UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

O.M., A MINOR AND THROUGH HIS PARENTS, ALEC AND JESSICA McCONNELL, *et al.*,	)	Case No. 1:21-cv-121
	)	Judge J. Philip Calabrese
Plaintiffs,	)	Magistrate Judge Thomas M. Parker
v.	)	
KLS MARTIN LP, *et al.*,	)	
Defendants.	)	

OPINION AND ORDER

Defendant KLS Martin LP designed and manufactures a mandibular distractor device used to treat micrognathia, also known as mandibular hypoplasia, a condition in which the jaw is underdeveloped with potential consequences for eating and speech during childhood development. Shortly after his birth, O.M. underwent surgery and had mandibular distractors inserted. They allegedly failed, necessitating explanation, multiple surgeries, and follow-up treatments and resulting in injuries and damages. Defendant moves to dismiss the first amended complaint. For the reasons the follow, the Court **GRANTS IN PART AND DENIES IN PART** 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 Plaintiffs' favor.

On January 8, 2019, when he was about two months old, O.M. had surgically implanted in his lower right and left jaw a mandibular distractor, a medical device used to treat micrognathia, also called mandibular hypoplasia. (ECF No. 16, ¶¶ 6–8, PageID #96.) KLS designed and manufactured each device. (*Id.*, ¶ 8.) Less than two weeks later, by January 17, 2019, Jessica McConnell, O.M.'s mother, noticed something wrong with O.M., and an x-ray revealed that the device on the left side of his jaw was broken, while the device on the right remained intact. (*Id.*, ¶¶ 9–10, PageID #97.) O.M. underwent a second surgery on January 22, 2019 to replace the broken device with another one, which KLS also designed and manufactured. (*Id.*, ¶ 10.) During this surgery, the mandibular distractor on the right "was examined and found to be intact." (*Id.*)

About a week after the second surgery, on January 31, 2019, O.M.'s mother again noticed something was not right, and an x-ray revealed that the right-side device was now broken. (*Id.*, ¶ 11.) In other words, the mandibular distractor in O.M.'s right jaw failed just over three weeks after its insertion, two weeks after x-ray confirmation that it remained intact, and nine days after examination during surgery confirmed it had not failed. In a third surgery, on February 5, 2019, both KLS devices were removed and replaced with a mandibular distractor a different manufacturer made. (*Id.*, ¶ 12.) Plaintiffs do not allege that the third KLS mandibular distractor, the one inserted in the surgery on January 22, 2019 in place of the broken device in O.M.'s left jaw, failed. By February 5, 2019, that replacement device (the one that

had not failed) had been in place since January 22, 2019—a period of two weeks, several days longer than it took the first device to fail.

As a result of these events, O.M. has suffered "physical injury, disability, medical expenses, pain and suffering, subsequent multiple surgeries, mental anguish and distress, loss of enjoyment of life and is now more vulnerable to the increased likelihood of future complications." (*Id.*, ¶ 14.)

STATEMENT OF THE CASE

Based on these allegations, Plaintiffs assert four causes of action: (1) statutory products liability; (2) breach of the implied warranties of merchantability and fitness for a particular purpose; (3) negligence; and (4) loss of consortium. Plaintiffs' products liability claim alleges that the mandibular distractors were defectively manufactured (*id.*, ¶ 17, PageID #98); defectively designed (*id.*, ¶ 18); defective due to an inadequate warning or instruction (*id.*, ¶ 19); and failed to conform to Defendant's representations about the product (*id.*, ¶ 20). Plaintiffs also seek punitive damages. (ECF No. 16, ¶¶ 41–45, PageID #101.) 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. 20, PageID #149–50; ECF No. 21, PageID #176–77.) 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 (First Cause of Action)

Plaintiffs bring claims under Ohio's Product Liability Act for manufacturing defect (Ohio Rev. Code § 2307.74), design defect (*id.* § 2307.75), inadequate warning or instruction (*id.* § 2307.76), and failure to conform to representations (*id.* § 2307.77).

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.

Plaintiffs allege that the "subject mandibular distractors were defectively manufactured within the meaning of O.R.C. Section 2307.74 and as otherwise provided by law." (ECF No. 16, ¶ 17, PageID #98.) Otherwise, the first amended complaint pleads only that Ms. McConnell noticed that "something was not right" with the devices a few weeks after they were implanted (*id.*, ¶¶ 16, 11, PageID #97),

x-rays revealed the devices broke (*id.*), and O.M. had to endure two additional surgeries to replace the broken devices (*id.*, ¶¶ 10, 12). Further, Plaintiffs allege that the product was unreasonably dangerous and caused O.M.'s injuries. (*Id.*, ¶ 13.)

