UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

Donna Hogue,

Plaintiff, **Case No. 2:10–cv–805**

v. **Judge Michael H. Watson**

Pfizer, Inc., *et al.*,

Defendants.

OPINION AND ORDER

Plaintiff sues Defendants in this product liability action alleging that her use of the prescription medication metoclopramide caused her to develop tardive dyskinesia. Plaintiff sues Defendants PLIVA, Inc., Teva Pharmaceuticals USA, Inc., and Qualitest Pharmaceuticals, Inc. ("Generic Defendants") for negligence, strict liability, breach of warranties, fraud and misrepresentation, and negligence *per se*. Generic Defendants move for judgment on the pleadings and request an oral argument. Mot., ECF No. 69. Defendants' request for an oral argument is denied, and for the following reasons, the Court grants Generic Defendants' motion.

I. FACTS

Donna Hogue ("Plaintiff") is a resident of Morgan County, Ohio. Defendant PLIVA, Inc. ("PLIVA") is a New Jersey Corporation with its principal place of business in New Jersey. Defendant Teva Pharmaceuticals USA, Inc. ("Teva") is

a Delaware corporation with its principal place of business in Pennsylvania. Defendant Qualitest Pharmaceuticals, Inc. ("Qualitest") is an Alabama corporation with its principal place of business in Alabama. Plaintiff seeks damages in excess of $75,000, and the Court has diversity jurisdiction over Plaintiff's state law claims.

Generic Defendants manufactured a generic version of metoclopramide tablets (the brand name of which is "Reglan") that Plaintiff alleges she ingested over a period of nine years. Metoclopramide is a prescription medication indicated for short-term treatment of symptomatic gastroesophageal reflux disease ("GERD") and acute and recurrent diabetic gastric stasis. It is indicated for use of no longer than twelve weeks, and longer usage puts patients at a risk of developing tardive dyskinesia, akathisia, central nervous system disorders, depression with suicidal ideation, tardive dystonia, visual disturbances, and interference with drug metabolism. Notwithstanding these potential side effects, Plaintiff alleges Generic Defendants represented that metoclopramide was safe to use for longer than twelve weeks.

In October 2000, Plaintiff's doctor prescribed her metoclopramide to treat abdominal pain and digestive problems. Plaintiff took metoclopramide until August 2009. In March 2009, Plaintiff developed abnormal movements and has since been diagnosed with tardive diskinesia, a permanent neurological disorder that can cause involuntary and uncontrollable movements of the head, neck,

face, arms, legs and/or trunk, involuntary facial grimacing and tongue movements, and tongue thrusting or tongue chewing.

II. STANDARD OF REVIEW

A motion for judgment on the pleadings under Rule 12(c) attacks the sufficiency of the pleadings and is reviewed under the same standard applicable to a motion to dismiss under Rule 12(b)(6). *Tucker v. Middleburg-Legacy Place*, 539 F.3d 545, 549 (6th Cir. 2008).

A claim survives a motion to dismiss pursuant to Rule 12(b)(6) if it "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (internal quotation omitted). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* A complaint's "[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all of the complaint's allegations are true." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555–56 (2007) (internal citations omitted).

A court must also "construe the complaint in the light most favorable to the plaintiff." *Inge v. Rock Fin. Corp.*, 281 F.3d 613, 619 (6th Cir. 2002). In doing so, however, a plaintiff must provide "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; *see also Iqbal*, 129 S. Ct. at 1949 ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice."); *Ass'n of Cleveland Fire Fighters v. City of Cleveland, Ohio*, 502 F.3d 545, 548 (6th Cir. 2007). "[A] naked

assertion . . . gets the complaint close to stating a claim, but without some further factual enhancement it stops short of the line between possibility and plausibility . . . ." *Twombly*, 550 U.S. at 557. Thus, "something beyond the mere possibility of [relief] must be alleged, lest a plaintiff with a largely groundless claim be allowed to take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value." *Id.* at 557–58 (internal citations omitted).

