IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION – CINCINNATI

HARRY W. GRUBBS,	:	Case No. 1:19-cv-248
	:	
Plaintiff,	:	Judge Matthew W. McFarland
	:	
v.	:	
	:	
SMITH & NEPHEW, INC.,	:	
	:	
Defendant.	:	

ORDER GRANTING IN PART AND DENYING IN PART MOTION TO DISMISS (Doc. 5)

This case is before the Court on the Motion to Dismiss Plaintiff's Complaint (Doc. 5) filed by Defendant Smith & Nephew, Inc. ("Defendant"). Plaintiff Harry W. Grubbs ("Plaintiff") filed a Response in Opposition (Doc. 6), to which Defendants filed a Reply (Doc. 7), making this matter ripe for the Court's review.

FACTS

In early 2017, Plaintiff underwent total hip arthroplasty ("THA surgery"), a surgery designed to alleviate the complications related to hip degeneration. Plaintiff's physician, as part of the THA surgery, installed a Verilast Hip ("Verilast Hip" or "product"), which is an artificial hip replacement product that Defendant manufactures. Defendant controls the manufacture, marketing, distribution, packaging, labeling, processing, promotion, and sales of the Verilast Hip. Sometime after Plaintiff's surgery, Plaintiff suffered extreme pain. As a result, his doctor had to perform revision surgery a

few months after the original THA surgery.

Plaintiff asserts that the Verilast Hip could loosen and separate from the hip socket, which could cause severe pain and/or require additional surgery. Plaintiff claims that (1) Defendant did not adequately warn him or his doctor of the risk associated with the Verilast Hip; (2) the product was defective in design; (3) the product was defectively manufactured; and (4) the product failed to conform to representations made by Defendant. All of these claims arise under the Ohio Products Liability Act § 2307.71 *et seq.* ("OPLA"). Plaintiff claims he has suffered from physical injuries and medical expenses as a result of Defendant's product. Plaintiff also alleges Defendant is liable under three common law products liability claims: breach of express warranty, breach of implied warranty, and negligence.

ANALYSIS

Fed. R. Civ. P. 8(a) requires that, to properly state a claim, a complaint must include a "short and plain statement of the claim showing that the pleader is entitled to relief." Rule 12(b)(6) allows, upon motion, the dismissal of a complaint "for failure to state a claim upon which relief can be granted." While courts on a motion to dismiss must accept the allegations in the plaintiff's complaint as true, courts "are not bound to accept as true a legal conclusion couched as a factual allegation." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct 1955, 1964, 167 L. Ed. 2d 929 (2007) (quoting *Papasan v. Allain*, 478 U.S. 265, 286, 106 S.Ct. 2932, 92 L.Ed.2d 209 (1986)). And, the factual allegations must be more than "speculative." *Id.*

To survive a motion to dismiss under Rule 12(b)(6), a complaint does not need

"detailed factual allegations," but it does require "more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal,* 556 U.S. 662, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009). The claim for relief must be "plausible on its face"; a plausible claim is defined as one where "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. Put differently, plausibility "asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* When a complaint lacks such plausibility in pleading its entitlement to relief, dismissal is warranted. *Id.*

A. The common law product liability causes of action

Under the OPLA, a product liability claim is defined as follows:

> a claim or cause of action that is asserted in a civil action pursuant to sections 2307.71 to 2307.80 of the Revised Code and that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person . . . that allegedly arose from any of the following:
>
> > (a) The design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product;
> > (b) Any warning or instruction, or lack of warning or instruction, associated with that product;
> > (c) Any failure of that product to conform to any relevant representation or warranty.

R.C. § 2307.71(A)(13). The current version of the OPLA is "intended to abrogate all common law product liability claims or causes of action." R.C. § 2307.71(B). Subsequent case law affirms that the OPLA governs product liability claims. *See Krumpelbeck v. Breg, Inc.*, 491 F.Appx. 713, 715 (6th Cir. 2012) ("The OPLA expressly abolished all common law product liability claims."). Accordingly, courts have "routinely dismissed non-statutory

product-liability claims brought under Ohio law." *McKinney v. Microsoft Corp.*, No. 1:10-CV-354, 2011 WL 13228141, at *7 (S.D. Ohio May 12, 2011).

Defendant attacks the common-law claims on abrogation grounds, asserting that because Plaintiff's non-statutory claims fit under the OPLA's definition of "product liability claims," the OPLA "provides for Plaintiff's *exclusive* remedy." (Doc. 5 at 8.) Plaintiff does not address the abrogation claim in his response.

