UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

WAYNE PARKER, Plaintiff, v. MEDTRONIC SOFAMOR DANEK USA, INC. DBA MEDTRONIC, Defendant.	)	Case No. 1:20-CV-02456 Judge J. Philip Calabrese Magistrate Judge Thomas M. Parker

OPINION AND ORDER

Defendant Medtronic Sofamor Danek USA, Inc., doing business as Medtronic, manufactures and distributes spinal implants that are surgically inserted. Around June 6, 2014, Plaintiff underwent surgery and had Defendant's anterior cervical plate system inserted. The system failed, requiring a second surgery and potentially a third, and causing Plaintiff pain and suffering, permanent injuries, and medical expenses. Defendant moves to dismiss the first amended complaint. For the reasons that follow, the Court **GRANTS** Defendant's motion.

STATEMENT OF FACTS

On this motion to dismiss, the Court takes the following allegations in the first amended complaint as true and construes them in Plaintiff's favor.

Around June 6, 2014, Plaintiff "received an anterior cervical diskectomy with interbody arthrodesis C4-5, C5-6, and C6-7 with the use of structural allograft and use of anterior cervical plate fixation." (ECF No. 15, ¶ 5, PageID #62.) Defendant designed, manufactured, and distributed the anterior cervical plate system and

developed the surgical technique that was used. (*Id.*) A few months later, on September 22, 2014, Plaintiff underwent a second surgery "due to the potential loosening of the cervical screw manufactured by Defendant." (*Id.*, ¶ 6.) Specifically, "the right C7 anterior cervical screw was noted to be backed out approximately 4 to 5 millimeters and was removed and the screw hole filled." (*Id.*) Then, around March 10, 2015, the left-side screw at C7 was "anteriorly displaced approximately 8 millimeters." (*Id.*, ¶ 7.) Plaintiff has not undergone or scheduled a third surgery to remove the left-side screw. (*Id.*, ¶ 8.)

As a result of these events, Plaintiff "endured great pain and suffering, sustained permanent injuries, and incurred medical expenses which will continue into the future." (*Id.*, ¶ 9.)

STATEMENT OF THE CASE

Based on these allegations, Plaintiff asserts four causes of action under the Ohio Product Liability Act: (1) manufacturing defect; (2) design defect; (3) nonconformance with the representations; and (4) supplier liability. Plaintiff also seeks punitive damages. Defendant moves to dismiss under Rule 12(b)(6).

ANALYSIS

At the outset, the parties dispute the standard for considering a motion to dismiss. (ECF No. 18, PageID #94; ECF No. 19, PageID #100.) In the Court's view, the standard under Rule 12(b)(6) is fairly well settled. At the motion to dismiss stage in any civil action, a complaint must "state[] a claim for relief that is plausible, when measured against the elements" of a claim. *Darby v. Childvine, Inc.*, 964 F.3d 440, 444 (6th Cir. 2020) (citing *Binno v. American Bar Ass'n*, 826 F.3d 338, 345–46 (6th

Cir. 2016)). A complaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678 (citing *Twombly*, 550 U.S. at 556). To survive a motion to dismiss, a complaint must "raise a right to relief above the speculative level" into the "realm of plausible liability." *Twombly*, 550 U.S. at 555.

When analyzing a complaint under this standard, the Court construes factual allegations in the light most favorable to the plaintiffs, accepts them as true, and draws all reasonable inferences in the plaintiffs' favor. *Wilburn v. United States*, 616 F. App'x 848, 852 (6th Cir. 2015). But a pleading must offer more than mere "labels and conclusions," because "a formulaic recitation of the elements of a cause of action will not do." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). Nor is a court required to accept "[c]onclusory allegations or legal conclusions masquerading as factual allegations[.]" *Eidson v. Tennessee Dep't of Child.'s Servs.*, 510 F.3d 631, 634 (6th Cir. 2007).

Therefore, the Court must distinguish between "well-pled factual allegations," which must be treated as true, and "naked assertions," which need not. *See Iqbal*, 556 U.S. at 678 ("Nor does a complaint suffice if it tenders naked assertions devoid of further factual enhancement.") (cleaned up); *see also, e.g.*, *Center for Bio-Ethical Reform, Inc. v. Napolitano*, 648 F.3d 365, 375 (6th Cir. 2011) (determining that,

because some of the plaintiff's factual allegations were "not well-pleaded[,]" "their conclusory nature 'disentitles them to the presumption of truth'"). Rule 8 "does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Iqbal*, 556 U.S. at 678–79.

Under this familiar standard, the Court considers whether the first amended complaint states claims on which relief may be granted.

