UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

AMANDA FREY, et al.,

Plaintiffs,

v. Case No. C-1-07-317

NOVARTIS PHARMACEUTICALS CORPORATION, et al.,

Defendants.

ORDER

Plaintiffs Amanda Frey, Sharon Lacy and Thomas Lacy bring this action against defendants Novartis Pharmaceuticals Corporation (Novartis) and John Does 1-10. The matter is before the Court upon Novartis' motion for partial dismissal of the amended complaint (doc. 24), plaintiffs' memorandum in opposition to the motion to dismiss and, to the extent the Court finds the complaint to be deficient, plaintiffs' motion for leave to file a second amended complaint (doc. 28), and Novartis' reply (doc. 30).

I. Introduction

Plaintiffs, residents of Ohio, originally filed this action in the Court of Common Pleas for Clermont County, Ohio. Defendants removed the action to this court based on the court's diversity jurisdiction. Plaintiffs subsequently filed an amended complaint in which they make the following allegations: Novartis, a pharmaceutical company incorporated under the laws of the

State of New Jersey with its principal place of business in New Jersey, and John Does 1-10 designed, manufactured, marketed, distributed and sold Trileptal (oxcarbazepine) in interstate commerce, including in Ohio. Trileptal is in a class of drugs known as anticonvulsants or antiepileptics, which generally prevent seizures, but more specifically Trileptal contains oxcarbazenpine. Trileptal's predecessor was Tegretol, which was also manufactured by Novartis, and Novartis marketed Trileptal as the "new Tegretol." On January 14, 2000, the Food and Drug Adminstration (FDA) approved Trileptal for the treatment of epilepsy, including partial seizures in adults. Subsequent to FDA approval, Trileptal was marketed by Novartis as a safe and effective anti-seizure medication. Defendants downplayed the health hazards and risks associated with Trileptal. Trileptal has been linked to several severe and life-threatening medical disorders, including multi-organ hypersensitivity, whose manifestations may include lymphadonopathy, hepatitis, liver function abnormalities, hematological abnormalities, pruritis, nephritis, oliguria, hepato-renal syndrome, arthralgia and asthenia. Defendants did not disclose these known material risks to plaintiff.[1] A labeling change was made in or about March 2005, adding a precaution regarding multi-organ hypersensitivity. On or about April 18, 2005, Novartis sent a warning letter to physicians of the label change.

Plaintiffs further allege that plaintiff Amanda Frey ingested Trileptal from March 25, 2005, until April 23, 2005; as a proximate result, she suffered multi-organ hypersensitivity and multiple related complications; and had she known of the risks and dangers associated with Trileptal, she would not have taken it and would not have been subject to its side effects.

[1]At various times throughout the amended complaint, plaintiffs refer to "plaintiff" in the singular. The Court presumes when plaintiffs do so that they are referring to plaintiff Amanda Frey, who ingested the Trileptal.

Based on these allegations, plaintiffs bring a claim for strict liability for defect in the manufacture of Trileptal under Ohio Rev. Code § 2307.74 (First Cause of Action). In support of this cause of action, plaintiffs allege as follows:

> ¶ 27. The product which was consumed by Plaintiff was defective in design and construction at the time it left the Defendants' control.
>
> ¶ 28. Defendants failed to design, manufacture, test, and control the quality of Trileptal such that when it left the control of the Defendant, 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.
>
> ¶ 29. As a direct and proximate result of the defect in manufacture or construction by Defendants, Plaintiff [] suffered the injuries [] and damages set forth herein.

Plaintiffs bring as their second cause of action a claim for strict liability for defect in design or formulation under Ohio Rev. Code § 2307.75. They claim that the risks created by Trileptal exceeded its benefits and that a practical and technically feasible alternative design was available which would have prevented the harm alleged without substantially impairing the product's usefulness or intended purpose.