Defendant is correct. "The OPLA preemption provision extinguishes any common-law claim that, as pled, actually meets the statutory definition of a product liability claim." *Volovetz v. Tremco Barrier Sols., Inc.*, 2016-Ohio-7707, ¶ 33, 74 N.E.3d 743, 753. Plaintiff's common law claims for breach of express and implied warranties and negligence fall under the OPLA's definition of a product liability claim. *See Parker v. ACE Hardware Corp.*, 2018-Ohio-320, ¶ 36, 104 N.E.3d 298, 307; *Miller v. ALZA Corp.*, 759 F. Supp. 2d 929, 943 (S.D. Ohio 2010). Since the clear statutory language forecloses such claims, the Court must dismiss them. As it has done in the past, however, the Court dismisses these non-statutory claims without prejudice, as they may potentially be pled under an appropriate OPLA section. *McKinney*, 2011 WL 13228141, at *7.

B. The OPLA causes of action

The standard of proof for establishing a manufacturer's liability for damages is laid out in Ohio Revised Code 2307.73. The plaintiff must establish that (1) the product was defective in manufacture or construction, defective in design or formulation, defective due to inadequate warning or instruction, or defective because it did not conform to a representation made by its manufacturer; (2) the defect was a proximate

cause of harm; and (3) the manufacturer designed, formulated, produced, constructed, created, assembled, or rebuilt the actual product that was the cause of harm for which the plaintiff seeks to recover. Ohio Rev. Code § 2307.73(A). A plaintiff may prove a defect by direct or circumstantial evidence. Ohio Rev. Code § 2307.73(B).

1. Count I: Failure to Warn (R.C. 2307.76)

Plaintiff brings a failure to warn claim under R.C. 2307.76. That statute provides in pertinent part that a product is defective due to inadequate warning or instruction if, when it left the manufacturer's control, "the manufacturer knew, or in the exercise of reasonable care, should have known about a risk associated with the product and that allegedly caused harm" to the plaintiff, and "the manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk." R.C. § 2307.76(A)(1).

Defendant argues that the learned intermediary doctrine forecloses Plaintiff's failure-to-warn claim. According to Defendant, the issue is whether the doctor, not Plaintiff, was adequately warned and would reasonably understand the risks associated with the product.

The learned intermediary doctrine is codified at R.C. 2307.76(C). *Vaccariello v. Smith & Nephew Richards, Inc.*, 94 Ohio St. 3d 380, 384, 2002-Ohio-892, 763 N.E.2d 160. The Ohio Supreme Court has held that the doctrine applies to prescription medical devices. *Id.* The rationale behind the learned intermediary doctrine is that "the physician stands between the manufacturer and the patient as a learned intermediary." *Id.* (quoting *Tracy v. Merrell Dow Pharm., Inc.*, 58 Ohio St. 3d 147, 149, 569 N.E.2d 875, 878 (1991)). "The

physician has the duty to know the patient's condition as well as the qualities and characteristics of the drugs or products to be prescribed for the patient's use." *Id.* "The learned intermediary doctrine does not relieve the manufacturer of liability to the ultimate user for an inadequate or misleading warning; it only provides that the warning reaches the ultimate user through the learned intermediary," that is, the physician. *Tracy v. Merrell Dow Pharm., Inc.*, 58 Ohio St. 3d 147, 149–50, 569 N.E.2d 875, 878 (1991).

In this light, therefore, Defendant is partially correct that a relevant issue is whether Plaintiff's doctor was adequately warned about the risks associated with the product. Defendant claims the problems with Plaintiff's Complaint are its failures to plead (1) how the warnings were inadequate for the doctor; (2) what warnings were provided to the doctor before the procedure; (3) what different warnings, if provided to the doctor, would have been appropriate or adequate; and (4) whether the doctor had any independent knowledge of the risks associated with the implantation and use of the device beyond what was provided in the warnings.

Here, since this case is at the motion-to-dismiss stage—during which the Court construes the complaint in the light most favorable to the plaintiff, *Laborers' Local 265 Pension Fund v. iShares Tr.*, 769 F.3d 399, 403 (6th Cir. 2014)—the Court finds that Defendant asks too much. Plaintiff asserts that Defendant knew or should have known that the Verilast Hip was reasonably unsafe, but failed to adequately warn patients, including himself, and healthcare providers, including his physician, of the risks associated with Verilast Hip. (Compl. at ¶¶ 11, 13, 15, 25, 28.) Those risks, according to Plaintiff, are that the Verilast Hip "could loosen and separate from the hip socket, causing

severe pain and injury, and requiring further treatment." (Compl. at ¶ 28.) Because of Defendant's failure to warn, Plaintiff "suffered serious and permanent injuries." (*Id.* at ¶ 36.)