III. ANALYSIS

Plaintiff brings claims for negligence, strict liability, breach of warranties, fraud and misrepresentation, and negligence *per se*. To support those claims, Plaintiff advances several theories of liability including failure to warn about the risks of metoclopramide, fraud in statements about the drug, failure to investigate the safety of the drug, and defective design of the drug.

1. Ohio Products Liability Act

Generic Defendants argue as an initial matter that Plaintiff purports to bring claims only under state common law, but her claims are abrogated by the Ohio Products Liability Act ("OPLA"). Plaintiff responds that even if she did not cite the OPLA in her Complaint, she has alleged facts sufficient to state claims under it and the Uniform Commercial Code ("UCC") such that she should be permitted to amend her Complaint to bring claims under the OPLA and UCC.

The Ohio Products Liability Act ("OPLA") states "Sections 2307.71 to 2307.80 of the Revised Code are intended to abrogate all common law product

liability claims or causes of action." Ohio Rev. Code § 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."). To the extent Plaintiff is making common law product liability claims, Plaintiff's claims are abrogated by the OPLA.

For the most part, however, her claims do fall into duties imposed by the OPLA. Only the alleged duty to test a product pre-marketing or to do post-market surveillance on the safety of the drug is not found in the OPLA.[1] Plaintiff argues that federal law requires a generic manufacturer to monitor its product once it is in the market place and take certain actions if it has concerns. Any violation of a federal duty does not create a duty under the OPLA and no common law remedy is available. Accordingly, to the extent Plaintiff's Count One - Negligence Claim is based on a theory of failure to use due care in testing its product and failure to conduct pre-clinic and clinical testing and post-marketing surveillance, the Court grants Defendant's motion for judgment on the pleadings as to that claim. All other claims will be construed as if they were brought under OPLA or the proper UCC provisions, and, therefore, leave to amend is denied.

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[1]The only product liability claims available under the OPLA are for products: (1) defective in manufacturing or construction, Ohio Revised Code § 2307.74; (2) defective in design or formulation, Ohio Revised Code § 2307.75; (3) defective due to inadequate warning or instructions, Ohio Revised Code § 2307.76; and (4) defective due to nonconformance with manufacturers' representations, Ohio Revised Code § 2307.77.

2. *PLIVA, Inc. v. Mensing*

Generic Defendants argue that the United States Supreme Court held in *PLIVA, Inc. v. Mensing* that state-law tort claims against generic drug manufacturers are preempted by federal law. Generic Defendants contend the *Mensing* case involved the same generic medication at issue in this case, the same alleged injuries, some of the same generic drug manufacturer defendants, the same claims, is indistinguishable from this case, and disposes of all of Plaintiff's claims. Plaintiff argues *Mensing's* holding is limited, does not apply to Teva, and does not dispose of all of her claims.

Mensing involved state common law claims that generic drug manufacturers failed to provide adequate warning labels for generic metoclopramide. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2572 (2011). The state common law at issue in *Mensing* required a drug manufacturer that was or should be aware of its drug's danger to label the drug in a way that renders it reasonably safe. *Id.* at 2573. At issue was "whether federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus pre-empt, these state law claims." *Id.* at 2572. The Supreme Court held that they do. *Id.*

First, the Supreme Court rejected the theories that generic drug manufacturers could use the "changes-being-effected" ("CBE") process to change their labels to satisfy the state law. "The CBE process permits drug manufacturers to 'add or strengthen a contraindication, warning, [or] precaution,

or to 'add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product[.]" *Id.* at 2575 (citations omitted). However, the FDA interprets the CBE process to allow generic manufacturers to change generic drug labels only "to match an updated brand-name label or to follow the FDA's instructions." *Id.* The FDA argued that any unilateral change to labels by generic drug manufacturers would violate the federal requirement that generic drugs be identical to brand name drugs in both substance and labeling ("sameness" requirement). The Supreme Court deferred to the FDA's interpretation and found that federal law did not permit the generic drug manufacturers to change drug labels through the CBE process. *Id.*