Plaintiffs allege as their third cause of action a claim for strict liability for inadequate warning or instruction pursuant to Ohio Rev. Code § 2307.76. They claim that Trileptal was defective due to inadequate warning or instruction at the time of marketing and post-marketing because defendants knew, or in the exercise of reasonable care should have known, about a risk associated with the product that caused the harm alleged, and defendants failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk.

As their fourth cause of action, plaintiffs allege strict liability for failure to conform to

representation under Ohio Rev. Code § 2307.77. Plaintiffs make the following allegations in support of this claim:

> ¶ 46. At the time that the product and its component parts left the control of the Defendants, the product did not conform to representation(s) made by Defendants.
>
> ¶ 47. Plaintiff relied on the representations of Defendants in consenting to consume Trileptal.

Plaintiffs bring a claim for liability of a supplier under Ohio Rev. Code § 2307.78 as their fifth cause of action. They claim that defendants "had a duty to exercise reasonable care in the sale, quality control and assurance, representations made regarding the performance and risks of failure of the product, conveyance, [and] sale and/or distribution of the product within the stream of commerce . . ." Plaintiffs claim that defendants negligently made representations to plaintiff regarding the safety of Trileptal which did not conform to the representations made by defendants at the time the product left their control. Plaintiffs contend that

> "Defendants suppliers" are liable as if they were the manufacturer because: (1) the supplier in question owned, or when it supplied that product, owned, in whole or in part, the manufacturer of that product; (2) the supplier in question created or furnished a manufacturer with a design or formulation that was used to produce, create, make[,] construct, assemble or rebuild the product or a component of that product; (3) [t]he supplier in question altered, modified, or failed to maintain that product after it came into the possession of, or before it left the possession of, the supplier in question and the alteration, modification or failure to maintain the product rendered it defective; or (4) the supplier marketed the product under its own label.

Finally, plaintiffs assert as their sixth cause of action in the amended complaint a claim for punitive or exemplary damages under Ohio Rev. Code § 2307.80, which has since been dismissed on stipulation of the parties (doc. 23), and a claim to recover economic loss sustained by plaintiffs Sharon Lacy and Thomas Lacy under Ohio Rev. Code § 2307.71 (seventh cause of action).

II. Applicable Law

A. Standard for Rule 12(b)(6) Motion to Dismiss

A motion to dismiss pursuant to Rule 12(b)(6) operates to test the sufficiency of the complaint. The first step in testing the sufficiency of the complaint is to identify any conclusory allegations. ***Ashcroft v. Iqbal***, __ U.S. __, 129 S.Ct. 1937, 1950 (2009). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." ***Id***. at 1949 (citing ***Bell Atl. Corp. v. Twombly***, 550 U.S. 544, 555 (2007)). "[A] plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." ***Twombly***, 550 U.S. at 555 (citations and quotation marks omitted). Although the court must accept well-pleaded factual allegations of the complaint as true for purposes of a motion to dismiss, the court is "not bound to accept as true a legal conclusion couched as a factual allegation." ***Id***.

After assuming the veracity of all well-pleaded factual allegations, the second step is for the court to determine whether the complaint pleads "a claim to relief that is plausible on its face." ***Iqbal***, 129 S.Ct. at 1949, 1950 (citing ***Twombly***, 550 U.S. at 556, 570) (rejecting the traditional 12(b)(6) standard set forth in ***Conley v. Gibson***, 355 U.S. 41, 45-46 (1957)). A claim is facially 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 1949 (citing ***Twombly***, 550 U.S. at 556). The standard for plausibility is not akin to a "probability requirement," but it requires "more than a sheer possibility that a defendant has acted unlawfully." ***Id***. (citing ***Twombly***, 550 U.S. 556).

