

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: DAVOL, INC./C.R. BARD,
INC., POLYPROPYLENE HERNIA
MESH PRODUCTS LIABILITY
LITIGATION**

Case No. 2:18-md-2846

**JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson**

**This document relates to:
Stinson v. Davol, Inc., et al.
Case No. 2:18-cv-1022**

DISPOSITIVE MOTIONS ORDER NO. 8

Defendants C.R. Bard, Inc. and Davol, Inc. moved for a pre-verdict judgment as a matter of law on all of Plaintiff's claims and filed briefing in support (*see* ECF Nos. 367 & 374), which Plaintiff opposed (ECF Nos. 370 & 387). The Court orally denied Defendants' motion on November 8, 2023, with an opinion to follow. Defendants renewed their motion post-verdict to preserve any issues for potential appeal or cross-appeal. (ECF No. 389.)

I. Background¹

Plaintiff's case is the third bellwether trial selected from thousands of cases in this multidistrict litigation ("MDL") against Defendants. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as "shar[ing] common factual questions arising out of allegations that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections." (No. 2:18-md-02846, ECF No. 1

¹ For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order in this case. (Dispositive Motions Order ("DMO") No. 7, ECF No. 225.) All docket citations are to the *Stinson* case, 2:18-cv-1022, unless otherwise noted.

at PageID #1–2.)

The relevant facts here are that in 2015 Plaintiff underwent a right inguinal hernia repair with an Extra-Large PerFix Plug mesh, a product manufactured by Defendants. In 2017, Plaintiff underwent exploratory surgery to determine whether he had a recurrent hernia or nerve entrapment because of chronic pain in his right groin area. The explanting surgeon, Dr. Radke, noted extensive scarring and found “a large ball approximately 2.5 cm in diameter of rolled up mesh next to the pubic tubercle.” (ECF No. 89-22 at PageID #1134.) Dr. Radke removed the mesh, which he described as “slow going and extremely difficult” because of the significant scarring. (*Id.*) Dr. Radke then repaired the hernia with another of Defendants’ products, a Bard Mesh. (*Id.*) Even after the explant surgery, Plaintiff claimed to have continuing chronic pain and other complications. On May 10, 2023, after undergoing nerve injections that did not provide him with permanent pain relief, Plaintiff had a right groin exploratory surgery that resulted in the removal of the Bard Mesh and the loss of Plaintiff’s right testicle and spermatic cord. (Case No. 18-md-2846, ECF No. 29-5.)

The crux of Plaintiff’s claims is that Defendants knew of certain risks presented by the PerFix Plug device but marketed and sold the device despite these risks and without appropriate warnings, causing Plaintiff’s injuries. Plaintiff alleged that the polypropylene in the PerFix Plug degrades after implantation, which enhances the chronic inflammatory response in the body. (ECF No. 124 at PageID #4826.) Plaintiff claimed that the inflammation and resulting fibrosis are exacerbated by the PerFix Plug’s shape, weight, and pore size. Plaintiff also claimed that the PerFix Plug has a high incidence of chronic pain. (*Id.*) According to Plaintiff, Defendants downplayed the rate and severity of complications caused by the PerFix Plug, even when faced with reports of negative outcomes, which created an unreasonable risk of significant and

permanent harm to patients. (*Id.*)

Trial began on October 16, 2023, and lasted for about three and a half weeks. (ECF Nos. 337, 380.) Plaintiff rested his case on October 30, 2023. (ECF No. 366.) After Plaintiff's presentation of his case at trial, Defendants moved for judgment as a matter of law and filed a brief in support of their motion. (ECF No. 367.) The Court permitted Plaintiff to respond. (ECF No. 370.) Defendants filed another brief in support of their motion at the close of evidence. (ECF No. 374.) The Court orally denied Defendants' motion before closing arguments, with an opinion to follow. On November 8, 2023, the jury returned a verdict for Defendants on Plaintiff's design defect claim and returned a verdict for Plaintiff on his failure to warn and negligence claims, with an award of \$500,000. (ECF No. 381.) In an answer to an interrogatory, the jury did not find that Defendants acted with malice, thereby foreclosing punitive damages. (*Id.*)

