IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

LORZENZO and FRANCIS TOLLIVER,	)	
	)	CASE NO.: 1:12 CV 00754
Plaintiffs,	)	
	)	
v.	)	JUDGE DONALD C. NUGENT
	)	
BRISTOL-MYERS SQUIBB CO., *et al.*	)	
	)	**MEMORANDUM OPINION AND ORDER**
Defendants.	)	

Plaintiffs Lorenzo and Francis Tolliver bring this suit against Defendants Bristol-Myers Squibb Company, Sanofi US Services Inc. (previously "Sanofi-Aventis U.S. LLC"), Sanofi-Aventis U.S. Inc., and Sanofi-Synthelabo Inc. (collectively, "Defendants"). Plaintiffs' Complaint seeks damages for injuries suffered by Mr. Tolliver allegedly resulting from his use of the prescription drug Plavix. Plaintiffs also seek damages for Mrs. Tolliver's alleged loss of consortium. Defendants filed a Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(c) and 8(a). (ECF #11). For the reasons stated herein, Defendants' motion is GRANTED.

I. FACTUAL BACKGROUND

The following facts are alleged in the Complaint. For the purpose of Defendants' motion to dismiss, they are accepted as true.

Defendants Bristol-Myers Squibb Company, Sanofi US Services Inc., and Sanofi-Aventis U.S. Inc. were partners in manufacturing and marketing Plavix, marketed as a "super-aspirin," in the United States. (Pls. Compl. ¶¶ 2-3, 11.) Defendant Sanofi-Synthelabo Inc. sponsored the

drug application for Plavix and was "instrumental" in bringing Plavix to the market. (Pls.' Compl. ¶ 4.)

On or about December 2002, Mr. Tolliver was prescribed Plavix. (Pls.' Compl. ¶ 19.) He continued taking Plavix, as prescribed and on a regular basis, until on or about February 2011. *Id.* "During the period of taking Plavix and as a result of taking Plavix, the Plaintiff, Lorenzo Tolliver suffered with [sic] numerous blood related medical problems, resulting in approximately 40–45 blood transfusions." (Pls.' Compl. ¶ 20.) In March 2010, the Food and Drug Administration ("FDA") issued a warning to alert healthcare providers and users that Plavix "can be less effective in people who cannot metabolize the drug to convert it to its active form by the liver enzyme known as CYP2C 19." (Pls.' Compl. ¶ 18.)

Plaintiffs filed this present suit in the Court of Common Pleas in Richland County, Ohio. The Complaint alleges the following Ohio law claims on behalf of Mr. Tolliver: strict liability, breach of warranty, negligence, negligence per se, and "defective in product conforming to representation made by manufacturer." It also alleges a loss of consortium claim on behalf of Mrs. Tolliver. Defendants subsequently removed the action to federal court in the Northern District of Ohio. On May 7, 2012, Defendants filed this Motion to Dismiss Pursuant to Fed R. Civ. P. 12(c) and 8(a) as to all of Plaintiffs' claims. Plaintiffs filed a response on June 5, 2012. Defendants filed their reply on June 19, 2012.

II. LEGAL STANDARD

The decision whether to dismiss a claim under Fed. R. Civ. P. 12(c) is reviewed under the same standard applied to motions to dismiss under Fed. R. Civ. P. 12(b)(6). *See Kottmyer v. Maas*, 436 F.3d 684, 689 (6th Cir. 2006). A motion to dismiss under Fed. R. Civ. P. 12(b)(6)

allows a defendant to test the legal sufficiency of a complaint without being subject to discovery. *See Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 566 (6th Cir. 2003). In evaluating a motion to dismiss, the court must construe the complaint in the light most favorable to the plaintiff, accept its factual allegations as true, and draw reasonable inferences in favor of the plaintiff. *See Directv, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007). The court will not, however, accept as true conclusions of law or unwarranted inferences cast in the form of factual allegations. *See Gregory v. Shelby County*, 220 F.3d 433, 446 (6th Cir. 2000).

In order to survive a motion to dismiss, a complaint must provide the grounds of the entitlement to relief, which requires more than labels and conclusions—a formulaic recitation of the elements of a cause of action alone will not suffice. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). That is, "[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* (internal citation omitted); *see Ass'n of Cleveland Fire Fighters v. City of Cleveland*, 502 F.3d 545, 548 (6th Cir. 2007) (recognizing that the Supreme Court "disavowed the oft-quoted Rule 12(b)(6) standard of *Conley v. Gibson*, 355 U.S. 41, 45–46, 78 S. Ct. 99, 2 L. Ed. 2d 80 (1957)"). Accordingly, the claims set forth in a complaint must be plausible, rather than merely conceivable. *See Twombly*, 550 U.S. at 570.

