UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

ELEANOR FULGENZI,	)	CASE NO.5:09CV1767
	)	
PLAINTIFF,	)	JUDGE SARA LIOI
	)	
vs.	)	
	)	OPINION AND ORDER
	)	
PLIVA, INC., et al.,	)	
	)	
DEFENDANTS.	)	

Before the Court is the motion of Defendant PLIVA, Inc. (PLIVA) to dismiss all claims on the ground of federal preemption. (Doc. No. 61.) Plaintiff Eleanor Fulgenzi (Plaintiff or Fulgenzi) opposes the motion (Doc. No. 63), and PLIVA has filed a reply (Doc. No. 64). PILVA has also filed a Notice of Supplemental Authority. (Doc. No. 66.) At the parties' request, the Court stayed the matter pending a ruling from the United States Supreme Court in two consolidated cases. It was anticipated that a ruling in these cases would resolve the question of whether regulations promulgated by the Federal Drug Administration (FDA) relating to the labeling of generic medication preempt state laws that may require generic drug manufacturers to provide more stringent safety warning labels on their products.

On June 23, 2011, the Supreme Court issued its decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), wherein the Court held that state-law causes of action alleging that generic manufacturers of prescription medication failed to provide adequate

warnings on their labels relating to possible risks and side effects of the mediation are preempted by federal law. *Id.* at 2572-73. Following the ruling, PLIVA filed the present motion to dismiss. Because the Supreme Court's ruling in *Mensing* forecloses the state-law claims raised in the Second Amended Complaint, PLIVA's motion to dismiss is granted and this case is dismissed.

I. BACKGROUND

Pursuant to the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et. seq*., the FDA is charged with the responsibility of approving new drugs. *See* 21 U.S.C. § 355(a); *Riegel v. Medtronic, Inc*., 552 U.S. 312, 315 (2008); *Merck KGaA v. Integra Lifesciences I, Ltd*., 545 U.S. 193, 196 (2005). A manufacturer seeking to market a new drug must file a New Drug Application (NDA) with the FDA. 21 U.S.C. § 355(b). As part of its application, the manufacturer must demonstrate through pre-market trials and other relevant evidence that the drug is safe, and that the proposed labeling properly sets forth the correct dosage and possible risks. The NDA requires, among other things, that the manufacturer supply the agency with "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use" and "specimens of the labeling proposed to be used for such drug." § 355(b)(1).

In contrast, drug manufacturers seeking to market a generic drug must file an Abbreviated New Drug Application (ANDA). The ANDA procedure, codified as amended in the Hatch-Waxman Act, 21 U.S.C. § 355, sets forth an expedited review process. To obtain approval, the manufacturer must demonstrate that the generic drug it

seeks to market is approved as a listed drug, meaning that the new drug is the functional equivalent of a name-brand drug already approved by the FDA. 21 U.S.C. § 355(j)(2). "One of the benefits to manufacturers who opt for the ANDA procedure is that they are required only to conduct 'bioequivalency' studies that establish that the generic and the reference-listed drug are pharmaceutically equivalent . . .." *Stacel v. Teva Pharms., USA*, 620 F. Supp. 2d 899, 905 (N.D. Ill. 2009). So long as the manufacturer can demonstrate that the generic drug is the pharmaceutical equivalent of its name-brand counterpart, the generic manufacturer need not duplicate the pre-market trials conducted by the name-brand manufacturer. This advantage serves the purpose of the Hatch-Waxman Act to increase the availability of low cost generic drugs. *See id*. at 907.

Federal regulations further require that "[a generic drug's] [l]abeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the drug product must be the same as the labeling approved for the reference listed drug, except for changes required because of differences approved under a petition filed under [21 C.F.R.] § 314.93 or because the drug product and the reference listed drug are produced or distributed by different manufacturers." 21 C.F.R. § 314.94(a)(8)(iv). The FDA can reject an ANDA application if the information submitted by the generic manufacturer is "insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug . . .." 21 C.F.R. § 314.127(a)(7).

According to the Second Amended Complaint, metoclopramide is a medication prescribed to treat symptomatic gastroesogphageal reflux and acute and recurrent diabetic gastric stasis. (Second Amended Complaint (SAC) at ¶ 19, Doc. No.