II. Legal Standard

A party may move for judgment as a matter of law under Federal Rule of Civil Procedure 50 when the opposing party has been fully heard and before the case is submitted to the jury. Fed. R. Civ. P. 50(a)(1) & (2). The Court may grant the motion if "the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Fed. R. Civ. P. 50(a)(1). The same standard for summary judgment motions applies to motions for judgment as a matter of law. *White v. Burlington N. & Santa Fe R. Co.*, 364 F.3d 789, 794 (6th Cir. 2004) (en banc) (citing *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000)). The Court must review the entire record and "draw all reasonable inferences in favor of the nonmoving party, and [it] may not make credibility determinations or weigh the evidence." *McCombs v. Meijer, Inc.*, 395 F.3d 346, 352 (6th Cir. 2005) (quoting *Reeves*, 530 U.S. at 150). This means that the Court "must disregard all evidence favorable to the moving party that the jury

is not required to believe.” *White*, 364 F.3d at 794–95 (quoting *Reeves*, 530 U.S. at 151). “District courts should grant judgment as a matter of law only if a complete absence of proof exists on a material issue in the action, or if no disputed issue of fact exists on which reasonable minds could differ.” *LaPerriere v. Int’l Union, United Auto., Aerospace, & Agric. Implement Workers of Am.*, 348 F.3d 127, 132 (6th Cir. 2003) (quoting *Clark v. Chrysler Corp.*, 310 F.3d 461, 479 (6th Cir.2002), *vacated on other grounds by Chrysler Corp. v. Clark* 124 S. Ct. 102 (2003)); *see also In re E.I. Du Pont De Nemours & Co.*, No. 2:13-md-2433, 2015 WL 5822663, at *2 (S.D. Ohio Oct. 1, 2015). To preserve for appeal the subject matter of a motion for judgment as a matter of law, a party must renew the motion after the verdict pursuant to Rule 50(b). *See Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 546 U.S. 394, 404 (2006) (“As an initial matter, *Cone*, *Globe Liquor*, and *Johnson* unequivocally establish that the precise subject matter of a party’s Rule 50(a) motion—namely, its entitlement to judgment as a matter of law—cannot be appealed unless that motion is renewed pursuant to Rule 50(b).”).

III. Analysis

Defendants filed a pre-verdict Motion for Judgment as a Matter of Law and renewed the motion post-verdict. (ECF Nos. 367, 374, and 389.) Both motions address the same topics and raise the same arguments. The Court will therefore collectively address the Motions as a singular Motion for Judgment as a Matter of Law for the sake of brevity and to avoid confusion.

Defendants’ Motion for Judgment as a Matter of Law raises issues that the Court addressed when ruling on Defendants’ Motion for Summary Judgment. In DMO No. 7 the Court addressed Defendants’ arguments that the PerFix Plug’s Instructions for Use (“IFU”) were adequate (ECF No. 225 at PageID #9126–27), that any alleged failure to warn was not the cause of Plaintiff’s injuries (*id.* at PageID #9127–28), and that Plaintiff’s negligence claims fail because his strict

liability claims fail (*id.* at PageID #9128–29). Because the jury found for Defendants on Plaintiff’s Strict Liability – Design Defect claim and did not award punitive damages, the Court will not address any arguments related to those claims.

A. Strict Liability – Failure to Warn

Defendants claim that Plaintiff failed to prove that the PerFix Plug’s IFU was inadequate or that any inadequate warning caused his injuries. However, the Court addressed these issues at the summary judgment stage and Defendants have not presented a compelling reason for the Court to depart from its prior ruling. The evidence presented at trial conformed to the same evidence adduced at summary judgment. Drawing all reasonable inferences in favor of Plaintiff, the Court cannot conclude that “no disputed issue of fact exists on which reasonable minds could differ.” *McCombs*, 395 F.3d at 352; *LaPerriere*, 348 F.3d at 132.