Next, the Supreme Court considered the plaintiff's argument that the generic drug manufacturers could have sent "Dear Doctor" letters as additional warnings. *Id.* at 2576. The Supreme Court disagreed, stating that Dear Doctor letters qualify as "labeling" and therefore must be "consistent with and not contrary to [the drug's] approved . . . labeling." *Id.* (citing 21 CFR § 201.100(d)(1)). Any Dear Doctor letter containing substantially new warnings would not conform to the approved labeling. *Id.* Moreover, "if generic drug manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'" *Id.* Thus, the Supreme Court "conclude[d] that federal law did not permit the [generic manufacturers] to

issue additional warnings through Dear Doctor letters." *Id.*

Finally, the Supreme Court considered whether the generic drug manufacturers could have complied with the state laws by proposing stronger warning labels to the FDA. The FDA argued the manufacturers had a federal duty to propose such labels under 21 U.S.C. § 352(f)(2), which states that a drug is "misbranded" unless it has an adequate label. *Id.* The FDA interprets that regulation "to require that 'labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug.'" *Id.* The Supreme Court did not decide whether the regulation imposes such an obligation on generic drug manufacturers, and held that, even assuming such a duty exists, fulfillment of that duty would not have satisfied the state law requirements. *Id.* Because it was impossible to comply with both federal law and state law, the plaintiff's state law claims were preempted. *Id.* at 2577.

Mensing has been applied by numerous courts, including the Sixth Circuit Court of Appeals, to preempt state law claims against generic metoclopramide manufacturers based on failure to warn. *See, e.g.*, *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011).

As an initial matter, Plaintiff argues the *Mensing* decision does not apply to Defendant Teva because the FDA designated Teva's metoclopramide as a reference listed drug ("RLD"). Pl.'s Resp. PAGEID # 656, ECF No. 75. She cites no authority for that proposition. Generic Defendants note the RLD designation

was only for Teva's metoclopramide *oral solution*, which Plaintiff never ingested. More to the point, however, the designation of a drug as an RLD does not change the manufacturer's status as an Amended New Drug Application ("ANDA") holder, and Plaintiff's counsel conceded as much when the issue was raised during oral argument before the U.S. Supreme Court in *Mensing*. Indeed, the FDA has expressly recognized the RLD designation does nothing to alter an ANDA holder's duties concerning labeling changes. Determination That Brethine (Terbutaline Sulfate) Injection Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 72 Fed. Reg. 39629-01, 2007 WL 2047956 (July 19, 2007); *see also Cooper v. Wyeth, Inc.*, No. 09-929-JJB, 2012 WL 733846, at *8 (M.D. La. Mar. 6, 2012) (rejecting identical argument and recognizing import of the FDA Brethine Detemination). Consequently, the Court finds no merit in Plaintiff's argument.

Plaintiff concedes that *Mensing* forecloses Plaintiff's failure to warn claim (Count One: negligence based on failure to warn).[2] In addition, regardless of how the claims are labeled by Plaintiff in her Complaint, *Mensing* preempts any claim that "hinge[s] on the warnings the drug manufacturers gave, or from Plaintiff's perspective, failed to give" because those claims are, in essence, failure to warn claims. *Fulgenzi v. PLIVA, INC.*, — F. Supp. 2d — , No. 5:09CV1767, 2012 WL 1110009, at *7 (N.D. Ohio Mar. 31, 2012) (dismissing, *inter alia*, strict products

[2]Because Plaintiff's negligence claim fails, her allegation of gross negligence also fails.

liability claim, breach of warranties claim, and misrepresentation and fraud claim.); *Miles v. Raymond Corp.*, 612 F. Supp. 2d 913, 921 (N.D. Ohio 2009) ("under Ohio law it is the substance of the claim, not the manner in which it is pleaded, that determines how it is treated.") Therefore, *Mensing* also preempts Count Two (strict products liability based on failure to warn), Count Three (breach of express and implied warranties based on fact that "Defendants marketed and promoted their Reglan/metoclopramide as safe and efficacious for its intended uses." Compl. ¶ 108), Count Four (misrepresentation and fraud based on representations made "in their advertising, labeling, marketing, and sales/detail persons" or "knowingly omitted and downplayed material information" because labels "concealed material information." Compl. ¶ 111), and Count Five (negligence per se based on theory that label was "misbranded" under federal law and because of "failure to adequately warn" or on failure to communicate. Compl. ¶ 118).