Similar allegations have been enough to survive a 12(b)(6) motion in this Court before. *E.g., Thompson v. DePuy Orthopaedics, Inc.*, No. 1:13-CV-00602, 2014 WL 2874268, at *7 (S.D. Ohio June 24, 2014). In *Thompson*, this Court rejected the argument that the learned intermediary doctrine applied, on the basis that the plaintiff alleged that the manufacturer knew or should have known about the product's risks, but had provided no warnings about the product's risks. Furthermore, the plaintiff was able to identify a specific risk. *Id.* Construing those allegations in the plaintiff's favor, the Court concluded that the alleged lack of any warning plausibly showed that the warning did not reach the physician or patient. *Id.* Therefore, the learned intermediary doctrine did not preclude the claim. *Id.*

Plaintiff has pled the same things here. He alleges that Defendant knew or should have known of the product's dangers. (Compl. ¶¶ 11, 33.) He also alleges that Defendant failed to adequately warn patient and healthcare providers. (*Id.* at ¶¶ 11, 25, 28, 33.) Additionally, he alleges that the specific risk in question is the product's propensity to loosen and separate from the patient's hip socket, causing injury and pain. (*Id.* at ¶¶ 10, 28.)

It is true that the failure to allege what warnings were provided to the physician or how the warnings failed to reach an adequate level has resulted in dismissal before. *See Grange Mutualty Causalty Co. v. Optimus Enterprises Inc.*, No. 1:15-cv-2394, 2016 WL

3078956, at *4 (N.D. Ohio June 1, 2016) (holding that where the plaintiff failed to plead what warnings were given to the physician and what warning would have been adequate, the plaintiff did not provide factual allegations to meet the elements of the statute). But in *Grange*, the plaintiff failed to allege that the defendant knew or should have known of the risks associated with the product. *Id.* at *4.

Here, Plaintiff has at least pled that Defendant knew or should have known of the risks. He also identifies a specific risk and alleges that Defendant failed to adequately warn him and his physician. This suffices to avoid application of the learned intermediary doctrine and state a failure-to-warn claim under R.C. 2307.76. *See, e.g., Gordon v. B. Braun Med. Inc.*, No. 1:19-CV-121, 2020 WL 1491378, at *9 (S.D. Ohio Mar. 27, 2020) (rejecting application of learned intermediary doctrine when plaintiff alleged that defendants failed to warn her and her health care providers, even though the complaint was vague as to the alleged risks); *Barreca v. AngioDynamics, Inc.*, No. 4:15CV1111, 2015 WL 5085260, at *3 (N.D. Ohio Aug. 27, 2015) (failure-to-warn claim survived motion to dismiss when plaintiff alleged that defendant knew of risks associated with the product, but failed to provide sufficient warnings to the plaintiff or her physician, and the complaint identified specific risks); *Thompson*, 2014 WL 2874268, at *7 (rejecting application of learned intermediary doctrine when plaintiff alleged that the warning did not reach the physician or the patient, and identified a specific risk).

For these reasons, Plaintiff has sufficiently alleged a claim based on inadequate warning under R.C. 2307.76.

2. Count II: Product Manufacturing Defect (R.C. 2307.74)

R.C. 2307.74 provides that a product is defective in manufacture 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." Plaintiff alleges that the Verilast Hip materially deviated from the manufacturer's design standards or from otherwise identical units manufactured to the same performance standards. He also alleges that the defects occurred while the product was in Defendant's control, and that the manufacturing defect was the direct and proximate cause of Plaintiff's injury. Defendant argues that Plaintiff's allegations simply mirror the language from R.C. 2307.74 without pleading specific facts that support his manufacturing defect claim.

Defendant is correct. Such formulaic recitations of the elements do not suffice to adequately plead claims for manufacturing and warrant dismissal. *Frey v. Novartis Pharm. Corp.*, 642 F.Supp.2d 787, 795 (S.D. Ohio 2009). For manufacturing defect claims, "[a]t a minimum, courts have required allegations that the defendant manufactured the product, that the product was used by the plaintiff, that the product failed while being used by the plaintiff, and that the portion of the product that failed could be identified and is so identified in the complaint." *Barreca*, 2015 WL 5085260, at *3. For hip replacement claims, in particular, a plaintiff insufficiently pleads a manufacturing defect claim if he fails to specifically identify "the defects or failures at issue." *Baldwin v. Zimmer*, No. 2:10-cv-01144, 2011 WL 3652411, at *2 (S.D. Ohio Aug. 19, 2011) (granting a motion to dismiss for manufacturing and design defect claims against the manufacturer of

artificial hips because the plaintiff did not allege the defects specifically but only that the hip failed). *Compare Clark v. Wright Med. Tech., Inc.*, No. 3:11-cv-162, 2011 WL 2689381, at *2 (S.D. Ohio July 11, 2011) (denying a motion to dismiss where the plaintiff alleged specifically what portion of the hip failed).

In the Complaint, Plaintiff alleges that the Verilast Hip left the manufacturer with a material deviation from the design specifications, and such a deviation caused him harm. This allegation, however, is simply a recital of the elements of a R.C. 2307.74 claim. *See Frey*, 642 F.Supp.2d at 795. As such, it is a legal conclusion the Court need not accept as true even at the pleading stage. *Bearden v. Health*, No. 20-5047, 2020 WL 4218305, at *2 (6th Cir. July 23, 2020) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009)). Plaintiff does not support the manufacturing defect claim with any factual allegations showing that his Verilast Hip was different from other Verilast Hips, or that it deviated in any way from Defendant's standards. He fails to identify the portion of the product that failed. *See Barreca*, 2015 WL 5085260, at *3. In other words, Plaintiff merely makes conclusory statements that it contained "defects."

Thus, Plaintiff has failed to sufficiently plead facts that support a manufacturing defect claim under R.C. 2307.74.

3. Count III: Defect in Design (R.C. 2307.75)

A product's design is defective under R.C. 2307.75 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." The statute also lays out factors to consider when analyzing these foreseeable risks and benefits. R.C.

2307.75(B), (C).

As with manufacturing defect claims, design defect claims require that the complaint contain factual allegations as to which portions of the product failed. *Grange Mut. Cas. Co*, 2016 WL 3078956, at *3; *Marcum v. DePuy Orthopedics, Inc.*, No.: 1:12–cv–834, 2013 WL 1867010, at *5 (S.D.Ohio May 2, 2013); *Baldwin,* 2011 WL 3652411, at *2. Such facts elevate allegations beyond "threadbare recitals or formulaic recitations of the elements of a claim." *Marcum*, 2013 WL 1867010, at *5.

Defendant claims that the complaint advances threadbare legal conclusions unsupported by sufficient factual allegations. Defendant points specifically to Plaintiff's allegation that the product "could" or "can"—as opposed to actually did—"loosen and separate from the hip socket, causing severe pain and injury." (Doc. 5 at 12, quoting Compl. at ¶¶ 10, 28.) In response, Plaintiff argues that he did allege that the product directly and proximately caused his injuries and that the defects caused him to require a surgery.

A review of the complaint reveals that Plaintiff merely recites the elements of the claim without sufficient factual content. He alleges that Defendant created a defective product which caused Plaintiff's injuries, but does not allege how the product was defectively designed or how that defect was the direct, proximate cause of his injury. The only mention of potential risk in the Complaint is Plaintiff's assertion that the Verilast Hip "could or "can loosen and separate from the hip socket." (Compl. at ¶¶ 10, 28.) But this does not amount to a factual allegation that this defect actually occurred in the product installed in Plaintiff. In other words, Plaintiff fails to identify the portion of

Defendant's product that had failed or even assert that such portion could be identified at all. Plaintiff's design defect claim simply recites the elements of the claim under the statute but does not allege facts that permits the Court to conclude that there was a design defect or that the defect was the proximate cause of Plaintiff's injuries. *See Frey*, 642 F.Supp.2d at 795.

Because his formulaic recitation of the elements amounts to asserting legal conclusions without any factual support, his design defect claim falls short of the *Twombly* standard.

4. Count IV: Failure to Conform to Representation (R.C. 2307.77)

Lastly, under R.C. 2307.77, a product is defective for failure to conform to representations if, when it left the manufacturer, it failed to conform to a representation made by that manufacturer. A plaintiff seeking to recover under this statute must show 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. *Cervelli v. Thompson/Ctr. Arms*, 183 F. Supp. 2d 1032, 1045 (S.D. Ohio 2002) (citing *White v. DePuy, Inc.*, 129 Ohio App.3d 472, 484–85, 718 N.E.2d 450 (1998)).

Plaintiff contends that the Verilast Hip was defective because it did not conform to representations Defendant had made, and that this non-conformity harmed him. Defendant claims that Plaintiff's allegations are conclusory and simply copy the operative language from R.C. 2307.77. Defendant further contends that Plaintiff does not allege

what representations Defendant made, or how the product failed to conform to the representations.

Defendant is correct again. Plaintiff's failure-to-conform claim lacks sufficient factual content. The complaint contains nothing about what Defendant's representations were, when they were made, or how the product did not conform to them. In his response, Plaintiff declares that the name of the product itself, Verilast, implies that it "lasts" and is "durable." (Doc. 6 at 4.) Two problems with this reasoning arise. First, this claim does not appear in the complaint. Second, even if it did, Plaintiff's appeal to the product's name is still not a sufficient factual allegation to show that Defendant made a representation that a patient using a Verilast Hip would never require an additional surgery.

For these reasons, the Court also dismisses Plaintiff's claim for failure to conform to representations.

C. Plaintiff's request for leave to amend his complaint

Plaintiff also makes an effort to amend his complaint. In part of one sentence, Plaintiff requests that, as an alternative to denying the motion, the Court should instead grant him leave to amend his complaint. (Doc. 6 at 4, citing *Trucking Servs., Inc. v. Triton Transp. Servs., Inc.*, 940 F.2d 663 (6th Cir. 1991) (leave to amend "shall be freely given when justice so requires" under Fed.R.Civ.P. 15(a).) In Defendant's view, Plaintiff's request for leave to amend is improperly sought and would be futile as evidenced by Plaintiff's lack of an adequate motion to amend and his failure to provide a copy of the proposed amendments. Based on these shortcomings, according to Defendant, Plaintiff

has not properly requested leave to amend and has not shown that the facts alleged in the new amended complaint would defeat the motion to dismiss.

Although Rule 15 instructs courts to "freely give leave" to amend, the Sixth Circuit has held that this liberal policy is not without constraints. When the request for leave comes in the form of "throwaway language" instead of an adequate motion, and without a copy of the revised complaint, it is appropriate deny that request. *Kuyat v. BioMetric Therapeutics, Inc.*, 747 F.3d 435, 444 (6th Cir. 2014).

In fact, Plaintiff's request here resembles the failed one-sentence request in *Kuyat*. In *Kuyat*, the plaintiffs sought leave to amend the complaint in the final sentence of their memorandum in opposition. *Id.* Similarly here, Plaintiff closes his memorandum in opposition this way: "This Court should deny Defendant's Motion to Dismiss or alternatively provide Grubbs leave to amend his Complaint." (Doc. 6 at 4.) Although Plaintiff captions his memorandum in opposition to the motion to dismiss alternatively as a motion for leave to file an amended complaint, it is in substance a memorandum in opposition with one clause reserved for seeking leave to amend. At less than a sentence long, the request provides no support for why the Court should grant him leave and does not attach an amended complaint to show why it is necessary. Such failure to develop any argument in support of his request is not well-taken. *See Moore v. Scott*, No. 1:18-CV-261, 2018 WL 6025572, at *3 (S.D. Ohio Nov. 16, 2018).

Furthermore, without a proposed amended complaint, the Court does not know the new facts Plaintiff intends to add. The *Moore* court identified this as an issue when it denied leave to amend, noting that "because [p]laintiff has failed to identify any

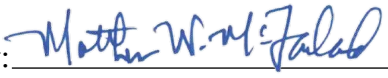
additional allegations or facts she would like to add to the complaint, the request for leave to amend is futile." 2018 WL 6025572, at *3. Plaintiff's response itself even fails to show any indication of additional factual allegations he would add if given leave to amend, and thus the response cannot show why allowing such amendment would not be futile. In the analogous case *Frey*, the court denied the plaintiff's request to amend for the same reason: the plaintiff's threadbare complaint and the response failed to show why an amendment would be fruitful. 642 F.Supp.2d at 795-796. As the courts in these cases have denied similar, unsupported requests, this Court denies the request for leave to amend.

CONCLUSION

The Court hereby **GRANTS IN PART AND DENIES IN PART** Defendant's Motion to Dismiss. Except for the inadequate warning claim under R.C. 2307.76, Plaintiff has failed to state plausible claims for relief. This case will proceed on Count I, Inadequate Warning or Instruction under R.C. 2307.76.

IT IS SO ORDERED.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO

By: 
JUDGE MATTHEW W. McFARLAND