60.) The FDA first approved metoclopramide, under the name-brand Reglan, in 1980. The drug has been available in its generic form since 1985. *Mensing*, 131 S. Ct. at 2572. Emerging studies have shown that extended use of metoclopramide can lead to a condition known as tardive dyskinesia, a severe neurological disorder, which presents symptoms that include involuntary and uncontrollable movements of the head, neck, and face, as well as grotesque facial grimacing and tongue thrusting. Patients who take metoclopramide for extended periods of time are 29 percent more likely to contract this incurable neurological disorder. *Id.* at 2572 (internal citations omitted).

In light of this risk, warning labels for the drug have been strengthened several times. In 2004, the FDA approved a label adding the warning that "[t]herapy should not exceed 12 weeks in duration." *Mensing*, 131 S. Ct. at 2572-73 (quoting Physician's Desk Reference 1635-36 (41st ed. 1987)). In 2009, the warning on the label was strengthened further by the addition of a black box warning--the strongest available under the FDA regulatory scheme—stating that "Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible . . .. Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases." *Id*. at 2573 (quoting Physician's Desk Reference 2902 (65th ed. 2011)).

After taking metoclopramide for an extended period of time, Fulgenzi alleges that she developed tardive dyskinesia. (SAC at ¶ 17.) Fulgenzi initially brought the action against certain manufacturers of the generic metoclopramide and the name-brand Reglan. At the core of all of Fulgenzi's claims is the basic assertion that the drug manufacturers should have provided warnings alerting doctors and patients to the

heightened risk of developing neurological complications from long-term use of metoclopramide. Because it is undisputed that Fulgenzi had been treated exclusively with the generic version of metoclopramide, Fulgenzi dismissed with prejudice the manufacturers of the name-brand drug. (*See* Stipulation and Order, Doc. No. 27.) One of the remaining defendants, PLIVA, a manufacturer of generic metoclopramide, now seeks dismissal of all claims under Rule 12(b)(6) of the Federal Rules of Civil Procedure.

II. STANDARD OF REVIEW

A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief[,]" Fed. R. Civ. P. 8(a)(2), in order to "give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Conley v. Gibson*, 355 U.S. 44, 47 (1957). Although this pleading standard does not require great detail, the factual allegations in the complaint "must be enough to raise a right to relief above the speculative level . . .." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citing authorities). In other words, "Rule 8(a)(2) still requires a 'showing,' rather than a blanket assertion, of entitlement to relief." *Id*. at 556, n.3 (criticizing the *Twombly* dissent's assertion that the pleading standard of Rule 8 "does not require, or even invite, the pleading of facts").

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (quoting *Twombly*, 550 U.S. at 570). Rule 8 does not "unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Id*. at 1950. "While legal conclusions can provide the framework of a

complaint, they must be supported by factual allegations. When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Id*.

III. DISCUSSION

State law that conflicts with federal law is preempted under the Supremacy Clause of the United States Constitution. The Supremacy Clause provides that the Constitution, federal law, and all treaties "shall be the supreme law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2; *see Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). "Consideration of issues arising under the Supremacy Clause 'start[s] with the assumption that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress.'" *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (quoting *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947)). Accordingly, congressional intent to preempt state law is the "ultimate touchstone" of the pre-emption analysis. *Id.* (internal citation omitted).

Federal law may preempt state law either expressly or impliedly. *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 152-53 (1982). One form of implied preemption is conflict preemption, which occurs "where compliance with both federal and state regulations is a physical impossibility, or where state law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress." *Grade*

v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992) (internal citation and quotation omitted); *see Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995) (federal and state law conflicts when it is "impossible for a private party to comply with both state and federal requirements") (internal citation and quotation omitted).