Plaintiff argues several of those claims are not based on a theory of failure to warn. Plaintiff states her breach of warranty claims were brought pursuant to Ohio Revised Code § 2307.77 and § 1302.26. She further contends that the Ohio law does not impose a duty on manufacturers to make a warranty; therefore, the law does not conflict with any federal requirement regarding labeling and is not preempted. She asserts the breach of warranty claims are not based on a failure to warn, contending the breaches did not occur because

warranties were made but rather because the product did not conform to the warranties made.

Plaintiff also argues that *Mensing* does not preempt a negligence claim based on Generic Defendants' failure to communicate the FDA-approved warnings through use of Dear Doctor letters. Plaintiff argues that *Mensing* only prohibits Dear Doctor letters that contain new or additional warnings and does not prohibit Dear Doctor letters that merely highlight information already contained on or recently added to labels. Where such a letter does not contain new or additional warnings, Plaintiff argues, it would not suggest a theraputic difference between the generic and brand name drug and is permitted. Presumably, Plaintiff's argument is that the failure to take such a permissible action serves as evidence of a breach of the standard of care and supports a negligence claim.[3]

Plaintiff further asserts that *Mensing* does not foreclose her claims based on design defect because the holding was specifically limited to a generic

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[3]As discussed herein, Plaintiff argues that Generic Defendants violated federal and state law by failing to communicate new warnings that were added to the labels in 2004 to prescribing physicians or consumers via Dear Doctor letters or otherwise. Plaintiff further argues PLIVA failed to include the new warning on its label and asserts some courts have construed that as a manufacturing defect claim. However, Plaintiff did not plead a manufacturing defect claim in her Complaint apart from making a conclusory allegation in support of her common law negligence claim that Defendants "failed to use due care in developing, testing, designing and manufacturing Reglan/metoclopramide so as to avoid the aforementioned risks to individuals . . . ." Compl. ¶ 100(a). She did not allege that PLIVA failed to conform its label to the RLD in her Complaint nor provide any further specific details supporting a claim based on a manufacturing defect. The Court will not construe the Complaint as stating a claim for manufacturing defect under OPLA. Additionally, the argument was raised and tacitly rejected by the Sixth Circuit in *Smith v. Wyeth*, 657 F.3d 420, 423 (6th Cir. 2011), *petition for reh'g en banc denied* (6th Cir. Nov. 22, 2011).

manufacturer's ability to unilaterally change its warning labels and did not foreclose the possibility that a defendant could be liable for continuing to sell an unreasonably dangerous product.

The Sixth Circuit has rejected each of these arguments. *Smith v. Wyeth, Inc.* was pending before the Sixth Circuit when *Mensing* was decided. After *Mensing* was decided, the plaintiffs' counsel in *Wyeth* submitted supplemental briefing to the Sixth Circuit, arguing that at least four types of claims were viable after *Mensing*: (1) claims against generic drug manufacturers for failing to effectively communicate FDA-approved warnings for metoclopramide; (2) claims against generic drug manufacturers for continuing to sell metoclopramide with knowledge that the labeling lacked adequate warnings; (3) claims against generic drug manufacturers for negligence, breach of warranty, design defect, and unfair trade practices; and (4) claims against brand defendants for fraud and misrepresentation, making many of the same arguments made in this case. Pl. Supp. Br. 1–2, *Smith v. Wyeth*, Nos. 09-5460, 09-5466, 09-5509, 2011 WL 3662688. Despite these arguments, the Sixth Circuit dismissed the plaintiff's state law claims, stating the claims were predicated "on the failure to provide adequate warnings on the product's label" and were preempted pursuant to *Mensing*. *Smith v. Wyeth*, 657 F.3d 420, 423 (6th Cir. 2011), *cert. denied* 132 S. Ct. 2103.

