UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

DAWN HARRIS, on behalf of her minor child, COY CALLAHAN	**CIVIL ACTION**
VERSUS	**NO. 10-3159**
PHARMACEUTICAL ASSOCIATES, INC., et al.	**SECTION "B"(5)**

ORDER AND REASONS

Before the Court is Defendant Pharmaceutical Associates, Inc., Defendant Beach Products, Inc., and Defendant Morton Grove Pharmaceuticals, Inc.'s ("Defendants") Motion to Amend Order, seeking to amend this Court's previous denial of Plaintiff Dawn Harris' ("Harris") Motion to Reopen this administratively closed case.[1] (Rec. Doc. No. 49). Also before the Court is briefing by both sides on the impact of the U.S. Supreme Court's ruling in *PLIVA, Inc., v. Mensing*, 131 S.Ct. 2567 (2011) ("*Mensing*") on the instant case. (Rec. Docs. No. 27, 28, 29, 34, 37, 40, 43, 45, & 48). Accordingly, and for the reasons articulated below,

IT IS ORDERED that Harris' state law claims are **DISMISSED** due to preemption by federal law, as interpreted by the *Mensing* Court.

IT IS FURTHER ORDERED that Defendants' motion is **DISMISSED** as moot in view of the above ruling.

[1]Defendants seek an order from this Court denying Harris' motion to reopen the case with prejudice.

Procedural History and Facts of the Case:

Harris filed the present action in this Court on September 17, 2010, on behalf of her minor child, Coy Callahan ("Callahan"), claiming that the drug metoclopramide[2], manufactured by Defendants, caused Callahan to suffer from tardive dyskinesia. (Rec. Doc. No. 1 at 1). Harris sought damages against Defendants under the Louisiana Products Liability Act[3] ("LPLA"), alleging various failure-to-warn claims. *Id*. at 9. On January 26, 2011, this Court granted defendant Morton Grove Pharmaceutical Inc.'s motion to stay the proceedings and administratively closed the case pending the U.S. Supreme Court's ruling in *Mensing*, which addressed preemption issues also implicated by Harris' claims. (Rec. Doc. No. 15). Following the U.S. Supreme Court's ruling in *Mensing*, Harris filed a Motion to Reopen the case on July 28, 2011. (Rec. Doc. No. 17). On September 14, 2011, this Court denied the motion to reopen without prejudice to reurge, and ordered the parties to provide additional memoranda on the *Mensing* case's impact on the preemption issues. (Rec. Doc. No. 26). The Court subsequently allowed both parties to file supplemental memoranda on the *Mensing* case, its progeny, and the impact on the instant matter. (Rec. Docs. No. 27, 28, 29, 34, 37, 40, 43, 45, & 48). Based on said supplemental

[2]The drug is also referred to by its brand name, "Reglan." Defendants are manufacturers of the generic version of the drug.

[3]La. Rev. Stat. Ann. § 9:2800.54, et seq. (2012).

memoranda, Defendants filed the instant motion to amend the Court's previous denial of Harris' motion to reopen to be a denial with prejudice. (Rec. Doc. No. 49).

Law & Analysis

A. Denial of Reopening with Prejudice

Defendants seek denial with prejudice of Harris' Motion to Reopen, submitted to this Court on the briefs. (Rec. Doc. No. 49). Defendants claim they are entitled to such denial because Harris' claims should be dismissed with prejudice, on the basis of conflict preemption under the U.S. Supreme Court's ruling in *Mensing*. (Rec. Doc. No. 48 at 7); *PLIVA, Inc., v. Mensing*, 131 S.Ct. 2567 (2011). Therefore, this Court applies the legal standard it would employ for dismissal with prejudice under Federal Rule of Civil Procedure 12. In determining whether dismissal is appropriate, the court must decide whether the facts alleged in the pleadings, if true, would entitle the plaintiff to some sort of legal remedy. *Ramming v. U.S.,* 281 F.3d 158, 162 (5th Cir. 2001); *Cinel v. Connick,* 15 F.3d 1338, 1341 (5th Cir. 1994). The Supreme Court has put it this way: "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) (citing *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 570 (2007)).

B. Preemption

Under the U.S. Constitution, federal law "shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. Therefore, when federal law conflicts with state law, state law must "give way." *Mensing*, 131 S. Ct. at 2577, citing *Wyeth v. Levine*, 555 U.S. 555, 583 (2009); *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995). In *Mensing*, the U.S. Supreme Court held that state law failure-to-warn claims against generic drug manufacturers are preempted by federal drug regulations. *Mensing*, 131 S. Ct. at 2572. Under federal law, "generic drug manufacturers have an ongoing federal duty of 'sameness.'" *Id*. at 2575. That is, the warning labels of a generic drug must exactly match those of its brand-name counterpart. *Id*. Therefore, the Court found that it was "impossible" for generic drug manufacturers to comply with state laws imposing a duty to warn while adhering to federal drug regulations requiring exact sameness with brand-name warning labels. *Id*. at 2574-75, 2579, citing *Wyeth*, 555 U.S. at 573 ("The question of 'impossibility' is whether the private party could independently do under federal law what state law requires of it;" "We find impossibility here. It was not lawful under federal law for the [generic manufacturers] to do what state law required of them."). Applying the Supreme Court's ruling in *Mensing*, several district courts have held that any state law claims against generic drug manufacturers based on a theory of inadequate warnings are