In *Mensing*, the Supreme Court addressed two cases involving plaintiffs who had ingested the generic form of metoclopramide for long periods of time and developed tardive dysknesia. *See Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010); *Mensing v. Wyeth, Inc*., 588 F.3d 603 (8th Cir. 2009). Both plaintiffs alleged that the drug manufacturers responsible for producing the metoclopramide they consumed violated state tort law by failing to adequately warn patients and doctors of the risks associated with long-term use of the medication. The drug manufacturers argued that they could not simultaneously comply with FDA regulations requiring them to use the same safety and efficacy labeling as the name-brand Reglan and any state-law tort duty that may require more stringent warnings. The Court agreed with the manufacturers, finding that "[i]f the [generic] Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law." *Mensing*, 131 S. Ct. at 2578. Ultimately, the Court concluded that it was "impossible for the [generic] Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same." *Id.*

In finding compliance with state law impossible, the Supreme Court rejected the plaintiffs' argument that the generic drug manufacturers could have (and should have) requested that the FDA consider including more stringent warnings in the

labeling. While the manufacturers of name-brand drugs may unilaterally update and strengthen their warning without FDA approval, *see* 21 C.F.R. 314.70(c)(6)(iii), the generic drug manufacturers were tied to the name-brand labeling and required the FDA's approval to change the labeling. Because there was no guarantee that the FDA would act on such a request, the Court noted that relying on the possibility that the actions of a third party would permit the generic drug manufacturers to comply with both state and federal law would "render conflict pre-emption largely meaningless because it would make most conflicts between state and federal law illusory." *Id.* at 2579. Such a conclusion meant that the availability of state-law remedies turned on whether the pharmacist filled the prescription with the name-brand or the generic drug:

> Had [the plaintiffs] taken Reglan, the brand-name drug prescribed by their doctors, *Wyeth* [*v. Levine*, 555 U.S. 555 (2009)][1] would control and their lawsuits would not be pre-empted. But because pharmacists, acting in full accord with state law, substituted generic metoclopramide instead, federal law pre-empts these lawsuits.

Id. at 2581. While acknowledging "the unfortunate hand that federal drug regulation has dealt [the plaintiffs], and others similarly situated[,]" it found that the plaintiffs were left without a state-law remedy because generic drug manufacturers were obligated to ensure that their labeling matched that of the name-brand drug. *Id*.

Following the decision in *Mensing*, courts have consistently concluded that state-law failure-to-warn claims were preempted in cases, such as the present one,

[1] In *Levine*, the Supreme Court ruled that FDA regulations relating to the warning labels on name-brand prescription medications did not preempt state failure-to-warn claims brought against name-brand manufacturers, noting that "Congress took care to preserve state law" in this area. 129 S. Ct. at 1196. In so ruling, the Court rejected the drug manufacturer's argument of impossibility on the ground that the "changes being effected" (CBE) regulation permitted a name-brand drug manufacturer to unilaterally strength a warning label before receiving the FDA's approval. *Id.* at 1199.

where the plaintiffs have consumed generic medication. *See, e.g., Smith v. Wyeth, Inc*., 657 F.3d 420, 423 (6th Cir. 2011) (state-law failure-to-warn claims preempted by *Mensing*); *Moore v. Mylan*, Case No. 1:11CV3037-MHS, 2012 WL 123986, at *7, n.11 (N.D. Ga. Jan. 5, 2012) (in denying plaintiffs' motion to amend, the court held that proposed claims relating to "the duty and ability of generic manufacturers to communicate existing warnings to the medical community, or to alert individuals to important safety related labeling changes made by the brand name labels[,]" would be preempted by *Mensing*); *Fullington v. PLIVA, Inc*., No. 4:10CV236 JLH, 2011 U.S. Dist. LEXIS 142931, at *10-*11 (E.D. Ark. Dec. 12, 2011) (collecting cases); *Whitener v. PLIVA, Inc*., Case No. 10-1552 Sec. L(4), 2011 U.S. Dist. LEXIS 140053, at *8 (E.D. La. Dec. 6, 2011) ("the holding [in *Mensing*] is clear: state-law failure-to-warn claims against a generic drug manufacturer are preempted by federal law"); *Waguespack v. PLIVA USA, Inc*., Case No. 10-692, 2011 U.S. Dist. LEXIS 135710 (E.D. La. Nov. 3, 2011) (granting generic metoclopramide manufacturers' motion for judgment on the pleadings because the plaintiff's claims involving inadequate warnings were preempted under *Mensing*); *Richardson v. Wyeth, Inc*., Case No. 6:10CV883, 2011 U.S. Dist. LEXIS 128544, at *5 (W.D. La. Oct. 20, 2011) (the plaintiff's failure-to-warn claim against a generic metoclopramide manufacturer preempted by *Mensing*), adopted by 2011 U.S. Dist. LEXIS 128529 (W.D. La. Nov. 7, 2011).

