure to warn, (g) negligent marketing, and (h) negligent promotion. *See* Master Complaint ¶¶ 89-94. Several of these negligence claims have no strict liability analogs under Georgia law. The Court assumes that the Defendants seek dismissal or consolidation only of the negligence claims that substantially overlap with the Plaintiffs' strict liability claims, namely the Plaintiffs' claims for negligent design defect, negligent manufacturing defect, and negligent failure to warn.

Count I of the Master Complaint contains a claim for negligent design defect, whereas Count VI of the Master Complaint states a claim for strict liability design defect. The demarcation line between negligent design defect claims and strict liability design defect claims is not entirely clear under Georgia law. "Georgia law has long recognized [the distinction] between negligence and strict liability theories of liability," and the Supreme Court of Georgia has declined "to conclude definitively that the two theories merge in design defect cases." *Banks v. ICI Americas, Inc.*, 264 Ga. 732, 735 n.3 (1994) (citations omitted). Nevertheless, Georgia courts apply the same risk-utility analysis to both types of claims, which requires plaintiffs to prove that the allegedly defective product poses an unreasonable risk of harm to the consumer. *See Banks*, 264 Ga. at 734-735, 735 n.3. Because the same analysis applies to both, some courts have elected to treat separately pleaded causes of action for negligent and strict liability design defects as one claim. *Cf. Frazier*

v. Mylan Inc., 911 F. Supp. 2d 1285, 1299 (N.D. Ga. 2012); *Schmidt v. C.R. Bard, Inc.*, No. 6:14-CV-62, 2014 WL 5149175, at *6 (S.D. Ga. Oct. 14, 2014). The Court agrees with the reasoning in these decisions and will order the Plaintiffs to consolidate their design defect claim into a single claim in the Pretrial Order. The Court emphasizes, however, that its decision in no way narrows the scope of the issues to be litigated at trial.

Count I of the Master Complaint also contains claims for negligent manufacturing defect and negligent failure to warn. These claims are distinct from, and can be brought concomitantly with, analogous claims sounding in strict liability. *See Williams v. St. Jude Med., S.C., Inc.*, No. 1:16-CV-04437-ELR, 2017 WL 11113322, at *2-*3 (N.D. Ga. Oct. 19, 2017) (analyzing distinct claims for strict liability manufacturing defect and negligent manufacturing defect); *Haynes v. Cyberonics, Inc.*, No. 1:09-CV-2700-JEC, 2011 WL 3903238, at *5-*7 (N.D. Ga. Sept. 6, 2011) (same); *Battersby v. Boyer*, 241 Ga. App. 115, 117 (1999) (“[Claims based on strict liability and negligent failure to warn] are separate and distinct claims arising from different duties owed by the manufacturer to consumers.”) (citing *Chrysler Corp. v. Batten*, 264 Ga. 723, 724(1) (1994); *Zeigler v. CloWhite*, 234 Ga. App. 627, 629(2) (1998)).

But, while the Plaintiffs’ negligent manufacturing defect claim is cognizable under Georgia law, the Plaintiffs have not adduced evidence necessary to establish the elements of the claim. “In order to establish a

negligent manufacturing claim, the plaintiff must come forward with evidence that, among other things, there was a defect in the product when it left the manufacturer that was caused by the manufacturer's negligence.” *Haynes*, 2011 WL 3903238, at *7 (quoting *Miller v. Ford Motor Co.*, 287 Ga. App. 642, 644 (2007)). “Generally, a manufacturing defect results from an error specifically in the fabrication process, as distinct from an error in the design process.” *Fletcher v. Water Applications Distribution Grp., Inc.*, 333 Ga. App. 693, 697, 773 S.E.2d 859, 863 (2015), *aff’d in part, rev’d in part sub nom. on other grounds Certainteed Corp. v. Fletcher*, 300 Ga. 327, 794 S.E.2d 641 (2016). The Defendants assert, and the Plaintiffs do not contest, that there is no record evidence tending to show that the specific product used in Mrs. May’s case deviated from design specifications in a manner that caused her injuries. Indeed, the Plaintiffs’ sole expert in this case, Dr. Nicholas Fogelson, opines that Mrs. May’s injuries arose from an adverse reaction to a thermoplastic material that is inherent to the product’s design. *See* Ex. D to Pls.’ Resp. in Opp. to Defs.’ Mot. for Partial Summ. J., at 23 [Doc. 20-2]. “When a plaintiff calls into question the safety of an entire product line ... the claim is one for a design defect and not for a manufacturing defect.” *See Fletcher*, 333 Ga. App. at 698. The Court will therefore enter summary judgment in the Defendants’ favor on the Plaintiffs’ negligent manufacturing defect claim.