On a motion brought under Fed. R. Civ. P. 12(b)(6), the court's inquiry is limited to the content of the complaint, although matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint may also be taken into account. *See Amini v. Oberlin College*, 259 F.3d 493, 502 (6th Cir. 2001).

III. ANALYSIS

A. Common Law Claims Abrogated by the OPLA

The Ohio Products Liability Act ("OPLA"), Ohio Rev. Code Ann. § 2307.71 *et seq.*, applies to any recovery of compensatory, punitive, or exemplary damages based on a product liability claim. Ohio Rev. Code Ann. § 2307.72(A), (B). The statute defines a "product liability claim" as one "that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question" allegedly resulting from a manufacturing or design defect, inadequate warning, or nonconformance with manufacturer representations. *Id.* § 2307.71(A)(13). The statute specifically covers injuries resulting from the use of an "ethical drug[]," defined as "a prescription drug that is prescribed or dispensed by a physician or any other person who is legally authorized to prescribe or dispense a prescription drug." *Id.* § 2307.71(A)(4).

Plaintiffs' own Complaint describes the practice of physicians prescribing Plavix. (Pls.' Compl. ¶¶ 16, 17.) Thus, Plavix is clearly an "ethical drug." As Plaintiffs seek damages for physical injury allegedly caused by Mr. Tolliver's ingestion of this "ethical drug," Plaintiff's claims are "products liability claims" as defined by the OPLA.

The OPLA expressly preempts all common law product liability claims. Ohio Rev. Code Ann. § 2307.71(B); *see also*, *Mitchell v. Proctor & Gamble*, No. 2:09–CV–426, 2010 WL 728222, at *3 (S.D. Ohio Mar. 1, 2010) ("[T]he OPLA eliminated common law product liability causes of action."). Specifically, Ohio district courts have held that neither negligence nor express or implied warranty claims are viable under the OPLA. *See e.g.*, *Boroff v. ALZA Corp.*, 685 F. Supp. 2d 704, 711 (N.D. Ohio 2010) (finding that the OPLA abrogates common law

claims of breach of express warranty, negligence, and negligence per se); *Miller v. ALZA Corp.*, 759 F. Supp. 2d 929, 943 (S.D. Ohio 2010) ("[C]ommon law warranty claims have also been abrogated by the OPLA . . . ."). Thus, the OPLA abrogates Plaintiffs' common law claims of negligence, negligence per se, and breach of warranty. As a result, these claims must be dismissed.

B. Insufficiency of OPLA Claims

Because the OPLA abrogates all common law product liability claims, Plaintiffs' product liability claims must fall under one of the four types of claims permitted by the OPLA: manufacturing defect, design defect, inadequate warning, and noncompliance with manufacturers' representations. Ohio Rev. Code Ann. §§ 2307.71(B), 2307.74-.77. When bringing claims under the OPLA, plaintiffs should clarify which OPLA provision governs the claims in their complaint. *See Delahunt v. Cytodyne Techs.*, 241 F. Supp. 2d 827, 843 n.6 (S.D. Ohio 2003). Plaintiffs here, however, have failed to even mention the OPLA, much less refer to the specific provision governing their claims.

Even more problematically for Plaintiffs, their Complaint fails to state a plausible claim for relief under any of the four applicable provisions of the OPLA. First, Plaintiffs fail to state a plausible manufacturing defect claim. Under the OPLA, a product has a manufacturing defect "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 Ann. § 2307.74. To succeed on a manufacturing defect claim under the OPLA, a plaintiff must show that "(1) [t]here was, in fact, a defect in the product

manufactured and sold by the defendant; (2) such defect existed at the time the product left the hands of the defendant; and (3) the defect was the direct and proximate cause of the plaintiffs' injuries or loss." *Saraney v. TAP Pharm. Prods., Inc.*, No. 1:04–CV–02026, 2007 WL 148845, at *7 (N.D. Ohio Jan. 16, 2007) (internal quotation and citation omitted).