Defendant argues that these allegations fail under Rule 8 because they do not explain how the subject devices deviated from Defendant's other mandibular distractors. (ECF No. 17, PageID #114–15.) But this argument seeks to hold Plaintiffs to a higher standard than the one Rule 8 imposes. At the pleading stage, the facts alleged support an inference that the two KLS mandibular distractors originally implanted in O.M.'s jaw on January 8, 2019 might have been defectively manufactured. Both devices implanted during that procedure failed, but a third KLS device inserted later did not. In the current procedural posture, Plaintiffs enjoy an inference that the first two devices were manufactured at approximately the same time. Because a third device inserted later did not fail and remained implanted longer than it took the first device to fail, the two devices originally inserted might plausibly have "deviated in a material way . . . from otherwise identical units manufactured to the same design specifications, formula, or performance standards." Ohio Rev. Code § 2307.74.

Defendant relies on *Tomlin v. Smith & Nephew, Inc.*, No. 3:19-CV-354, 2020 WL 5230830, at *5 (S.D. Ohio Sept. 2, 2020). There, the court dismissed a manufacturing defect claim where the plaintiff merely alleged that he experienced pain and discomfort after implantation of a knee and required revision surgery. Accordingly, the *Tomlin* Court dismissed the claim as too conclusory. So too did the

other authorities on which Defendant relies. (ECF No. 17, PageID #115.) Unlike this case, *Tomlin* did not allege that the device broke while implanted. If Plaintiffs had filed suit based only on the allegation that Ms. McConnell observed that something was not right with O.M., then *Tomlin* would support an argument for dismissal. However, the first amended complaint states a plausible manufacturing-defect claim under Section 2307.74 of the Ohio Revised Code.

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 facts pleaded in the first amended complaint and already discussed, Plaintiffs allege that the "subject mandibular distractors [were] defective in design and/or formulation pursuant to the provisions of O.R.C. Section 2307.75 and as otherwise provided by law." (ECF No. 16, ¶ 18, PageID #98.) Plaintiff's allegations of a design defect do little more than recite the elements of the cause of action under

Section 2307.74. But "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, therefore, the first amended complaint raises the question whether a product failure, without more, alleges a plausible product defect. As a matter of law, it does not. Plaintiffs point to no authority suggesting otherwise.

Another case from this District supports this conclusion. In *Redinger v. Stryker Corp.*, No. 5:10 CV 104, 2010 WL 1995829, at *3 (N.D. Ohio May 19, 2010), the court denied a motion to dismiss a design defect claim. As here, the implanted device at issue in *Redinger* failed. Unlike this case, however, the defendant recalled the product at issue in *Redinger*, giving rise to a plausible inference that the foreseeable risks associated with the design of the device outweighed its benefits. *Id.* The first amended complaint contains no such allegation (or any other) giving rise to an inference that the design defect of the mandibular distractor is defective.

Shortly after *Redinger*, the Southern District of Ohio denied a motion to dismiss where the complaint alleged only that the device failed while implanted. *See Foust v. Stryker Corp.*, No. 2:10-cv-00005, 2010 WL 2572179, at *5 (S.D. Ohio June 22, 2010). Unlike *Redinger*, *Foust* did not involve a product recall, presenting the same question as this case—namely, whether the naked allegation that a product failed, without more, states a plausible design defect claim. Respectfully, the Court disagrees with the conclusion in *Foust*. Under *Foust*'s reasoning, every product

failure would give rise to a design defect claim. That is not the law, and the Ohio Product Liability Act requires more, even at the pleading stage.

Plaintiffs object that they cannot plead more than they did without access to information "not readily available publicly [that] will have to be obtained through discovery." (ECF No. 20, PageID #156; *see also id.*, PageID #157.) But 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. Contrary to Plaintiffs' argument, the first amended complaint fails to state a claim for design defect under the basic Rule 8 standard, not a heightened standard. (*Id.*, PageID #157–58.) In the end, Plaintiffs' design defect claim simply fails to plead facts that Defendant's mandibular distractor was defectively designed beyond the fact that it broke. That fact alone does not state a claim on which relief may be granted.

I.C. Inadequate Warning or Instruction

The Ohio Product Liability Act provides that a product can be defective due to an inadequate warning or instruction either at the time of marketing, when it left the control of its manufacturer, or at post-marketing. Ohio Rev. Code § 2307.76(A) & (B). Under the statute, a claim for inadequate warning or instruction has three elements: "(1) a duty to warn against reasonably foreseeable risks; (2) breach of this duty; and (3) an injury that is proximately caused by the breach." *Mitchell v. Michael Weinig, Inc.*, No. 2:17-cv-905, 2020 WL 5798043, at *10 (S.D. Ohio Sep. 28, 2020) (quoting *Monroe v. Novartis Pharms. Corp.*, 29 F. Supp. 3d 1115, 1125 (S.D. Ohio 2014) (quoting *Graham v. American Cyanamid Co.*, 350 F.3d 496, 514 (6th Cir. 2003)).