In the Second Amended Complaint, Fulgenzi sets forth claims for relief under Ohio common law for strict products liability, strict liability-manufacturing defect, strict liability-design defect, breach of express warranty, breach of implied warranties,

negligence, negligent misrepresentation, breach of undertaking special duty, fraud and misrepresentation, constructive fraud, fraud by concealment, and intentional infliction of emotional distress. (*See* SAC.) She also raises four statutory claims under the Ohio Product Liability Act (OPLA), Ohio Rev. Code § 2307.71 *et seq*., for defective manufacturing, pursuant to Ohio Rev. Code § 2307.74; design defect, pursuant to § 2307.75; defect due to inadequate warning, pursuant to Ohio Rev Code § 2307.76; and non-conformance with representations, pursuant to Ohio Rev. Code § 2307.77. A fifth statutory claim is brought under the Ohio Consumer Sales Practice Act (OCSPA), Ohio Rev. Code § 1345.01 *et seq.*

"In Ohio, three basic theories of liability exist 'under which a claimant may assert a product liability action: (1) under the Ohio Product Liability Act; (2) negligence; and (3) breach of warranty.'" *Wimbush v. Wyeth*, 619 F.3d 632, 636-37 (6th Cir. 2010) (quoting Christopher M. Ernst, et al., *Baldwin's Ohio Practice, Ohio Tort Law*, § 6.1 (2009)). "The Ohio Products Liability Act defines a statutory product liability claim." *Id*. at 639 (citing Ohio Rev. Code § 2307.71(M)).

Plaintiff's common law tort claims are abrogated by the OPLA. Ohio Revised Code § 2307.71(B) was revised in 2005 to provide that "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). This amendment to the statute eliminated common law torts as an avenue for relief from injuries suffered from allegedly defective products. *See Wimbush*, 619 F.3d at 639; *Younker v. Ohio State Univ. Med. Ctr*., Case No. 2:11CV749, 2011 U.S. Dist. LEXIS 113196, at *6 (S.D. Ohio Sept. 29,

2011); *see, e.g., Erie Indem. Co. v. Keurig, Inc.*, Case No. 1:10CV2899, 2011 U.S. Dist. LEXIS 76998, at *16 (N.D. Ohio July 15, 2011) (dismissing plaintiffs' claims for negligent manufacture, design defect, inadequate testing, improper sale, and failure-to-warn as prototypical product liability claims abrogated by the OPLA). The OPLA also abrogates Plaintiff's product liability claim brought under the OCSPA. *See, e.g., Mitchell v. Proctor & Gambl*e, Case No. 2:09CV426, 2010 U.S. Dist. LEXIS 17956, at *11-*13 (S.D. Ohio Mar. 1, 2010) (finding OCSPA "claims primarily rooted in product liability" abrogated by OPLA); *Bourchard v. Am. Home Prods. Corp*., Case No. 3:98CV7541, 2002 U.S. Dist. LEXIS 27517, at *33 (N.D. Ohio May 24, 2002) (dismissing plaintiff's OCSPA claim as foreclosed by OPLA).

The remaining statutory claims sound in defective design, defective manufacturing, inadequate warnings, and non-comformance with representations. While the OPLA recognizes such causes of action, the defective design and manufacturing claims are not sufficiently plead. For example, in her defective manufacturing claim, Plaintiff merely recites the statutory requirements for a defective manufacturing claim, and alleges that the product was defective because it deviated from the product specifications. (SAC at ¶¶ 97-101.) Such a conclusory allegation, unsupported by any facts, is not sufficient to state a manufacturing defect claim. *See Ashcroft*, 129 S. Ct. at 1949-50 (noting that "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice"); *see, e.g*., *Morris v. Wyeth, Inc*, Case No. 3:09CV854, 2011 U.S. Dist. LEXIS 121052, at *8 (W.D. La. Oct. 19, 2011) (mere recital of the elements of claims for defective design, breach of express warranty, and

inadequate warning was insufficient to satisfy pleading requirements); *Boroff v. Alza Corp*., 685 F. Supp. 2d 704, 708 (N.D. Ohio 2010) ("The complaint in this case, however, is bereft of any allegation that the Duragesic used by the decedent deviated from any design specifications, formula, or performance standards, or any factual allegations that would support such a claim. Plaintiff thus fails to state a claim for violation of Ohio Rev. Code § 2307.74."). Plaintiff's statutory design defect claim suffers from the same pleading deficiencies. The pleaded allegations do little more than set forth the test for determining whether a product is unreasonably dangerous, and offer the conclusion that PLIVA's product was dangerous under the test.[2] (SAC at ¶ 114.)

