UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

KLARA OHALL,

Plaintiff,

v. Case No. 8:20-cv-1927-T-60TGW

BOSTON SCIENTIFIC CORP.,

Defendant.
_____/

ORDER GRANTING IN PART AND DENYING IN PART "BOSTON SCIENTIFIC CORPORATION'S MOTION FOR SUMMARY JUDGMENT"

This matter is before the Court on "Boston Scientific Corporation's Motion for Summary judgment and Memorandum of Law in Support," filed on May 13, 2019. (Doc. 47). Plaintiff Klara Ohall responded in opposition on May 28, 2019. (Doc. 49). Upon review of the motion, response, court file, and record, the Court finds as follows:

Background

This case is one of thousands of similar cases filed since 2010.[1] Plaintiff Klara Ohall sued Defendant Boston Scientific Corporation directly in the Southern

[1] In the seven MDLs, over 100,000 cases have been filed, approximately 26,000 of which are in the Boston Scientific MDL. *See* MDL 2187 (C.R. Bard) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2187; MDL 2325 (American Medical Systems) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2325; MDL 2326 (Boston Scientific) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2326; MDL 2327 (Johnson & Johnson, Ethicon) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2327; MDL 2387 (Coloplast) Member List of Cases,

District of West Virginia as part of the multidistrict litigation ("MDL") entitled *In re: Boston Scientific Corp., Pelvic Repair Sys. Prods. Liab. Lit.*, MDL No. 2326. The case was not resolved by the MDL transferee court (the "MDL Court"), and on August 19, 2020, the case was transferred to this Court.

On November 19, 2013, Klara Ohall was implanted with Boston Scientific's Obtryx Transobturator Mid-Urethral Sling System ("Obtryx") and Repliform Tissue Regeneration Matrix ("Repliform") at a hospital in Brandon, Florida. Both devices were designed and manufactured by Defendant Boston Scientific Corporation. Ms. Ohall underwent revision/removal procedures in 2015.

On June 13, 2018, Plaintiff sued directly in the MDL using a short-form complaint, alleging: Negligence (Count I), Strict Liability – Design Defect (Count II), Strict Liability – Manufacturing Defect (Count III), Strict Liability – Failure to Warn (Count IV), Breach of Express Warranty (Count V), Breach of Implied Warranty (Count VI), Discovery Rule, Tolling, and Fraudulent Concealment (Count VIII), and Punitive Damages (Count IX).

Legal Standard

Summary judgment is appropriate "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." Fed. R. Civ. P. 56(a). A properly supported motion for summary

https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2387; MDL 2440 (Cook Medical) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2440; and MDL 2511 (Neomedic) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2511.

judgment is only defeated by the existence of a genuine issue of material fact. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986).

The moving party bears the initial burden of showing that there are no genuine issues of material fact. *Hickson Corp. v. N. Crossarm Co.*, 357 F.3d 1256, 1260 (11th Cir. 2004). When the moving party has discharged its burden, the nonmoving party must then designate specific facts showing the existence of genuine issues of material fact. *Jeffery v. Sarasota White Sox, Inc.*, 64 F.3d 590, 593-94 (11th Cir. 1995). If there is a conflict between the parties' allegations or evidence, the nonmoving party's evidence is presumed to be true and all reasonable inferences must be drawn in the nonmoving party's favor. *Shotz v. City of Plantation*, 344 F.3d 1161, 1164 (11th Cir. 2003).

Analysis

Repliform Device

In its motion for summary judgment, Defendant argues that Plaintiff cannot stablish that the Repliform caused her injuries where none of her experts identify a specific defect applicable to the device. Plaintiff indicates that she does not assert her claims with respect to the Repliform. As such, the Court finds that Defendant is entitled to summary judgment on Plaintiff's claims to the extent that they are based on the Repliform device.

Count I: Negligence

Defendant seeks summary judgment on Count I to the extent that Plaintiff's negligence claim relies on (1) a manufacturing defect, (2) a design defect, and (3) an alleged failure to warn.

Manufacturing Defect

Defendant seeks summary judgment on Count I to the extent the claim is based on an alleged manufacturing defect. Plaintiff indicates that she does not intend to pursue any claims based on a manufacturing defect. Based on Plaintiff's concession and the applicable case law, Defendant is entitled to summary judgment on this portion of Count I.