Defendants argue that Plaintiff did not show that the PerFix Plug’s IFU was inadequate. According to Defendants, the trial testimony of Dr. Grischkan, Dr. Kessler, and Dr. Tan could not show that the PerFix Plug’s IFU did not adequately warn of the device’s risks. (ECF No. 370 at PageID #13804–07.) Yet Defendants’ arguments focus more on the witnesses’ conclusions than the sufficiency of the evidence. Although Defendants may disagree with Plaintiff’s argument that the IFU should have included warnings of pain, excessive fibrosis, and chronic pain, which they could and did argue at trial, the Court does “not make credibility determinations or weigh the evidence” in ruling on a motion for judgment as a matter of law. *McCombs*, 395 F.3d at 352 (quoting *Reeves*, 530 U.S. at 150).

Defendants also argue that Plaintiff failed to introduce sufficient evidence to demonstrate that any allegedly inadequate warning caused his injuries. (ECF No. 367 at PageID #13496–97.) Under the learned intermediary doctrine, a manufacturer’s duty to warn is fulfilled when the

manufacturer has adequately warned the physician, rather than the plaintiff himself. *Doe v. Solvay Pharms., Inc.*, 350 F. Supp. 2d 257, 271 (D. Me. 2004), *aff'd*, 153 F. App'x 1 (1st Cir. 2005) (quoting *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 80 (1st Cir.1992)). According to Defendants, their duty to warn was fulfilled because Plaintiff's implanting surgeon, Dr. Tan, was aware of the risks of the complications Plaintiff claims to have suffered. (ECF No. 367 at PageID #13497–99.) Defendants point to Dr. Tan's testimony that she warned Plaintiff about risks of pain and nerve damage, and that she was "fully aware of the risk of fibrosis, inflammation and long-term pain." (*Id.* at PageID #13498.) They also point to a patient education brochure that Dr. Tan provided to Plaintiff. (*Id.* at PageID #13499.) The brochure, published by the American College of Surgeons, warns that risks of hernia repair surgery can include nerve injury and "continued pain." (ECF No. 367-5.) Therefore, according to Defendants, Dr. Tan was aware of "each of the relevant risks and complications at issue in this case." (ECF No. 367 at PageID #13499.)

However, the Court addressed these same arguments in denying the failure to warn portion of Defendants' motion for summary judgment. As the Court noted in its ruling, "Dr. Tan testified that she would have expected the device's IFU to include warnings of any increased risk specific to the PerFix Plug of chronic pain, mesh contraction, and increased fibrotic reaction." (DMO No. 7, ECF No. 225 at PageID #9128 (citing ECF No. 124-1 at PageID #4895–96).) Although Defendants claim Dr. Tan knew of the risks of inguinal hernia repair generally, Plaintiff argued that Dr. Tan was unaware of the increased risks specific to the PerFix Plug. (*Id.*)

Defendants also argue that Plaintiff has not shown that Dr. Tan's decision to implant the PerFix Plug would have changed had any added warnings been provided. (ECF No. 367 at PageID #13499–504.) Yet Defendants do not point to any new evidence or testimony that was unavailable at the time of the Court's summary judgment ruling, in which it explained that "Dr. Tan testified

that if she had known about any increased risk, it would have affected her decisions regarding Plaintiff's course of treatment. There is a genuine issue of material fact as to whether any deficient warnings were the cause of Plaintiff's injuries." (DMO No. 7, ECF No. 225 at PageID #9128.) Defendants present no argument that would compel the Court to revisit its summary judgment ruling on this issue. The Court cannot find "that a reasonable jury would not have a legally sufficient evidentiary basis to find for [Plaintiff] on that issue." Fed. R. Civ. P. 50(a)(1).

B. Negligence

On the verdict form, the jury indicated that it found for Plaintiff on his negligence claim on the grounds of failure to warn, and not on design defect. (ECF No. 381 at PageID #14493-94.) Therefore, the Court will only address Defendants' arguments related to failure to warn. As they did in their Motion for Summary Judgment, Defendants argue that, because Plaintiff's claims fail under a strict liability theory, they also fail under a negligence theory. (ECF No. 367 at PageID #13496, n.3.) Defendants again present no argument that would compel the Court to revisit its summary judgment ruling on this issue, and therefore judgment as a matter of law is not warranted.

IV. Conclusion

For the reasons set forth above, Defendants' Motion for Judgment as a Matter of Law (ECF Nos. 367, 374) and Post-Verdict Renewed Motion for Judgment as a Matter of Law (ECF No. 389) are **DENIED**.

IT IS SO ORDERED.

1/31/2024
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE