IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

IN RE: REGLAN/METOCLOPRAMIDE LITIGATION	JANUARY TERM, 2010 NO. 1997 CONTROL NO. 11090904	

ORDER

AND NOW, this 18th day of November, 2011, upon consideration of Generic Defendants'[1] Master Preliminary Objections to Plaintiffs' Third Amended Master Long Form Complaint, Plaintiffs' Answer and Defendants' Reply thereto, and Joinder of Defendant Hospira, Inc.,[2] and after oral argument, it is hereby **ORDERED** that Defendants' Master Preliminary Objections are **OVERRULED** without prejudice to raise this issue in a motion for summary judgment.

It is further **ORDERED** that Defendant Hospira Inc.'s Joinder is **OVERRULED.**

BY THE COURT:

Sandra Mazer Moss, J.
Coordinating Judge
Complex Litigation Center

[1] For the sake of brevity, the names of all the Generic Defendants will not be listed in herein but can be found on page 6 of Defendants Master Preliminary Objections.
[2] Defendant Hospira has filed a special joinder to these preliminary objections raising issues distinct to Hospira.

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IN RE:	:	JANUARY TERM, 2010
REGLAN/METOCLOPRAMIDE	:	NO. 1997
LITIGATION	:	CONTROL NO. 11090904

OPINION

Sandra Mazer Moss, J. November 18th, 2011

Approximately two thousand Plaintiffs have initiated suit in Philadelphia against brand name and generic manufacturers of the prescription drug metoclopramide, commonly used to treat digestive tract problems and sold under the brand name Reglan. Plaintiffs allege they suffer from, among other things, Tardive Dsykinesia, an incurable neurological disorder causing involuntary, repetitive movements. Plaintiffs' have asserted claims for strict liability, negligence, negligence per se, fraud, misrepresentation and suppression, constructive fraud, breach of express and implied warranties, unfair and deceptive trade practices, unjust enrichment, civil conspiracy, loss of consortium, wrongful death and survival.

Presently before this Court are the Generic Defendants'[1] Master Preliminary Objections to Plaintiffs' Third Amended Master Long Form Complaint. Defendants' preliminary objections seek dismissal of all claims, based on federal preemption and the Supremacy Clause of the United States Constitution pursuant to the United States Supreme Court's recent decision in *Pliva v. Mensing*, 564 U.S. _, 131 S.Ct. 2567 (2011), *reh'g denied.* [2] We have carefully

[1] For the sake of brevity, the names of all the Generic Defendants will not be listed in this opinion but can be found on page 6 of Defendants Master Preliminary Objections at Control No. 11090904.
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considered counsel's arguments both written and oral and the preliminary objections are now ripe for disposition.

I. DISCUSSION

Pennsylvania law is well established regarding preliminary objections raising legal insufficiency. "We note initially that the standard for review for preliminary objections is a limited one." *Emplrs. Ins. of Wausau v. DOT*, 581 Pa. 381, 389 (Pa. 2005). "Preliminary objections to a complaint in the nature of a demurrer admit as true all well-pleaded material facts set forth in the complaint, as well as all inferences reasonably deducible therefrom, but not the pleader's conclusions of law." *Clevenstein v. Rizzuto*, 439 Pa. 397, 400 (Pa. 1970). "The question presented by the demurrer is whether, on the facts averred, the law says with certainty that no recovery is possible." *Emplrs. Ins. of Wausau v. DOT*, 581 Pa. 381, 389, n.5 (Pa. 2005) (citing *Hoffman v. Misericordia Hospital of Philadelphia*, 439 Pa. 501, 267 A.2d 867 (1970)). "The test on preliminary objections is whether it is clear and free from doubt from all the facts pleaded that the pleader will be unable to prove facts legally sufficient to establish his right to relief." *Bourke v. Kazaras*, 746 A.2d 642, 643 (Pa. Super. Ct. 2000). "Where a doubt exists as to whether a demurrer should be sustained, this should be resolved in favor of overruling it." *Clevenstein,* 439 at 401, *citing Birl v. Philadelphia Electric Co.*, 402 Pa. 297 (1960).

"The Supreme Court held in *Mensing* that federal drug regulations applicable to generic drug manufacturers directly conflicted with, and thus preempted, state law failure-to-warn claims for inadequate warning labels on generic drugs." *Hughes v. Mylan Inc.*, 2011 U.S. Dist. LEXIS 123544 (E.D. Pa. Oct. 25, 2011) (citing *Mensing*, 564 U.S. at 1). *Mensing* noted "brand-name and generic drug manufacturers have different drug labeling duties" under the Federal Food,

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Those issues will be addressed later in this opinion. Preliminary objections filed on behalf of Defendants Wyeth and Morton Grove, and preliminary objections filed in *Hassett v. Dafoe,* August Term, 2008, No. 1551, will be addressed in separate orders.

Drug and Cosmetic Act (FDCA), 21 U.S.C. S 301, *et seq. Mensing,* 564 U.S. at 5. The Court explained under the FDCA a "manufacturer seeking federal approval must prove that it is safe and effective and that the proposed label is accurate and adequate." *Id.* However, the Hatch-Waxman Amendments allowed generic drugs to "gain FDA approval simply by showing equivalence to a reference listed drug (RLD) that has already been approved by the FDA." *Id.* The result of this regulatory dichotomy is a "brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label" while a "manufacturer seeking generic drug approval…is responsible for ensuring that its warning *label* is the *same* as the brand name's." *Id.* at 5-6 (emphasis added). *Mensing* thus held "it was impossible for the [generic m]anufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same" as the corresponding brand-name label. *Id.* at 12.

Defendants argue the Supreme Court's *Mensing* decision completely forecloses *any* state law cause of action against generic prescription drug manufacturers. They further argue Plaintiffs' allegations herein mirror those in the *Mensing* complaint whose claims our Supreme Court held were preempted. *See* Defendants Memorandum of Law in Support of Master Preliminary Objections (hereafter "Defendants' Memorandum"), p. 2. Defendants assert federal law eclipses state law failure to warn claims because generic drug manufacturers cannot comply with both "federal laws governing generic medication and state tort law." *Id.* Further, because Plaintiffs' fourteen claims ultimately sound in 'failure to warn' theories and seek to impose obligations different from federal rules and regulations established by the Federal Drug Administration (FDA), they are also preempted. *Id.* at 5.

Plaintiffs espouse a more narrow reading. They argue the *Mensing* Court foreclosed only claims requiring generic manufacturers to unilaterally change their drug's warning label to

include information different from and additional to the brand manufacturer's approved FDA label. *See* Plaintiffs' Memorandum of Law in Support of Their Response in Opposition to the Master Preliminary Objections (hereafter "Plaintiffs' Memorandum"), p. 4. Plaintiffs contend only in such situations would it be impossible for generic manufacturers to comply with both federal and state law and, further, *Mensing* does not insulate Defendants from state law duties not requiring label changes. *Id.* Plaintiffs' assert because their amended complaint asserts only theories not requiring label changes, *Mensing* does not affect their claims. *Id.*

Plaintiffs' argue Defendants should have more effectively communicated their FDA approved label to the medical community, engaged in risk minimization strategies and/or suspended drug sales. They additionally argue FDA approved label changes in 2003 (warning use in geriatric patients) and 2004 (warning therapy should not exceed 12 weeks) were never included on some generic manufacturers' labels and were never communicated to the larger medical community because the *Physicians Desk Reference* (PDR) contained the 2002 metoclopramide label only. Plaintiffs conclude since the *Mensing* Court failed to consider the aforementioned theories, their claims are not preempted.