B. The Parties' Positions

Defendants move to dismiss plaintiffs' first, second and fifth causes of action on the

grounds that (1) plaintiffs fail to allege facts sufficient to state a claim for manufacturing defect under Ohio Rev. Code § 2307.74 because plaintiffs rely on only a "formulaic recitation of the elements of a cause of action" and they actually allege that Amanda Frey's injuries arose from the purported effects of Trileptal as designed and not from a deviation in the manufacture of the specific tablets she ingested; (2) a claim of design defect in an ethical drug under Ohio Rev. Code § 2307.75 is foreclosed in accordance with subsection (D) so long as the manufacturer provides an adequate warning, and further, plaintiffs do not allege that Trileptal poses a unique risk to consumers that is not present with other similar drugs; and (3) plaintiffs' claim for supplier liability under Ohio Rev. Code § 2307.78 fails because Novartis, as the manufacturer of Trileptal, cannot be held liable under this statutory provision. ***See*** Ohio Rev. Code § 2307.71(15)(b)(i) (specifying that the definition of "supplier" under Ohio's product liability statutes does not include "[a] manufacturer.") Although defendants also originally sought dismissal of plaintiffs' third and fourth causes of action to the extent they are preempted by the FDA's exercise of its regulatory authority, as well as the seventh cause of action insofar as the Court should determine that none of plaintiffs' other claims withstand the motion to dismiss, defendants no longer seek dismissal of these claims under Rule 12(b)(6) in light of the United States Supreme Court's decision in ***Wyeth v. Levine***, __ U.S. __, 129 S.Ct. 1187 (2009).

Plaintiffs contend that they have sufficiently pled all of the elements of the first and second causes of action for manufacturing defect and design defect. In support of the design defect claim, plaintiffs allege that Novartis marketed a drug whose risks were not known to the general public, specifically, the risk of multiorgan hypersensitivity disorders. Plaintiffs allege that they cannot particularly allege that the scientific makeup of the drug is defective for a

specific reason without conducting discovery, which requirement would exceed ***Twombly's*** plausibility standard.

Plaintiffs argue that they are entitled to proceed with their fifth cause of action for supplier liability because they allege that Novartis is both the manufacturer and supplier of the product and if the facts establish that Novartis is one and not the other, plaintiffs are entitled to proceed on the alternate theory of liability.

Finally, plaintiffs request that they be permitted to amend the complaint pursuant to Fed. R. Civ. P. 15(a) in the event the Court finds their complaint is deficient.

C. Ohio Products Liability Act

The concept of strict liability in tort for a defective product is codified at Ohio Rev. Code Ch. 2307. Section 2307.73 provides that a manufacturer is subject to liability for compensatory damages based on a product liability claim only if the plaintiff proves, by a preponderance of the evidence, that (1) "the manufacturer's product in question was defective in manufacture or construction as described in section 2307.74 of the Revised Code, was defective in design or formulation as described in section 2307.75 of the Revised Code, was defective due to inadequate warning or instruction as described in section 2307.76 of the Revised Code, or was defective because it did not conform to a representation made by its manufacturer as described in section 2307.77 of the Revised Code"; and (2) such defect was a proximate cause of harm for which the plaintiff seeks to recover compensatory damages.

Ohio Rev. Code § 2307.74 provides that

> 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. A product may be defective in manufacture or construction as described in this section even though its manufacturer exercised all possible care in its manufacture or construction.

Ohio Rev. Code § 2307.75(A) provides that

Subject to divisions (D), (E), and (F) of this section, a product is 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 as determined pursuant to division (B) of this section exceeded the benefits associated with that design or formulation as determined pursuant to division (C) of this section.

Subsection (D) provides that

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 under section 2307.76 of the Revised Code concerning that unavoidably unsafe aspect.

Ohio Rev. Code § 2307.76 provides, in pertinent part, that:

(A) Subject to divisions (B) and (C) of this section, a product is defective due to inadequate warning or instruction if either of the following applies: (1) It is defective due to inadequate warning or instruction at the time of marketing if, when it left the control of its manufacturer, both of the following applied:

(a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;

(b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

(2) It is defective due to inadequate post-marketing warning or instruction if, at a relevant time after it left the control of its manufacturer, both of the following applied:

(a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;

(b) The manufacturer failed to provide the post-marketing warning or instruction

that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

(B) A product is not defective due to lack of warning or instruction or inadequate warning or instruction as a result of the failure of its manufacturer to warn or instruct about an open and obvious risk or a risk that is a matter of common knowledge.