Tellingly, one of the only factual allegations offered in support of the statutory design defect claim alleges that defendant manufacturers failed to "include the FDA approved warning against therapy in excess of 12 weeks that was included in Schwarz's warning labels . . .." (SAC at ¶ 114(b)). There is, however, no requirement under Ohio law that a generic manufacturer's label mirrors that of the name-brand label. Instead, the requirement that the generic manufacturer's label match that of the name-brand label flows from federal regulations governing prescription medication. There is no private cause of action for violations of FDA regulations.[3] Further, a similar argument

[2] Count 5 provides that "[t]he Reglan/Metoclopramide manufactured and supplied by Defendants was defective in design or formulation, in that, when it left the hands of the Defendants, the foreseeable risks of the product, as defined by Ohio Rev. Code §§ 2307.75(B) exceeded the benefits associated with its design or formulation, as defined by Ohio Rev. Code §§ 2307.75(C), or it was more dangerous than an ordinary consumer would expect." (SAC at ¶ 113.)

[3] Specifically, 21 U.S.C. § 337(a) provides that the enforcement of FDA regulations is reserved for the federal government. *See* 21 U.S.C. § 337(a). "Courts interpret 21 U.S.C. § 337(a) to restrict enforcement of the FDCA to the FDA, and that 'no private cause of action exists for a violation of the FDCA.'" *Loreto v. Procter & Gamble Co*., 737 F. Supp. 2d 909, 918-19 (S.D. Ohio 2010) (quoting *Kemp v. Medtronic, Inc*., 231 F.3d 216, 236 (6th Cir. 2000)).

that the failure to include the 2004 amendment to the warning label gives rise to a state failure-to-warn claim was raised in supplemental briefing in *Smith v. Wyeth*, and was implicitly rejected by the Sixth Circuit. (Aug. 15, 2011 Supplemental Brief Letter from Plaintiffs/Appellants, Doc. No. 64, Ex. 4 at 3-4.) In ultimately finding all of the claims preempted by *Mensing*, the Sixth Circuit failed to carve out an exception for state-law warning claims tied to alleged failures to comply with FDA regulations. *See Smith*, 657 F.3d at 423-24.

Even if the pleading deficiencies could be remedied, dismissal of these claims would still be appropriate because, regardless of how Plaintiff attempts to cast these claims, they are, at the core, failure-to-warn claims that are clearly preempted by *Mensing*. *See Grinage v. Mylan Pharms,, Inc*., Case No. CCB-11-1436, 2011 U.S. Dist. LEXIS 149667, at *18 (D. Md. Dec. 30, 2011) (rejecting design claim as failure-to-warn claims preempted by *Mensing)*; *Stevens v. PLIVA, Inc*., Case No. 6:10-886, 2011 U.S. Dist. LEXIS 147684, at *5-*6 (W.D. La. Nov. 15, 2011) (report recommending the dismissal of design defect claim, reasoning that "a generic pharmaceutical product must be the same as the referenced listed drug . . . in active ingredients, safety and efficacy and hence, as was the case with labeling, federal law pre-empts state laws imposing the duty to change a drug's design upon generic manufacturers"), *adopted by* Case No. 6:10-886 (W.D. La. Dec. 2, 2011) (Doc. No. 66, Ex. H); *Morris*, 2011 U.S. Dist. LEXIS 121052, at *2 (The court granted an opposed motion for judgment on the pleadings, finding the plaintiff's claims for defective destruction or composition, defective design, breach of express warranty, and inadequate warning all "sounded in failure to warn" and were,

therefore, preempted under *Mensing*.). Likewise, Plaintiff's final two statutory causes of action are preempted by *Mensing*. Count Six (defect due to "inadequate warning") and Count Eight ("nonconformance with representations") are both premised on an alleged failure-to-warn of the risks associated with use of the product. (SAC at ¶¶ 119-128, 141.)