Since the *Mensing* decision, federal and state courts nationwide have weighed in on both sides of this equation. Some federal courts, relying on *Mensing*, have entirely dismissed Plaintiffs claims. *See Demahy v. Actavis, Inc.*, 650 F.3d 1045 (5th Cir. La. 2011); *Smith v. Wyeth, Inc.*, 2011 U.S. App. LEXIS 19393 (6th Cir. Ky. 2011); *Guarino v. Wyeth LLC, et al*, 2011 U.S. Dist. LEXIS 128630 (M.D. Fla. Nov. 7, 2011); *Guilbeau v. Wyeth Inc.*, 2011 U.S. Dist. LEXIS 119251 (W.D. La. Oct. 14, 2011). Other courts, both federal and state, have refused to grant blanket dismissals and have carved out varying exceptions to the *Mensing* holding. *See Fisher v. Pelstring*, 2011 U.S. Dist. LEXIS 116162 (D.S.C. Sept. 30, 2011) (denying motion to dismiss

based on federal preemption because of defendant PLIVA's failure to include strengthened warnings in its 2003 and 2004 metoclopramide labels); *Brasley-Thrash v. Teva Pharms. USA, Inc.*, 2011 U.S. Dist. LEXIS 102858 (S.D. Ala. Sept. 12, 2011) (granting plaintiff's motion to amend complaint to add claims for failure to send 'Dear Doctor' letters advising of strengthened warnings in 2004 Reglan label); *Keck v. Endoscopy Center*, 2011 WL 3921690, slip op. (Nev. Dist. Aug. 19, 2011) (holding no preemption under *Mensing* for failure to send 'Dear Doctor' letters "consistent with and not contrary to the drug's approved label and which [do] not provide substantially new or additional warnings").

"Plaintiffs offer a number of reasons why *Mensing* does not foreclose their failure to warn claims," many of which have been recognized by other courts since that decision was delivered. *Hughes v. Mylan Inc.*, 2011 U.S. Dist. LEXIS 123544, p. 15 (E.D. Pa. Oct. 25, 2011). As previously discussed, "[t]he question presented by the demurrer is whether, on the facts averred, the law says with certainty that no recovery is possible." *Emplrs. Ins. of Wausau v. DOT*, 581 Pa. 381, 389, n.5 (Pa. 2005). Thus, Defendants herein "face a heavy burden" because "they must show that [the] law would not recognize *any* of the claims asserted against them." *Id.* (emphasis added). We find Defendants have failed to sustain this "heavy burden" to show with certainty there is no legal recovery. Therefore, Defendants' Preliminary Objections are OVERRULED.

Moreover, many of the actions in this Reglan/Metoclopramide Litigation have been filed by plaintiffs from across the country. Regarding plaintiffs' individual *Mensing* "carve outs", We have decided under our choice of law rules, there is a rebuttable presumption the domicile state's law applies. *See* Hormone Replacement Therapy Litigation, 0311-0001, Order dated 8/4/09. We conclude the same rebuttable presumption applies here. Therefore, any global decision on

Plaintiffs' allegations of *Mensing* "carve outs" is premature and must await a state by state analysis.

Defendant Hospira filed a separate joinder to these Preliminary Objections.[3] Hospira argues in addition to the aforementioned reasons raised by Generic Defendants, there exists an additional reason unique to them. They allege their version of metoclopramide is *injected* rather than ingested orally. Hospira asserts Plaintiffs' argument against preemption for failure to mirror the brand manufacturer's 2004 tablet label, which warned metoclopramide therapy should not exceed twelve weeks, does not apply to its product. Hospira argues unlike oral metoclopramide which is used to treat chronic conditions like gastroesophageal reflux disease (GERD), its product has limited uses, and is almost always administered for short term hospital stays to treat acute conditions. *See* Hospira Joinder, pp. 2-3.

Plaintiffs respond despite Hospira's argument it has failed to prove said product was never used for continuous therapy exceeding twelve weeks and thus dismissal is inappropriate.

For the many reasons enunciated above and because we agree issues of material fact remain, Hospira's Joinder to Preliminary Objections is OVERRULED.

II. CONCLUSION

For the foregoing reasons, Defendants Master Preliminary Objections and Hospira Inc.'s Joinder are OVERRULED without prejudice to raise this issue in a motion for summary judgment.

BY THE COURT:

Sandra Mazer Moss, J.

[3] Hospira's Joinder filed September 9, 2011 under control no. 11090904.