The record is similarly lacking when it comes to the Plaintiffs’ failure to

warn claim. To prevail on their failure to warn claim, the Plaintiffs must show that the Defendants (1) had a duty to warn, (2) that the Defendants breached that duty, and (3) that the breach proximately caused Mrs. May's injuries. *Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 815 (11th Cir. 2010) (citing *Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d 1351, 1362 (N.D. Ga. 1999)). Under Georgia's learned intermediary doctrine, a medical device manufacturer's duty to warn runs to the patient's doctor rather than to the patient herself. *See In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1365-66 (M.D. Ga. 2010) (citing *McCombs v. Synthes (U.S.A.)*, 277 Ga. 252, 253, 587 S.E.2d 594, 595 (2003)). "In cases where 'a learned intermediary has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided, courts typically conclude that ... the causal link is broken and the plaintiff cannot recover.'" *Dietz*, 598 F.3d at 816 (quoting *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1279-81 (11th Cir. 2002) (per curiam)). Dr. John R. Miklos performed Mrs. May's implantation surgery. Dr. Miklos has not been deposed in this case and there is no evidence on the record from which to glean whether he would have acted differently had he received a proper warning from the Defendants. The Defendants argue that the Plaintiffs cannot sustain their failure to warn claim in the absence of such testimony.

The Defendants' argument assumes that the Plaintiffs bear the burden of production on the issue of whether the implanting physician would have acted differently had he been provided with a proper warning. In cases arising under Georgia law, courts have granted summary judgment to defendant manufacturers where the learned intermediaries affirmatively testified that a proper warning would not have altered their decision-making. *Cf. Dietz*, 598 F.3d at 816 (11th Cir. 2010) ("The doctor provided explicit, uncontroverted testimony that, even when provided with the most current research and FDA mandated warnings, he still would have prescribed Paxil for Dietz's depression. Pursuant to Georgia's learned intermediary doctrine, this assertion severs any potential chain of causation through which Appellant could seek relief, and Appellant's claims thus fail."); *Wheat*, 46 F. Supp. 2d at 1364 ("Each of the plaintiffs' treating physicians testified that he was aware of the risks associated with spinal implant surgery, that such risks were well known in the medical community, and that he would have taken the same course of action in spite of the information Plaintiffs contend should have been provided. Consequently, summary judgment is demanded."). But the Defendants do not provide, and the Court has not independently identified, any Georgia precedent holding that testimony from the treating physician on the efficacy of the device manufacturer's warning is necessary to establish

proximate causation.³

Nevertheless, and despite the lack of Georgia precedent on this issue, the Court agrees with the Defendants that the Plaintiffs' failure to warn claim cannot proceed in the absence of any testimony at all from the implanting physician. The Plaintiffs cannot establish the necessary elements of their failure to warn claim without any evidence indicating how the implanting physician—to whom the duty to warn was owed—responded to the Defendants' warning or how he might have responded to some different, more comprehensive warning. The Plaintiffs do not meaningfully contest the Defendants on this point. Accordingly, the Court will enter summary judgment in the Defendants' favor on the failure to warn claim alleged in Count I of the Master Complaint.

B. Count XIV – Gross Negligence

As with Count I alleging negligence, the Defendants argue that Count

³ The Defendants cite numerous cases from other jurisdictions in which courts have held that lack of testimony from the learned intermediary precludes a finding of proximate causation. *See, e.g., Higgins v. Ethicon, Inc.*, No. 2:12-cv-01365, 2017 WL 2813144 (S.D. W. Va. Mar. 30, 2017) (applying Texas law); *Contreras v. Boston Sci. Corp.*, No. 2:12-CV-03745, 2016 WL 1436682, at *4 (S.D. W. Va. Apr. 11, 2016) (applying California law); *Sowder v. Boston Sci. Corp.*, No. 2:13-CV-05149, 2015 WL 5838507, at *5 (S.D. W. Va. Oct. 5, 2015) (applying Florida law); *Bennett v. Boston Sci. Corp.*, No. 2:13-CV-06641, 2015 WL 2088733, at *4 (S.D. W. Va. May 5, 2015) (applying West Virginia law); *Mullins v. Ethicon, Inc.*, No. 2:12-CV-02952, 2017 WL 345865, at *2 (S.D. W. Va. Jan. 20, 2017) (applying West Virginia law).

XIV alleging gross negligence should be dismissed because negligence is not a “stand-alone claim” in a products liability action. The Defendants’ argument is unavailing. O.C.G.A. § 51-1-4 defines gross negligence as the absence of even “slight diligence,” which in turn is defined as “that degree of care which every man of common sense, however inattentive he may be, exercises under the same or similar circumstances.” The Defendants do not explain why a claim for gross negligence ought not to be separately pleaded, nor why a jury should be prevented from determining whether the Plaintiffs can meet the standard set forth in O.C.G.A. § 51-1-4 at trial. Accordingly, the Court declines to dismiss the Plaintiffs’ gross negligence claim.

IV. Conclusion

For the foregoing reasons, the Defendants Ethicon, Inc. and Johnson & Johnson’s Motion for Partial Summary Judgment [Doc. 18] is GRANTED in part and DENIED in part.

SO ORDERED, this 11 day of February, 2020.

/s/Thomas W. Thrash
THOMAS W. THRASH, JR.
United States District Judge