In fact, a review of the allegations supporting each claim in the Second Amendment Complaint reveals that all of the claims, including those otherwise abrogated by the OPLA, hinge on the warnings the drug manufacturers gave, or from Plaintiff's perspective, failed to give. Because the essence of these claims is that PLIVA and others marketed and sold a product as safe when they should have advised doctors and patients of the risk created by long-term use of the medication, the case comes down to the warning.[4] *See, e.g., Gross v. Pfizer, Inc.*, Case No. 8:10CV10, 2011 U.S. Dist. LEXIS 134895, at *11 (D. Md. Nov. 22, 2011) (allegations that drug manufacturers failed to continue to monitor, test and inspect the product post-market are "but a piece of Plaintiff's larger failure to warn claims"). As such, the claims in this action are preempted

[4]Analysis of the SAC's shared factual allegations as to wrongdoing by defendants drives this point home. These allegations provide that defendants: "had a duty to ensure their warnings to the medical community [were] accurate and adequate" (SAC at ¶ 40); "failed to communicate the true and accurate risks" (*id*. at ¶ 59); "failed to update its/their label(s) as to metoclopramide to include the July, 2004 label change warning …" (*id.* at ¶ 60); "failed to disclose material safety information" (*id*. at ¶ 69); "failed to report data … regarding the adequacy and/or accuracy of its warnings …." (*id*. at ¶ 70); "knowingly concealed from physicians material facts bearing on the interpretation of package insert disclosures that exposure to Reglan/metoclopramide can lead to Tardive Dyskinesia …" (*id.* at ¶ 71); "concealed the fact that earlier false information … representing long term Reglan/metoclopramide therapy to be reasonably safe, was unscientific and false" (*id*. at ¶ 72); "concealed the fact that Reglan/metoclopramide is a neuroleptic agent and dopamine antagonist, which can be excepted to lead to Tardive Dyskinesia …" (*id.* at ¶ 73); and "concealed the fact that treatment … with Reglan/metoclopramide products for longer than 12 weeks is unlikely to be reasonably safe." (*id.* at ¶ 74.) Coupled with the shared causation paragraph that provides that Plaintiff's injuries were the foreseeable result of defendants' "dissemination of inaccurate, misleading, materially incomplete, false, and other inadequate information …." (SAC at ¶ 76), these factual allegations leave little doubt that each claim rises and falls with the adequacy of the warnings.

by *Mensing*.[5] *See, e.g., Schrock v. PLIVA USA, Inc.*, Case No. CIV-08-452-M, 2011 U.S. Dist. LEXIS 141171, at *6-*7 (W.D. Ok. Dec. 8, 2011) (dismissing claims for breach of express and implied warranties as preempted by *Mensing*, finding that the "gravamen" of the claims was a challenge to the manufacturers' representations as to the safety of the medication); *Metz v. Wyeth*, Case No. 8:10-CV-2658, 2011 U.S. Dist. LEXIS 121549 (M.D. Fla. Oct. 20, 2011) (dismissal of claims against the generic drug manufacturer for negligence, strict liability, breach of warranties, misrepresentation and fraud, and negligence per se as preempted); *Guarino v. Teva*, Case No. 8:10-CV-2885-T-30TGW, 2011 U.S. Dist. LEXIS 128630, at *5 (M.D. Fla. Nov. 7, 2011) (dismissing negligence, strict liability, breach of warranty, misrepresentation, and fraud claims as "on their face, premised on an allegedly inadequate warning").

IV. **CONCLUSION**

For the reasons set forth above, PLIVA's motion to dismiss is **GRANTED**.

IT IS SO ORDERED.

Dated: March 31, 2012

HONORABLE SARA LIOI
UNITED STATES DISTRICT JUDGE

[5] Finally, the Court rejects Plaintiff's argument that impossibility preemption does not apply because PLIVA could have complied with both state and federal law by choosing to stop selling metoclopramide. While such an argument was embraced by the Eight Circuit in *Mensing v. Wyeth, Inc*., 588 F.3d 603, 611 (8th Cir. 2009), the Supreme Court did not find the argument persuasive as it reversed the Eighth Circuit and dismissed all of the claims as preempted under federal law. "Thus, [this argument] has been overruled." *Fullington*, 2011 U.S. Dist. LEXIS 142931, at *18 (rejecting a similar argument under *Mensing*).