IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

WALTER & GINGER LASHLEY	§	**PLAINTIFFS**
	§	
v.	§	**Civil Action No. 1:09cv749HSO-JMR**
	§	
PFIZER, INC., WYETH, INC.,	§	
SCHWARZ PHARMA, INC.,	§	**DEFENDANTS**
WATSON PHARMA, &	§	
WATSON LABORATORIES, INC.	§	

MEMORANDUM OPINION AND ORDER GRANTING MOTION FOR SUMMARY JUDGMENT FILED BY PFIZER, INC., WYETH, LLC, AND SCHWARZ PHARMA, INC., AND GRANTING MOTION TO DISMISS FILED BY WATSON PHARMA, INC., AND WATSON LABORATORIES

BEFORE THE COURT is a Motion for Summary Judgment [75] filed September 19, 2011, on behalf of Pfizer, Inc., Wyeth, LLC, and Schwarz Pharma, Inc. ["Pfizer Defendants"]. Plaintiffs Walter and Ginger Lashley filed a Response to the Pfizer Defendants' Motion for Summary Judgment [97] on November 23, 2011. The Pfizer Defendants filed a Rebuttal in support of the Motion for Summary Judgment [99] on December 5, 2011. In addition, the parties have filed a number of Notices of Supplemental Authority [106, 113, 78, 80, 81, 102, 108, 112], in support of their respective positions.

Also pending before the Court is a Motion to Dismiss [73] filed September 16, 2011, and a Motion for Summary Judgment [71] filed September 19, 2011, on behalf of Watson Laboratories, Inc., and Watson Pharma, Inc. ["Watson Defendants"]. On November 22, 2011, Plaintiffs filed Responses to the Motion to Dismiss [93] and Motion for Summary Judgment [92]. On December 5, 2011, Watson Defendants filed a

Rebuttal in support of the Motion to Dismiss [101] and a Rebuttal in support of the Motion for Summary Judgment [95].

After due consideration of the record, the submissions on file, and the relevant legal authorities, the Court finds that because Plaintiffs are unable to maintain their claims as a matter of law against the Pfizer Defendants, they are entitled to summary judgment. The Court further finds that because Plaintiffs' claims against the Watson Defendants are preempted, the Watson Defendants' Motion to Dismiss should be granted.

I. FACTS AND PROCEDURAL HISTORY

This products liability case arises out of injuries allegedly sustained by Plaintiff Walter Lashley after being prescribed and taking the drug Reglan®, metoclopramide, and/or metoclopramide HCI. Compl. [1], ¶ 10; Am. Compl. [6], ¶ 10; Sec. Am. Compl. [36], ¶ 11. At various times during the period between 1989-2002, Defendants Pfizer Inc., Wyeth LLC, and Schwarz Pharma, Inc., manufactured and distributed the name-brand Reglan®, a drug approved by the United States Food and Drug Administration ["FDA"], and prescribed for certain gastroesophageal conditions.[1] Aff. of Warren L. Sunshine, [75-1], at p. 1, att. as Ex. "1" to Defs.' Mot. for Summ. J. Defendants Watson Pharma, Inc., and Watson Laboratories, Inc., along with other companies, manufactured, sold, and distributed metoclopramide,

[1] Schwarz Pharma acquired the rights to manufacture and distribute Reglan® on December 27, 2001, and produced, sold, and distributed it until 2008. Aff. of Jeff Siefert, [75-2], at p. 2, att. as Ex. "2" to Defs.' Mot. for Summ. J.

the generic equivalent of Reglan®, beginning in the mid 1980's. Aff. of Warren L. Sunshine, [75-1], at p. 2, att. as Ex. "1" to Defs.' Mot. for Summ. J.

In 2002, a physician prescribed Mr. Lashley a 20 milligram dosage of Reglan® for heartburn. *Id*. at ¶ 16. Mr. Lashley "ingested the Reglan/metoclopramide as prescribed."[2] *Id*. at ¶ 21. Sometime in late 2006, Mr. Lashley began exhibiting abnormal movements, at ¶ 25, which later developed into tardive dyskinesia. Plaintiffs allege that this condition resulted from Mr. Lashley's long-term ingestion of Reglan/metoclopramide. *Id*. ¶¶ 25-26. Beginning in 1985, warning labels on metoclopramide were modified to include the potential for development of tardive dyskinesia. In 2004, the warning label on metoclopramide was further strengthened.[3]

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[2]The record contains a "Notice of Product Identification" [23] which identifies Watson Pharma, Inc., NDC#00591, as the manufacturer of the generic brand metoclopramide Mr. Lashley ingested. This is the only indication in the record tending to show whether Mr. Lashley ingested the brand-name or generic version of the drug.

[3]The United States Supreme Court described the metoclopramide labeling changes as follows:

> In 2004, the brand-name Reglan manufacturer requested, and the FDA approved, a label change to add that "[t]herapy should not exceed 12 weeks in duration." . . . And in 2009, the FDA ordered a black box warning—its strongest—which states: "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." *See* Physician's Desk Reference 2902 (65th ed. 2011).

PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2572-73 (2011)(internal citations omitted).

On October 30, 2009, Plaintiffs filed their Complaint [1] naming the following Defendants: Pfizer Inc., Wyeth, LLC, Schwarz Pharma, Inc., and Watson Pharmaceuticals, Inc. Plaintiffs filed an Amended Complaint [6] on January 26, 2010, naming Watson Pharma, Inc., as a Defendant, and deleting Watson Laboratories, Inc., as a Defendant. On May 24, 2010, Plaintiffs filed a Second Amended Complaint [36], naming all of the previously identified Defendants, and once again including Watson Laboratories, Inc., as a Defendant. In their Second Amended Complaint, Plaintiffs assert claims for negligence, strict liability, breach of warranty of merchantability and fitness for particular purpose, misrepresentation, suppression of evidence, fraud, and gross negligence. Plaintiffs also seek punitive damages. *Id.* ¶¶ 94-121.

On March 22, 2011, the Court held a Status Conference in this case, during which the parties requested that the Court stay this matter pending the United States Supreme Court's decisions in two cases, *PLIVA, Inc. v. Mensing*, ___ U.S. ___, 131 S. Ct. 2567 (2011), and *Demahy v. Actavis, Inc.*, ___ U.S. ___, 131 S. Ct. 817 (2011). On April 19, 2011, this Court granted the parties' request, and stayed the case. On June 23, 2011, subsequent to the filing of Plaintiffs' Second Amended Complaint, the United States Supreme Court decided *PLIVA, Inc. v. Mensing*, ___ U.S. ___, 131 S. Ct. 2567 (2011).

At issue in *Mensing* was whether state tort law claims based on certain drug manufacturers' alleged failure to provide adequate warning labels for generic

metoclopramide were preempted by federal law. *Id*. at 2571. The Supreme Court held that federal drug regulations applicable to generic drug manufacturers directly conflicted with, and thus preempted, a plaintiff's state law claims for failure to provide an adequate warning label. *Id*. The Court determined that because the FDA requires generic drug manufacturers to use the same warning labels that it requires brand-name manufacturers to affix to their products, and because FDA regulations prohibit generic manufacturers from unilaterally changing or strengthening their product labeling without prior FDA approval, FDA regulations preempt state law failure to warn claims against generic drug manufacturers. Claims brought under state tort law were preempted because "it was not lawful under federal law for the manufacturers to do what state law required of them." *Id.* at 2577. On August 19, 2011, the Court entered an Order lifting the Stay and reopening this case. Defendants then filed the present dispositive Motions.

II. DISCUSSION

A. Pfizer Defendants' Motion for Summary Judgment

As brand-name manufacturers, Pfizer Defendants move for summary judgment on Plaintiffs' failure to warn claims under MISS. CODE ANN. § 11-1-63(a)(i)(2), and breach of warranty claims pursuant under MISS. CODE ANN. § 11-1-63(a)(i)(4). They argue that because Mr. Lashley ingested generic metoclopramide, and Pfizer, Wyeth, and Schwarz Pharma did not manufacture or distribute this product, Plaintiffs cannot, as a matter of law, sustain these claims against them

under the Mississippi Products Liability Act, MISS. CODE ANN. § 11-1-63, *et seq*. ["MPLA"].

Because jurisdiction in this case is premised upon diversity of citizenship, state substantive law applies. *Erie R. Co. v. Tompkins*, 304 U.S. 64, 79-80 (1938); *Krieser v. Hobbs*, 166 F.3d 736, 739 (5th Cir. 1999).

> The core of what has become known as the '*Erie* Doctrine' is that the substantive law to be applied by a federal court in any case before it is state law, except when the matter before the court is governed by the United States Constitution, an Act of Congress, a treaty, international law, the domestic law of another country, or in special circumstances, by federal common law.

Hanley v. Forester, 903 F.2d 1030, 1032 (5th Cir. 1990) (citing *Erie R. Co. v. Tompkins*, 304 U.S. 64, 79-80 (1938)).

1. Applicable Legal Standard

Rule 56(a) of the Federal Rules of Civil Procedure states that the Court shall grant summary judgment on each claim or defense on which summary judgment is sought if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. FED. R. CIV. P. 56(a). The purpose of summary judgment is to isolate and dispose of factually unsupported claims or defenses. *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986); *Meyers v. M/V Eugenio C.*, 842 F.2d 815, 816 (5th Cir. 1988).

To rebut a properly supported motion for summary judgment, the opposing party must present significant probative evidence, since there is no issue for trial unless there is sufficient evidence favoring the nonmoving party for a jury to return

a verdict for that party. *Booth v. Wal-Mart Stores, Inc.*, 75 F. Supp. 2d 541, 543 (S.D. Miss. 1999). If the evidence is merely colorable, or is not significantly probative, summary judgment is appropriate. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). The nonmovant may not rely on mere denials of material facts, nor on unsworn allegations in the pleadings or arguments and assertions in briefs or legal memoranda. *Booth,* 75 F. Supp. 2d at 543.

The mere existence of a disputed factual issue does not foreclose summary judgment. The dispute must be genuine, and the facts must be material. *Id.* With regard to "materiality," only those disputes or facts that might affect the outcome of the lawsuit under the governing substantive law will preclude summary judgment. *Id.* (citing *Phillips Oil Company v. OKC Corp.,* 812 F.2d 265, 272 (5th Cir. 1987)). Where "the summary judgment evidence establishes that one of the essential elements of the plaintiff's cause of action does not exist as a matter of law, ... all other contested issues of fact are rendered immaterial." *Id.* (quoting *Topalian v. Ehrman*, 954 F.2d 1125, 1138 (5th Cir. 1987)).

2. Plaintiffs' Failure to Warn, Negligence, Strict Liability, and Misrepresentation Claims

Plaintiffs generally contend that all Defendants, as producers, merchants, and marketers of the drug metoclopramide, "failed to warn that Reglan/metoclopramide as designed and marketed was capable of causing serious personal injuries such as those suffered by Plaintiffs during foreseeable use. Such a failure to warn rendered the Reglan/metoclopramide unreasonably dangerously

defective as designed and marketed." Sec. Am. Compl. [36], ¶¶ 103-108, at pp. 19-20.

Numerous district courts have recognized that the MPLA subsumes common law negligence and misrepresentation claims based on a defective product. *Murray v. Gen. Motors, LLC*, 2011 WL 3684517, *3 (S.D. Miss. Aug. 22, 2011); *McSwain v. Sunrise Med., Inc.*, 689 F. Supp. 2d 835, 844-846 (S.D. Miss. 2010); *Jowers v. BOC Group, Inc.*, 2009 WL 995613, at *3-4 (S.D. Miss. Apr. 14, 2009), *vacated in part on other grounds*, *Jowers v. Lincoln Elec. Co.*, 617 F.3d 346 (5th Cir. 2010); *Walker v. George Koch Sons, Inc.*, 610 F. Supp. 2d 551, 562-63 (S.D. Miss. 2009).

The MPLA, states in relevant part, that:

> (a) The manufacturer or seller of the product shall not be liable if the claimant does not prove by the preponderance of the evidence that at the time the product left the control of the manufacturer or seller:
>
> (i) 1. The product was defective because it deviated in a material way from the manufacturer's specifications or from otherwise identical units manufactured to the same manufacturing specifications, or
>
> 2. The product was defective because it failed to contain adequate warnings or instructions, or
>
> 3. The product was designed in a defective manner, or
>
> 4. The product breached an express warranty or failed to conform to other express factual representations upon which the claimant justifiably relied in electing to use the product; and
>
> (ii) The defective condition rendered the product unreasonably dangerous to the user or consumer; and

> (iii) The defective and unreasonably dangerous condition of the product proximately caused the damages for which recovery is sought.

MISS. CODE ANN. § 11-1-63(a).

Precedent directs this Court to consider together, in a single inquiry, the adequacy of the warnings provided by the Pfizer Defendants as to Plaintiffs' failure to warn, strict liability, misrepresentation, and negligence claims. *Swayze v. McNeil Laboratories*, 807 F. 2d 464 (5th Cir. 1987). In *Swayze*, the Fifth Circuit, in examining the adequacy of the warnings on the drug Fentanyl, considered Plaintiff's alternative theories of strict liability and negligence, and held that:

> [u]nder principles of strict liability, the defendant's drug is "unreasonably dangerous" if not accompanied by adequate warnings; under negligence principles, the reasonableness of the defendant's conduct in this case also depends on the adequacy of its warning. If the warnings provided health care practitioners, through the PDR, package inserts and detail men, [sic] were adequate, then the drug was not unreasonably dangerous, and the defendant's conduct was neither unreasonable nor negligent.

Id. at 467 (quoting § 402A of the Restatement (Second) of Torts (1965)).

Federal statutes and regulations govern labeling requirements for prescription medications. The FDA regulates and approves both brand-name prescription medication labels such as Reglan®, *see* 21 C.F.R. § 314.50, and generic brand medication labels such as metoclopramide, *see* 21 C.F.R. § 314.94(a)(8). A manufacturer seeking federal approval for a new drug must first prove that it is safe and effective, and that the proposed label is both accurate and adequate.

Mensing, 131 S. Ct. at 2574 (citing Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq*.).

Since the Supreme Court decided *Mensing*, the Sixth Circuit Court of Appeals has rendered a decision on a factually similar case involving Reglan® and its generic counterpart, metoclopramide. In *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011), *cert. denied,* 132 S. Ct. 2103 (U.S. 2012), the plaintiffs, who ingested metoclopramide and later developed tardive dyskinesia, sued both the brand-name and generic manufacturers. The Sixth Circuit affirmed the dismissal of the plaintiffs' claims against the generic manufacturer on preemption grounds. The Court also affirmed the dismissal of the brand-name manufacturers, inasmuch as the record reflected that the plaintiffs had not ingested the brand-name drug, Reglan®. The Court concluded that:

> as have the majority of courts to address this question, we reject the argument that a brand-name drug manufacturer owes a duty of care to individuals who have never taken the drug actually manufactured by that company. Moreover, and most significantly, the plaintiffs have not convinced us that the state courts of Kentucky would adopt their vicarious-liability argument under the Kentucky Products Liability Act.

Smith, 657 F.3d at 424.

Since *Mensing*, district courts in Florida, Louisiana, and Texas, as well as in this District, have also considered factually similar cases against generic and brand-name drug manufacturers. *See Johnson v. Teva Pharmaceuticals USA, Inc.*, 2012 WL 1866839 (W.D. La. May 21, 2012); *Eckhardt v. Qualitest Pharmaceuticals,*

Inc., 2012 WL 1511817 (S.D. Tex. Apr. 30, 2012); *Metz v. Wyeth, LLC*, 2012 WL 1058870 (M.D. Fla. Mar. 28, 2012); *Cooper v. Wyeth, Inc.*, 2012 WL 733846 (M.D. La. Mar. 6, 2012); *Deese v. Immunex Corp.,* 2012 WL 463722 (S.D. Miss. Feb. 13, 2012); *Whitener v. PLIVA, Inc.*, 2011 WL 6056546 *2 (E.D. La. Dec. 6, 2011); *Del Valle v. PLIVA, Inc.*, 2011 WL 7168620 (S.D. Tex. Dec. 21, 2011); *Metz v. Wyeth, LLC*, 830 F. Supp. 2d 1291 (M.D. Fla. Nov. 18, 2011).