Counsel then filed a petition for rehearing en banc, reiterating several of the arguments asserted in this case and arguing the Sixth Circuit failed to consider them in its initial Opinion. Specifically, as in this case, counsel argued that *Mensing* did not preempt a claim based on PLIVA's failure to update its label in 2004 because *Mensing* "in no way suggests that generic drug companies may not be held liable under state law for failing to provide warnings that federal law required them to provide." Petition for En Banc Reh'g at 2, *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011) (Nos. 09-5460, 09-5466, 09-5509). Likewise, counsel reiterated its prior argument that a claim based on the defendants' failure to communicate the FDA-approved warnings was not preempted by *Mensing*. *Id.* at 5 n.1, 6. The Sixth Circuit denied the petition for rehearing, stating that the issues raised therein "were fully considered upon the original submission and decision of the cases." Order, *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011) (Nos. 09-5460, 09-5466, 09-5509).

Thus *Smith v. Wyeth, Inc.* confirms the Court's finding that Plaintiff's claims for breach of warranty (Count Three), strict liability for design defect (Count Two), and negligence based on failure to adequately communicate warnings, PLIVA's failure to update its label, or design defect (Count One) are foreclosed.[4]

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[4]In addition, this Court notes that several other district courts have held *Mensing's* reasoning forecloses a design defect claim against generic manufactures. The same statute analyzed in *Mensing*, 21 U.S.C. § 355(j), requires that an Abbreviated New Drug Application ("ANDA") include information showing the generic drug is bioequivalent to the referred listed drug. 21 U.S.C. § 355(j)(2)(iv). Several courts have reasoned that if, as the *Mensing* court

IV. CONCLUSION

Plainitff's negligence claim based on an alleged breach of the duties to test its product pre-marketing or to do post-market surveillance on the safety of the drug does not state a claim under the OPLA. Each of Plaintiff's remaining claims, even if brought under the OPLA or UCC, fail as preempted by federal law under *Mensing*. Therefore, the Court **GRANTS** judgment on the pleadings for Generic Defendants, ECF No. 69. The Clerk shall remove ECF No. 69 from the Civil Justice Reform Act list.

In a separate Opinion, the Court granted summary judgment in favor of the Brand Defendants, Schwartz Pharma, n/k/a UCB, Inc., Pfizer, Inc., and Wyeth LLC. As this Opinion dismisses all of Plaintiff's remaining claims, the Court **DIRECTS** the Clerk to enter final judgment in this matter in favor of Defendants and against Plaintiff, dismissing this action in its entirety with prejudice.

IT IS SO ORDERED.

MICHAEL H. WATSON, JUDGE
UNITED STATES DISTRICT COURT

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stated, the inability to change warnings means that it is impossible to comply with federal law and meet the requirements of state law, then federal law requiring the design of the drug to be copied directly from the reference listed drug preempts state law which would hold generic manufactures liable for defective design. *See Stevens v. Pliva, Inc.*, Case No. 6:10-886, 2011 WL 6224569, at *2 (W.D. La. Nov. 15, 2011) (report recommending dismissal of design claim applying same reasoning), *adopted by* Case No. 6:10-866, 2011 WL 622456 (W.D. La. Dec. 2, 2011); *In re Accutane Products Liability*, MDL No. 1626, 2012 WL 3194952, at *2 (M.D. Fla. Aug. 7, 2012) (collecting cases adopting same reasoning). Because the Sixth Circuit's holding in *Smith v. Wyeth, Inc.* forecloses Plaintiff's design claim the Court does not reach the specific issue of whether Mensing's reasoning applies to Plaintiff's design claims.