Design Defect

Defendant also seeks summary judgment on Count I to the extent that it relies on a design defect. Defendant argues that, under the government rules defense, Plaintiff has failed to overcome the rebuttable presumption that the Obtryx device is not defective or unreasonably dangerous because it was FDA approved. Plaintiff argues that the Obtryx device went through an approval process that does not trigger the government rules defense.

Under the government rules defense, when a device complies with federal or state regulations, a rebuttal presumption arises that the product is not defective or unreasonably dangerous. *See* § 768.1256(1), *F.S.* The Obtryx device was approved as a Class II medical device through the FDA's § 510(k) process. (Doc. 47-3). However, the § 510(k) approval process is "focused on equivalence with a

preexisting device rather than safety …" *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 751 (S.D. W. Va. 2014) (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008)). As a result, the government rules defense is inapplicable to devices, such as the Obtryx device, that are approved under § 510(k). *See, e.g.*, *Salinero v. Johnson & Johnson*, No. 1:18-cv-23643-UU, 2019 WL 7753441, at *9 (S.D. Fla. Oct. 28, 2019); *Oliver v. Boston Sci. Corp.*, No. 2:13-cv-01736, 2015 WL 5838506, at *4 (S.D. W. Va. Oct. 5, 2015). Accordingly, the Court denies Defendant's motion as it applies to this portion of Count I.

Failure to Warn

Defendant further seeks summary judgment on Count I to the extent that the claims is based on an alleged failure to warn. Specifically, Defendant contends that it "was under no duty to warn Plaintiff directly of the potential risks associated with use of the Obtryx." (Doc. 47 at 11). Plaintiff responds that her claim is based on Defendant's failure to warn her implanting physician.

Defendant's sole argument as to Plaintiff's failure to warn claim is that it had no duty to warn Plaintiff directly of any risks associated with the product. However, Plaintiff's claim is based on Defendant's alleged failure to provide adequate warnings to the implanting physician. As a result, the motion for summary judgment is denied as to this portion of Count I.

Count II: Strict Liability – Design Defect

Defendant moves for summary judgment on Plaintiff's strict liability design defect claim. For the reasons discussed in its analysis of Count I, the Court denies Defendant's motion for summary judgment as to Count II.

Count III: Strict Liability – Manufacturing Defect

In its motion, Defendant seeks summary judgment on Plaintiff's strict liability manufacturing defect claim. Plaintiff indicates that she does not intend to pursue her manufacturing defect claim. Accordingly, the motion for summary judgment is granted as to Count III.

Count IV: Strict Liability – Failure to Warn

Defendant moves for summary judgment on Plaintiff's strict liability failure to warn claim. For the reasons discussed in its analysis of Count I, the Court denies Defendant's motion for summary judgment as to Count IV.

Counts V & VI: Breach of Express & Implied Warranty

Defendant seeks for summary judgment as to Plaintiff's claims for breach of express and implied warranty. Plaintiff indicates that she does not intend to pursue these claims. Consequently, the Court grants summary judgment as to Count V and Count VI.

Count VIII: Discovery Rule, Tolling, & Fraudulent Concealment

In its motion, Defendant moves for summary judgment as to Plaintiff's claim for fraudulent concealment. Plaintiff indicates that she does not intend to proceed on her claim for fraudulent concealment. Accordingly, the motion for summary

judgment is granted as to Count VIII to the extent that it relies on fraudulent concealment.

Accordingly, it is

ORDERED, **ADJUDGED**, and **DECREED**:

1. "Boston Scientific Corporation's Motion for Summary judgment and Memorandum of Law in Support" (Doc. 47) is **GRANTED IN PART AND DENIED IN PART**.
2. The motion is **GRANTED** to the extent that the Court finds that Defendant Boston Scientific Corporation is entitled to summary judgment in its favor, and against Plaintiff, on all claims related to the Repliform device.
3. The motion is **FURTHER GRANTED** to the extent that the Court finds that Defendant Boston Scientific Corporation is entitled to summary judgment on Counts III, V, VI, and VIII. The Court will enter a final judgment once all claims have been resolved.
4. The motion is otherwise **DENIED**.

DONE and **ORDERED** in Chambers, in Tampa, Florida, this 14th day of September, 2020.

TOM BARBER
UNITED STATES DISTRICT JUDGE