Here, Plaintiffs' Complaint states that Defendants breached their duty to "manufacture Plavix in a safe a [sic] suitable manner for its intended purpose," (Pls.' Compl. ¶ 25), and that Mr. Tolliver "suffered injury and damages as a direct and proximate result," (Pls.' Compl. ¶ 26). Plaintiffs' Complaint contains no factual allegations to support these legal conclusions, however, and thus, under *Twombly* and *Iqbal*, these statements need not be accepted as true. *See Gregory*, 220 F.3d at 446. For instance, the Complaint contains no allegations or facts which would tend to show that Plavix deviated from any design specifications, formula, performance standard, or otherwise identical model, as required for a manufacturing defect claim. *See Boroff*, 685 F. Supp. 2d at 708 (dismissing a manufacturing defect claim under the OPLA for failure to include such factual allegations). Although the Complaint does allege that the FDA issued a warning stating that Plavix may be less effective for a certain class of people, (Pls.' Compl. ¶ 18), it never alleges that this lower level of effectiveness in any way resulted from a design deviation. Moreover, even if this lower level of effectiveness were considered indicative of a manufacturing defect, the Complaint fails to allege that Mr. Tolliver was in this class of people for whom Plavix is less effective. In fact, the Complaint contains no factual allegations at all to support a causal relationship between Mr. Tolliver's taking of Plavix and his medical problems. Because Plaintiffs' Complaint fails to make any factual allegations in regards to a manufacturing

defect or a causal relationship between Mr. Tolliver's ingestion of Plavix and the alleged injuries, Plaintiffs' Complaint fails to state a plausible manufacturing defect claim.

Plaintiffs' Complaint also fails to make out a cognizable design defect claim. The OPLA recognizes a design defect claim "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 Ann. § 2307.75(A). "An ethical drug or ethical medical device is not defective in design or formulation because some aspect of it is unavoidably unsafe, if the manufacturer of the ethical drug or ethical medical device provides adequate warning and instruction . . . concerning that unavoidably unsafe aspect." *Id.* § 2307.75(D).

Here, Plaintiffs' Complaint alleges only that Defendants breached their duty to design Plavix in a safe manner, (Pls.' Compl. ¶ 25), and that "the risk of suffering a heart attack, stroke, internal bleeding, blood disorder, or death outweighed many potential benefits," (Pls.' Compl. ¶ 12). Once again, these bare legal conclusions, without any specific fact-based allegations as to how the product was defective, are insufficient to make out a design defect claim. *See Mills v. Bristol-Myers Squibb Co.*, No. CV 11–968–PHX–FJM, 2011 WL 3566131, at *2 (D. Ariz. Aug. 12, 2011) (dismissing a design defect products liability claim involving Plavix for plaintiff's failure to allege a specific defect in her complaint). Furthermore, Plaintiffs' Complaint contains no allegation that Defendants failed to provide an adequate warning with respect to this alleged defect. And finally, as with the manufacturing defect claim, Plaintiffs fail to put forth any factual allegations to support a connection between the alleged design defect and the medical

problems suffered by Mr. Tolliver. Thus, Plaintiffs cannot make out a plausible design defect claim.

Plaintiffs' Complaint also fails to allege sufficient facts to make out an inadequate warning claim. The OPLA recognizes an inadequate warning claim if the manufacturer knew or should have known about a harmful risk associated with the product yet unreasonably failed to warn about that risk. Ohio Rev. Code Ann. § 2307.76(A). For ethical drugs such as Plavix, the OPLA requires that the manufacturer warn the prescribing physician, rather than the ultimate consumer. *Id.* § 2307.76(C). For a plaintiff to succeed on an inadequate warning claim, the risk about which the manufacturer allegedly failed to warn must be the same risk which harmed the plaintiff. *Id.* § 2307.76(A).

Here, Plaintiffs' allege only that Defendants breached their duty to "warn the Plaintiff and related individuals, of the true risks and dangers of taking Plavix." (Pls.' Compl. ¶ 23.) Once again, such a generic legal conclusion need not be accepted as true under *Twombly* and *Iqbal*. As discussed above, Plaintiffs have failed to allege a specific risk or danger about which Defendants would need to provide warning. Moreover, although the Complaint does allege that Defendants exaggerated the potential benefits of Plavix, (Pls.' Compl. ¶ 11, 14), it provides no factual allegations as to how Defendants allegedly failed to warn of any dangers of Plavix. *See Mills*, 2011 WL 3566131, at *3 (dismissing a failure to warn claim when plaintiff's complaint contained no factual allegations related to a specific defect or how the provided warning was deficient). In fact, the Complaint fails to reference the Plavix warning label altogether. And although the Complaint alleges that Defendants inadequately warned "Plaintiff and related individuals," it contains no reference at all to the Plaintiff's prescribing physician—the relevant

recipient of the warning for the purposes of the OPLA. Finally, due both to Plaintiffs' failure to name the prescribing physician in their Complaint as well as the absence of any factual allegations in the Complaint connecting Mr. Tolliver's consumption of Plavix to his medical problems, Plaintiffs have once again failed to put forth any facts to support a plausible causal connection between the allegedly inadequate warning and Mr. Tolliver's injuries. As Plaintiffs have failed to allege any facts that tend to show the existence of a defect, the inadequacy of the warning, or a causal relationship between the alleged failure to warn and Mr. Tolliver's injuries, Plaintiffs have not made out a cognizable inadequate warning claim.