(C) An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that ethical drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it.

Ohio Rev. Code § 2307.78 provides as follows:

(A) Subject to division (B) of this section, a supplier is subject to liability for compensatory damages based on a product liability claim only if the claimant establishes, by a preponderance of the evidence, that either of the following applies:

(1) The supplier in question was negligent and that, negligence was a proximate cause of harm for which the claimant seeks to recover compensatory damages;

(2) The product in question did not conform, when it left the control of the supplier in question, to a representation made by that supplier, and that representation and the failure to conform to it were a proximate cause of harm for which the claimant seeks to recover compensatory damages. A supplier is subject to liability for such a representation and the failure to conform to it even though the supplier did not act fraudulently, recklessly, or negligently in making the representation.

(B) A supplier of a product is subject to liability for compensatory damages based on a product liability claim under sections 2307.71 to 2307.77 of the Revised Code, as if it were the manufacturer of that product, if the manufacturer of that product is or would be subject to liability for compensatory damages based on a product liability claim under sections 2307.71 to 2307.77 of the Revised Code and any of the following applies:

(1) The manufacturer of that product is not subject to judicial process in this state;

(2) The claimant will be unable to enforce a judgment against the manufacturer of

that product due to actual or asserted insolvency of the manufacturer;

(3) The supplier in question owns or, when it supplied that product, owned, in whole or in part, the manufacturer of that product;

(4) The supplier in question is owned or, when it supplied that product, was owned, in whole or in part, by the manufacturer of that product;

(5) The supplier in question created or furnished a manufacturer with the design or formulation that was used to produce, create, make, construct, assemble, or rebuild that product or a component of that product;

(6) The supplier in question altered, modified, or failed to maintain that product after it came into the possession of, and before it left the possession of, the supplier in question, and the alteration, modification, or failure to maintain that product rendered it defective;

(7) The supplier in question marketed that product under its own label or trade name;

(8) The supplier in question failed to respond timely and reasonably to a written request by or on behalf of the claimant to disclose to the claimant the name and address of the manufacturer of that product.

The question of the adequacy of the warning given is considered to be of central importance in determining whether the product at issue in a strict liability case is unreasonably dangerous. ***Graham v. American Cyanamid Co.,*** 2000 WL 1911431, *9 (S.D. Ohio 2000) (unpublished decision) (citing ***Seley v. G.D. Searle & Co.,*** 67 Ohio St.2d 192, 197, 423 N.E.2d 831 (1981)). If an adequate warning has been provided for a pharmaceutical product, then the manufacturer cannot be held strictly liable, irrespective of whether there is a causal connection between the plaintiff's use of the drug and the plaintiff's injury, and despite the fact that the product is unavoidably unsafe. ***Id.*** (citing ***Seley,*** 67 Ohio St.2d at 197, 423 N.E.2d 831). A warning is adequate if it reasonably discloses to the medical profession all risks inherent in the use of the drug which the manufacturer knew or should have known to exist. ***Id***. (citing ***Seley***, 67

Ohio St.2d at 198, 423 N.E.2d 831). "A warning may be unreasonable in its factual content, its expression of the facts, or the method or form in which it is conveyed." ***Id***. (citing ***Seley,*** 67 Ohio St.2d at 198, 423 N.E.2d 831). "The adequacy of warnings is measured not only by what is stated, but also by the manner in which it is stated." ***Id.*** "A reasonable warning not only conveys a fair indication of the nature of the dangers involved, but also warns with the degree of intensity demanded by the nature of the risk." ***Id.***