I. Ohio Product Liability Act

Plaintiff brings claims under Ohio's Product Liability Act for manufacturing defect (Ohio Rev. Code § 2307.74), design defect (*id.* § 2307.75), and failure to conform to representations (*id.* § 2307.77) brought against Defendant as a manufacturer of the device. Plaintiff also asserts a nonconformity claim against Defendant as a supplier (*id.* § 2307.78).

I.A. Manufacturing Defect

Under the Ohio Product Liability Act, a "product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards." Ohio Rev. Code § 2307.74.

Plaintiff alleges that the device inserted into him "was defective as manufactured and/or constructed because, when they left the control [of] the Defendants [*sic*], they deviated in a material way from the design specifications, formula, and/or performance standards of the manufacturer." (ECF No. 15, ¶ 13, PageID #63.) Further, he alleges the produce was defective because "it deviated in a

material way from otherwise identical units manufactured to the same design specifications, formula and/or performance standards." (*Id.*, ¶ 14.) Otherwise, Plaintiff alleges two screws became loose sometime after the device was implanted. (*Id.*, ¶¶ 6–7, PageID #62.) Defendant argues these allegations are deficient because they fail to specifically identify the defects or deviations in the device. (ECF No. 17, PageID #79–82.) The Court agrees.

The facts alleged do not support an inference that the device implanted into Plaintiff was defectively manufactured. There is no plausible basis to infer the device at issue materially deviated from otherwise identical units, which the Act requires. Rather, Plaintiff's allegations of a manufacturing defect do little more than recite the elements of the cause of action under Section 2307.74, and "a formulaic recitation of the elements of a cause of action will not do." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). "Nor does a complaint suffice if it tenders naked assertions devoid of further factual enhancement." *Id.* (cleaned up). As pleaded, the first amended complaint fails to state a claim for a manufacturing defect.

Plaintiff does not direct the Court to any authority to conclude otherwise. As Defendant points out (ECF No. 19, PageID #101–02), Plaintiff's reliance on *Saylor v. Providence Hosp.*, 113 Ohio App. 3d 1, 680 N.E.2d 193 (Ohio Ct. App. 1996), is misplaced. In *Saylor*, the plaintiffs sued the manufacturer of screws surgically implanted into a patient's back, the hospital where the surgery was performed, and the doctor who performed it. *Id.* at 194. Applying the State court procedural standard for a Rule 12 motion to dismiss, the appellate court found the lower court erred in

granting the hospital's motion to dismiss the plaintiff's product liability claim for inadequate warning. *Id.* at 196. Between the different procedural standard and the different legal claim, *Saylor* has no application here.

In contrast, Defendants rely on *Grubbs v. Smith & Nephew, Inc.*, No. 1:19-cv-248, 2020 WL 5305542 (S.D. Ohio Sept. 4, 2020). (ECF No. 17, PageID #81.) In *Grubbs*, the court dismissed product liability claims for design defect, manufacturing defect, and nonconformity to representations related to an artificial hip that loosened and required the plaintiff to undergo revision surgery. *Id.* at *4–6. With respect to the manufacturing defect claim, the plaintiff alleged the hip implant at issue deviated from the manufacturer's design standards or other identical united, but failed to identify the specific defects or failures at issue. *Id.* at *4. Plaintiff's allegations are similarly formulaic and conclusory. They do not sufficiently plead a manufacturing defect claim under the governing Rule 8 standard.

I.B. Design Defect

The Ohio Product Liability Act defines a product as defective in design or formulation "if, at the time it left the control of its manufacturer, the foreseeable risks associated with its design or formulation . . . exceeded the benefits associated with that design or formulation . . . ." Ohio Rev. Code § 2307.75(A). To plead a design defect claim, the complaint must allege: "(1) the existence of a defect in the product at issue, (2) that the defect existed at the time the product left the hands of the manufacturer, and (3) the defect was the direct and proximate cause of the plaintiff's injury." *Tomlin v. Smith & Nephew, Inc.*, No. 3:19-cv-354, 2020 WL 5230830, at *4

(S.D. Ohio Sep. 2, 2020) (quoting *Jones v. Staübli Motor Sports Div. of Staübli Am. Corp.*, 897 F. Supp. 2d 599, 607 (S.D. Ohio 2012)).

In addition to the allegations already discussed, Plaintiff alleges that at the time the anterior cervical plate system left Defendant's control, the foreseeable risks associated with it exceeded the benefits (ECF No. 15, ¶ 21, PageID #64); the product carried risks of harm associated with its intended and reasonably foreseeable uses (*id.*, ¶ 22); it did not conform to applicable public or private product standards in effect (*id.*, ¶ 25, PageID #65); and it was more dangerous than a reasonably prudent consumer would expect (*id.*, ¶ 26).