preempted by federal law. *See Jacobsen v. Wyeth, LLC, et al.*, No. 10-0823, 2012 WL 3575293 (E.D. La. Aug. 20, 2012); *Guilbeau v. Wyeth, Inc., et al.*, No. 09-1652, 2011 WL 4948996 (W.D. La. Oct. 14, 2011); *Waguespack v. Plivia*, USA, Inc., et al., No. 10-692, 2011 WL 5826015 (E.D. La. Nov. 3, 2011); *Beck v. Teva Pharmaceutical Industries, Ltd.*, No. 10-1901, 2011 WL 4062219 (E.D. La. Sept. 13, 2011).

In *Mensing*, the Supreme Court consolidated cases from the Fifth and Eighth Circuit Courts of Appeal, in which plaintiffs brought suit against the generic manufacturers of metoclopramide, a drug designed to speed the movement of food through the digestive system, which was first approved by the Food and Drug Administration ("FDA") in 1980 under the brand name Reglan. *Mensing* 131 S.Ct. at 2572. The plaintiffs in each case sued the generic drug manufacturers alleging that long-term use of the drug caused a neurological disorder, and that the manufacturers were liable under state tort law for inadequate warning labels. *Id*. at 2573. Both the Fifth and Eighth Circuits rejected the manufacturers' arguments that the state tort claims were preempted by FDA regulations. *Id*. In the case arising out of the Fifth Circuit, the plaintiff's claims were based on Louisiana law, specifically the LPLA. *Id*. Among the claims alleged under the LPLA was the argument that the generic drug manufacturers could have used "Dear Doctor" letters to warn prescribing physicians and

healthcare professionals about the risk associated with the drug. *Id*. at 2576. However, the U.S. Supreme Court rejected these claims as preempted, accepting the FDA's assertion that any such letters qualified as "labeling." *Id*. ("... 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.'"). Accordingly, the Court reversed the judgments of the Fifth and Eighth Circuits and held that federal law preempted the plaintiffs' state tort lawsuits. *Id*. at 2581.

The facts of Harris' claims are similar to those at issue in *Mensing*. Harris' state law claims are based on a theory of: "Defendants' total failure to provide physicians with any warning or instructions for proper use of their drug."[4] (Rec. Docs. No. 27 at 3 & 40 at 1). Harris asserts that the means Defendants could have employed to minimize the identified risks associated with the drug include "Dear Doctor" letters, training programs for healthcare practitioners, and specialized packaging, in addition to other similar steps to warn physicians and patients about the drug. (Rec. Docs. No. 27 at 17 and 40 at 16-17). Harris claims that the

[4]The Court rejects Harris' argument that she asserts theories of liability distinct from state failure-to-warn claims. Harris' factual allegations are based entirely on failure-to-warn claims. (*See* Complaint, Rec. Doc. No. 1). Harris' description of a failure to "communicate" risks of the drug is in essence identical to a failure to warn, as is the "breach of express warranty claim" which essentially restates a breach of a state law duty to warn. (Rec. Doc. No. 40 at 1 & 10).

Defendants should have widely disseminated information about the risks of the drug independent of their brand-name counterparts. (Rec. Doc. No. 27 at 16). Harris' interpretation of the Supreme Court's holding is misguided. It is precisely this kind of independent action that *Mensing* prohibits.

Under the federal duty of "sameness" imposed by the FDA regulations on generic drug manufacturers, Defendants are prohibited from taking actions which imply any differences between their generic drug and the brand-name drug originally approved by the FDA. *Mensing*, 131 S. Ct. at 2581. Therefore, the proposed avenues which Harris cites in her briefs to this Court, including but not limited to "Dear Doctor" letters and informational sessions for physicians and healthcare professionals, are unavailable to generic drug manufacturers such as the Defendants. All of the means suggested by Harris in one form or another address an inadequacy in warnings about the dangers of the drug. The Supreme Court has adopted the FDA's position that such actions are "labeling" in the sense that they must be consistent with the brand-name warnings and labels. Because it would be impossible for Defendants to have adopted the efforts Harris suggests to comply with state law, and still adhere to the federal duty of "sameness," all of Harris' state law claims against Defendants are preempted.

Under the U.S. Supreme Court's ruling in *Mensing*, Harris' claims under state law are preempted by federal drug regulations.

Accordingly, Harris' state law claims are dismissed as preempted by federal law and the latter ruling in *Mensing*.

New Orleans, Louisiana, this 3rd day of December, 2012.

UNITED STATES DISTRICT JUDGE