III. Resolution of the Motion to Dismiss

Plaintiffs' first cause of action for strict liability for defect in the manufacture of Trileptal under Ohio Rev. Code § 2307.74 must be dismissed pursuant to Rule 12(b)(6) for failure to state a plausible claim for relief. Plaintiffs have done nothing more than provide a formulaic recitation of the elements of a claim under the statute. They have failed to allege any facts that would permit the Court to conclude that a manufacturing defect occurred and that the defect was the proximate cause of Amanda Frey's alleged injuries. Plaintiffs' allegations in this regard fall far short of the sufficiency standard set forth in ***Twombly.***

As for plaintiffs' second cause of action for strict liability for defect in the design or formulation of Trileptal under Ohio Rev. Code § 2307.75, the Court disagrees with Novartis that this claim is foreclosed by the Ohio court of appeals' decision in ***Kennedy v. Merck & Co., Inc.,*** 2003 WL 21658613, *3 (Ohio Ct. App. July 3, 2003) (unpublished decision). Novartis contends that the court of appeals held at page 3 of its opinion that the plaintiff's design defect claim for the pharmaceutical drug VIOXX was barred because the plaintiff claimed that the alleged health risk was common to other drugs in the same class. In fact, the court did not make a holding to this effect at page 3 of its opinion but instead stated at page 6 that one of the reasons for

upholding the trial court's grant of summary judgment on the design defect claim was that there was no evidence that VIOXX posed a greater risk to the ordinary consumer than other drugs in its class. The decision in ***Kennedy*** does not mandate dismissal of a design defect claim whenever a plaintiff alleges that a health risk posed by a drug is common to other drugs in the class.

Plaintiffs' design defect claim must nonetheless be dismissed because plaintiffs have once again simply provided a formulaic recitation of the elements of a claim under the statute. They have not alleged any facts that would permit the Court to conclude that there was a defect in the design or formulation of Trileptal and that the defect was the proximate cause of Amanda Frey's alleged injuries. Because plaintiffs' allegations fall far short of the sufficiency standard set forth in ***Twombly,*** their claim for design defect must be dismissed.

Finally, plaintiffs' fifth claim for relief against Novartis for supplier liability under Ohio Rev. Code § 2307.78 must be dismissed because the claim is precluded under Ohio law. Plaintiffs allege unequivocally in the complaint that Novartis is the manufacturer of Trileptal. As the manufacturer of the drug, Novartis falls outside the statutory definition of a "supplier" of Trileptal pursuant to Ohio Rev. Code § 2307.71(15)(b)(i). Plaintiffs therefore cannot proceed against Novartis under a theory of supplier liability.

IV. Request for Leave to Amend

Plaintiffs have requested that they be granted leave to amend the complaint in the event the Court finds the complaint to be deficient in any respect. Fed. R. Civ. P. 15(a) provides that leave to amend ". . . shall be freely given when justice so requires." Denial of leave to amend is warranted where there is undue delay, bad faith or a dilatory motive on the part of the movant, the amendment would be futile, or undue prejudice would result to the opposing party. ***Foman v. Davis,*** 371 U.S. 178, 182 (1962); ***see also Yuhasz v. Brush Wellman, Inc.,*** 341 F.3d 559, 569 (6th Cir. 2003).

Plaintiffs have not shown that they are able to allege facts that would state plausible claims for relief under their first, second or fifth causes of action so as to satisfy the ***Twombly*** standard. Thus, plaintiffs have failed to demonstrate that an amendment to the complaint would not be futile. The Court will therefore deny plaintiffs' request for leave to amend the complaint.

V. Conclusion

In accordance with the foregoing, defendants' motion for partial dismissal of the complaint (doc. 24) is **GRANTED in part** as set forth herein. Plaintiffs' first, second and fifth causes of action are **DISMISSED** insofar as plaintiffs bring these claims against Novartis. These causes of action remain pending to the extent plaintiffs bring them against the John Doe defendants. The case will proceed on plaintiffs' third, fourth and seventh causes of action against Novartis and on plaintiffs' causes of action against the John Doe defendants.

IT IS SO ORDERED.

S/ Herman J. Weber
HERMAN J. WEBER, SENIOR JUDGE
UNITED STATES DISTRICT COURT