Plaintiffs allege that the "subject mandibular distractors [were] defective due to inadequate warning or instruction" and that the "failure to furnish proper warning and instruction directly and proximately caused" the alleged injuries and damages. (ECF No. 16, ¶¶ 19 & 21, PageID #98.) Beyond this allegation, and the facts previously discussed, Plaintiffs fail to allege facts that state a claim. Even assuming the foreseeability of the risk of the device breaking after implantation, the first amended complaint contains no allegation that Defendant knew of that risk. Nor does it contain any information about whether Defendant warned of the risk or that the absence of a warning caused the alleged injuries.

The authorities on which Plaintiffs rely are unavailing. (ECF No. 20, PageID #158.) In *Tomlin*, the court declined to dismiss the plaintiff's failure to warn claim. 2020 WL 5230830, at *2. But the plaintiff there at least alleged that the defendant knew about the defect and failed adequately to warn the medical community and consumers about the risks associated with it. *Id.* at *6. In *Frey v. Novartis Pharmaceuticals Corp.*, 642 F. Supp. 2d 787, 795 (S.D. Ohio 2009), the defendant did not move to dismiss the claim for inadequate warning claim. So, it offers no support for Plaintiffs who make conclusory allegations of a violation of Section 2307.76 that merely recite the elements. Again, such a pleading does not conform to the basic Rule 8 standard.

I.D. 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: (1) that the manufacturer made a representation as to a material fact concerning the character or quality of the manufacturer's product; (2) that the product did not conform to that representation; (3) that the plaintiff justifiably relied on that representation; and (4) that 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)). Plaintiffs do not allege facts to support the elements of the claim. For example, the first amended complaint identifies no representation to which the device did not conform. Instead, it merely concludes that the "subject mandibular distractors were defective because they did not conf[o]rm to representations made by Defendant pursuant to the provisions of O.R.C. Section 2307.77 and as otherwise provided by law." (ECF No. 17, ¶ 20, PageID #98.) Such allegations fail to state a claim under the Rule 8 standard.

II. Breach of Implied Warranty

Plaintiffs allege that Defendant breached the implied warranties of merchantability and fitness for a particular purpose as their second cause of action. (ECF No. 16, ¶¶ 23–31, PageID #99.) An implied warranty claim may be brought on a tort-based theory or a contract-based theory. *In re Porsche Cars N. Am., Inc. Plastic Coolant Tubes Prods. Liab. Litig.*, 880 F. Supp. 2d 801, 865 (S.D. Ohio 2012); *Caterpillar Fin. Servs. Corp. v. Harold Tatman & Son's, Enters.*, 2015-Ohio-4884, 50 N.E.3d 955, ¶ 25 (Ohio Ct. App.). Contract-based claims require privity between the

parties; tort-based claims do not. *In re Porsche*, 880 F. Supp. 2d at 865 (citations omitted); *Caterpillar*, 2015-Ohio-4884, at ¶ 25 (citing *Lonzrick v. Republic Steel Corp.*, 6 Ohio St. 2d 227, 218 N.E.2d 185, paragraph one of the syllabus (1966)).

II.A. Implied Warranty in Contract

The first amended complaint does not explicitly state whether Plaintiffs bring a theory of implied warranty in contract, tort, or both. Plaintiffs, however, invoke the Uniform Commercial Code as adopted in Ohio and allege that Defendant supplied implied warranties of merchantability and fitness for a particular purpose under Sections 1302.27 and 1302.28 of the Ohio Revised Code. (ECF No. 16, ¶¶ 26–27, PageID #99.) Reference to the warranty of merchantability, at least, sounds in contract. *Mooradian v. FCA US, LLC*, No. 1:17-cv-1132, 2017 U.S. Dist. LEXIS 178558, at *14 (N.D. Ohio Oct. 27, 2017) (citing *In re Porsche*, 880 F. Supp. 2d at 865). But there are no allegations that support the existence of contractual privity with Defendants or some exception to privity, which a claim in contract requires. Indeed, the allegations of the first amended complaint logically support an inference that Plaintiffs have no privity with Defendant.

Further, Plaintiffs insist in their brief that they are pursuing a claim in tort. (*See* ECF No. 20, PageID #163 ("Plaintiff is not seeking any 'remedy' available through the UCC as the right to damages for personal injuries arises from the common law of torts."); *id.*, PageID #164 ("It must also be stressed that the First Amended Complaint includes general allegations that enforceable express and implied warranties existed which are not based upon the UCC of any state.").) To the

extent there is any doubt Plaintiffs seek to pursue an implied warranty claim in tort only, they concede that "Defendant KLS has justified only a partial dismissal of the theories of recovery that are predicated upon breaches of the warranties implied by R.C. § 1302.27 and 1302.28." (*Id.*, PageID #164.) Based on Plaintiffs' representations, the Court dismisses the implied warranty claim to the extent it is based in contract.