Once again, Plaintiff's claims are conclusory and merely recite the statutory elements without providing factual allegations to support the elements. At most, Plaintiff alleges the product failed while implanted, which is not enough to allege a plausible design defect claim. *McConnell v. KLS Martin LP, et al.*, ___ F. Supp. 3d ___, 2021 WL 425035, at *3 (N.D. Ohio Sept. 17, 2021).

I.C. Failure to Conform to Representations

Under the Act, a "product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer." Ohio Rev. Code § 2307.77. "A plaintiff seeking to recover under § 2307.77 must prove that: (1) the manufacturer made a representation as to a material fact concerning the character or quality of the manufacturer's product; (2) the product did not conform to that representation; (3) the plaintiff justifiably relied on that representation; and (4) the plaintiff's reliance on the representation was the direct and proximate cause of the plaintiff's injuries." *Tomlin*, 2020 WL 5230830, at *2–3 (citing *Gawloski v.*

Miller Brewing Co., 98 Ohio App. 3d 160, 164, 644 N.E.2d 731, 734 (Ohio Ct. App. 1994)). Plaintiff fails to allege facts to support the elements of this claim. For example, the first amended complaint identifies no specific representation to which the device did not conform. Plaintiff merely alleges that Defendant represented the cervical plate system "was safe and fit for the particular purpose" for which Plaintiff used it. (ECF No. 15, ¶ 32, PageID #66.) Without alleging a specific representation identifying how the product failed to conform, the first amended complaint fails to state a claim. *Kenny v. LC Holdings, LLC*, No. 1:18-cv-472, 2018 WL 6676397, at *3–4 (S.D. Ohio Dec. 18, 2018).

I.D. Supplier Liability

The Act also permits recovery against suppliers, Ohio Rev. Code § 2307.78, and Plaintiff alternatively alleges a failure to conform against Defendant as a supplier of the device, rather than its manufacturer (ECF No. 15, ¶¶ 36–40, PageID #66–67). A "supplier may be liable under the OPLA as if it were a manufacturer of a product" under certain circumstances. *Chamberlain v. American Tobacco Co.*, 70 F. Supp. 2d 788, 796 (N.D. Ohio 1997); *see also* Ohio Rev. Code § 2307.78.

Plaintiff alleges that Defendant is liable as a supplier because "the product did not conform to representations made by Defendant, including those representations to Plaintiff that the [device] was safe and fit for the particular purpose which Plaintiff . . . used the product." (ECF No. 15, ¶ 39, PageID #67.) Assuming Defendant qualifies as a supplier, the first amended complaint fails adequately to allege any basis for liability under the Act. Plaintiff's claim for supplier liability is

similarly as conclusive and barebones as his claims for manufacturer liability and likewise fails.

I.E. Causation

Defendant also argues the first amended complaint fails to adequately plead causation. (ECF No. 17, PageID #87–89.) The Court need not take up the issue given the conclusion that Plaintiff's claims otherwise fail to state claims.

II. Punitive Damages

Plaintiff seeks punitive damages pursuant to Section 2307.80 of the Ohio Product Liability Act. The Act permits punitive damages against a manufacturer or supplier where the plaintiff proves "by clear and convincing evidence, that harm for which the claimant is entitled to recover compensatory damages . . . was the result of misconduct of the manufacturer or supplier in question that manifested a flagrant disregard of the safety of persons who might be harmed by the product in question." Ohio Rev. Code § 2307.80(A). Further, the Act provides that the "fact by itself that a product is defective does not establish a flagrant disregard of the safety of persons who might be harmed by that product." *Id.*

In support of his request for punitive damages, Plaintiff alleges that "[t]o the extent that Plaintiff's damages were caused by Defendant's misconduct that manifested a flagrant disregard of the safety of persons who might be harmed by the product in question, Plaintiff is entitled to recover punitive or exemplary damages[.]" (ECF No. 15, ¶ 43, PageID #67.) This conclusive recitation does not satisfy Rule 8, and the first amended complaint does not otherwise contain any factual allegations

that do. Moreover, having dismissed Plaintiff's claims under the Act, he is not entitled to punitive damages under it.

CONCLUSION

For the foregoing reasons, the Court **GRANTS** Defendant's motion (ECF No. 17).

SO ORDERED.

Dated: October 12, 2021

J. Philip Calabrese
United States District Judge
Northern District of Ohio