Plaintiff's last potential OPLA claim, for nonconformance with the manufacturer's representation, fails as well. Such a claim arises if a product "did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer." Ohio Rev. Code Ann. § 2307.77. The statute defines a "representation" as "an express representation of a material fact concerning the character, quality, or safety of a product." *Id.* § 2307.71(A)(14). To succeed on such a claim, a plaintiff must show that (1) the manufacturer made a representation as to a material fact relating to the character or quality of the product; (2) the product did not conform to that representation; (3) the plaintiffs justifiably relied on that representation; and (4) the plaintiffs' reliance on the representation was the direct and proximate cause of the plaintiffs' injuries. *See Saraney*, 2007 WL 148845, at *8.

Here, Plaintiffs' Complaint only states that "Defendants are liable to the Plaintiffs for breaching express and implied products representations that they made regarding Plavix. These product representations include fitness of merchantability and/or fitness for a particular use." (Pls.' Compl. ¶ 40.) The Complaint also states that Defendants' breach of such representations

was the "direct and proximate cause" of Plaintiff's injuries. (Pls.' Compl. ¶ 41.) Once again, however, Plaintiffs' Complaint contains no factual allegations to support these conclusory legal statements, and thus these statements need not be accepted as true. Most notably, Plaintiffs fail to identify any specific representations made by Defendants regarding Plavix. *See Saraney*, 2007 WL 148845, at *8 (dismissing a claim for noncompliance when plaintiff's complaint alleged only that defendant had advertised an ethical drug as of "good, safe and merchantable quality"). Moreover, as in all of Plaintiffs' potential claims under the OPLA, the Complaint fails to provide any factual allegations connecting the supposed nonconformance with Mr. Tolliver's injuries. Because Plaintiffs have provided no factual allegations to develop a plausible claim of nonconformance with the manufacturer's representation, Plaintiffs' claim fails as a matter of law.

Under Ohio law, loss of consortium is a derivative claim. *See Rife v. Matrixx Initiatives, Inc.*, No. 2:06–CV–267, 2007 WL 1831064, at *1 (S.D. Ohio June 25, 2007). Because Plaintiffs' underlying claims all fail as a matter of law, so too does Plaintiff's claim for loss of consortium. *See Graham v. Am. Cyanid Co.*, 350 F.3d 496, 514–15 (6th Cir. 2003) ("A derivative cause of action may not provide greater relief than that available under the primary cause of action.").

C. Denial of Leave to Amend

Plaintiffs' request for leave to amend consists only of a single sentence in their response brief that states, "[i]n the event that the Court finds that the Plaintiff failed to plead a claim accordingly, Plaintiffs respectfully request leave to amend their Complaint." (Pls.' Br. 6–7.) The grounds for such a request, however, should be stated with particularity in a motion to the

court. *See Evans v. Pearson Enters., Inc.*, 434 F.3d 839, 853 (6th Cir. 2003) (requests for leave to amend are governed by Fed. R. Civ. P. 7(b)). This Circuit has repeatedly upheld district court denials of requests for leave to amend when plaintiffs offered similarly brief and vague requests. *See e.g.*, *Evans*, 434 F.3d at 853 (6th Cir. 2003) (affirming denial of leave to amend when plaintiff's request was made in one sentence and failed to provide grounds for the request or a proposed amended complaint to support the request); *Begala v. PNC Bank, Ohio, Nat'l Ass'n*, 214 F.3d 776, 784 (6th Cir. 2000) ("What plaintiffs may have stated, almost as an aside, to the district court in a memorandum in opposition to the defendant's motion to dismiss is . . . not a motion to amend."). This Court similarly denies Plaintiffs' request for leave to amend, and dismisses all of Plaintiffs' claims with prejudice.

III. CONCLUSION

For the reasons stated above, Plaintiffs have not pled sufficient facts to state a plausible claim for relief under the OPLA. *See Iqbal*, 129 S.Ct. at 1950. Thus, Defendants' Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(c) and 8(a), (ECF #11), is GRANTED. IT IS SO ORDERED.

. */s/Donald C. Nugent*
DONALD C. NUGENT
United States District Judge

DATED: July 30, 2012