II.B. Implied Warranty in Tort

"Plaintiffs bringing implied warranty in tort claims must allege that (1) a defect existed in a defendant's product that made it unfit for its ordinary, intended use; (2) the defect existed at the time the product left the defendant's possession; and (3) the defect was the proximate cause of the plaintiff's injuries." *In re Porsche Cars*, 880 F. Supp. 2d at 867 (citing *White v. DePuy, Inc.*, 129 Ohio App. 3d 472, 480, 718 N.E.2d 450 (Ohio Ct. App. 1998)). "Implied warranty in tort is a common-law cause of action that imposes liability upon a manufacturer or seller for breach of an implied representation that a product is 'of good and merchantable quality, fit and safe for its ordinary intended use.'" *Miles v. Raymond Corp.*, 612 F. Supp. 2d 913, 923 (N.D. Ohio 2009) (quoting *White*, 129 Ohio App. 3d at 485, 718 N.E.2d at 454). As Defendant notes (ECF No. 21, PageID #190), as a matter of law, the Ohio Products Liability Act preempts implied warranty claims brought in tort under the common law. *Miles*, 612 F. Supp. 2d at 924 (citing Ohio Rev. Code § 2307.71(A)(13)(c)); s*ee also infra*, Part III (discussing preemption in further detail). Accordingly, the Court dismisses Plaintiff's implied warranty claim.

III. Negligence

Plaintiffs bring a claim for common-law negligence as their third cause of action. (ECF No. 16, ¶¶ 32–36, PageID #100.) The elements of a negligence claim under Ohio law are "(1) the existence of a legal duty, (2) the defendant's breach of that duty, and (3) injury that is the proximate cause of the defendant's breach." *Beckemeyer v. Gelco Corp.*, 828 F. App'x 251, 253 (6th Cir. 2020) (quoting *Wallace v. Ohio Dep't of Com.*, 96 Ohio St. 3d 266, 2002-Ohio-4210, 773 N.E.2d 1018, ¶ 22 (2002)).

The Ohio Products Liability Act "abrogate[s] all common law product liability claims or causes of action." Ohio Rev. Code § 2307.71(B). Under the Act, a product liability claim includes any claim based on the design or production of a product, the warning or instruction associated with a product, or the failure of a product to conform to a representation or warranty. *Id.* § 2307.71(A)(13). Accordingly, courts routinely dismiss "non-statutory product-liability claims brought under Ohio law." *McManus v. Smith & Nephew, Inc.*, No. 3:19-cv-066, 2020 WL 127702, at *2 (S.D. Ohio Jan. 10, 2020) (collecting cases).

Plaintiffs attempt to avoid preemption by arguing that their negligence claim could be based upon Defendant providing "substandard services instead of defective products." (ECF No. 20, PageID #167.) Effectively, their argument asks the Court to allow them to proceed on a claim Plaintiffs did not plead. The amended complaint alleges Defendant owed a duty of care to avoid foreseeable harm to Plaintiffs and "negligently manufactured, designed, assembled, distributed, and/or furnished the

mandibular distractors," causing Plaintiffs' damages. (*Id.*, ¶¶ 33–35.) There is no indication in the amended complaint that Plaintiffs seek to bring a negligence action based on substandard services rather than a defective product. Accordingly, the Ohio Products Liability Act abrogates the negligence claim Plaintiffs pleaded.

IV. Loss of Consortium

Plaintiffs' fourth cause of action is for loss of consortium. (ECF No. 16, ¶¶ 37–40.) As a derivative cause of action, this claim survives to the same extent as Plaintiffs' substantive claims.

V. Punitive Damages

Plaintiffs seek punitive damages pursuant to Section 2307.80 of the Ohio Product Liability Act. (ECF No. 16, ¶¶ 41–45, PageID #101.) Defendant argues only that the request, styled as the fifth cause of action, should be dismissed because Plaintiffs have not stated a claim for relief under the Act. (ECF No. 17, PageID #128.) A claim for punitive damages is not an independent cause of action, but a remedy. *John W. Harry v. Kent Elastomer Prods.*, No. 5:20CV1248, ___ F. Supp. 3d ___, 2021 WL 2885877, at *5 n.12 (N.D. Ohio May 6, 2021) (citations omitted). Plaintiffs may pursue this remedy to the extent the law permits.

CONCLUSION

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

SO ORDERED.

Dated: September 17, 2021

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