Applying Florida law, *Guarino v. Wyeth*, *LLC*, 2012 WL 1138631 (M.D. Fla. Apr. 3, 2012), determined that the brand-name drug defendants were entitled to judgment as a matter of law based upon the undisputed fact that the plaintiff had not used the brand-name form, or any other metoclopramide product, manufactured by Wyeth and/or Schwarz Pharma. *Guarino*, 2012 WL 1138631 *1; *see also Metz v. Wyeth LLC,* 830 F. Supp. 2d 1291 (M.D. Fla. 2011)(Plaintiff did not ingest brand-name metoclopramide; therefore generic manufacturers not held liable for plaintiff's injuries); *see also Phelps v. Wyeth, Inc.*, 2012 WL 1499343 (D. Or. Apr. 24, 2012); *Gross v. Pfizer, Inc.,* 2011 WL 5865267 *4 (S.D. Md. Nov. 22, 2011)).

Here, the record evidence in this case is insufficient to support any claims by Plaintiffs that Mr. Lashley ingested brand-name Reglan®. In this respect, Plaintiffs have not carried their summary judgment burden, and based on the foregoing persuasive authorities, the Court is of the view that Defendants are entitled to summary judgment on Plaintiffs' claims for failure to warn, negligence, strict liability, and misrepresentation.

In addition, Mississippi adheres to the "learned intermediary" doctrine, which holds in part "'that where prescription drugs are concerned, a manufacturer's duty to warn only extends to physicians and not to laymen.'" *Windham v. Wyeth Laboratories, Inc*., 786 F. Supp. 607, 611 (S.D. Miss. 1992) (quoting *Wyeth Laboratories, Inc. v. Fortenberry,* 530 So.2d 688, 691 (Miss. 1988) (quoting *Swayze v. McNeil Laboratories, Inc.,* 807 F.2d 464, 470 (5th Cir.1987)). If there is no physician in the role of "learned intermediary," then the drug manufacturer has a duty to adequately warn the consumer. *Swayze,* 807 F.2d at 470.

> When the product is a prescription drug, Mississippi follows the "learned intermediary doctrine" which holds that "the manufacturer's failure to warn the patient of the product's risks does not render the product defective or unreasonably dangerous so long as the manufacturer adequately warns the learned intermediary." *Janssen Pharm., Inc. v. Bailey,* 878 So.2d 31, 58 (Miss.2004) (citing *Thomas,* 949 F.2d at 811)). Under this doctrine, "[a] drug manufacturer has a duty to adequately warn the prescribing physician of any known adverse effects which might result from use of its prescription drugs," but the "duty to warn only extends to physicians and not to laymen." *See Wyeth,* 530 So.2d at 691 (citation and quotation marks omitted)).

Deese v. Immunex Corp., 2012 WL 463722 *4 (S.D. Miss. Feb. 13, 2012).

There is no dispute that the drug Mr. Lashley ingested was prescribed by his physician. While Plaintiffs contest the accuracy and the sufficiency of the warnings on Reglan® and metoclopramide, there is no dispute as to the actual presence of the warnings. Pfizer Defendants are therefore also entitled to summary judgment on the learned intermediary doctrine.

3. Plaintiffs' Breach of Implied Warranty Claims

Nor is the Court persuaded that Plaintiffs have sufficiently pled breach of warranty as to merchantability or fitness for a particular purpose pursuant to Federal Rule of Civil Procedure 8(a)[4]. Even if these claims were properly pled, the Court finds that Plaintiffs have failed to state a breach of warranty claim as a matter of law.

a. Breach of Implied Warranty of Merchantability

Plaintiffs allege that:

> Defendants have impliedly warranted to the public generally and specifically to Plaintiffs that Reglan/metoclopramide was merchantable and fit for safe use for gastrointestinal relief, the purpose for which Defendants marketed Reglan/metoclopramide. Reglan/metoclopramide was not merchantable as warranted because, as designed, Reglan/metoclopramide was capable of causing serious personal injuries such as those suffered by Plaintiffs during foreseeable use. Therefore, Defendants have breached the implied warranty of merchantability with respect to Reglan/metoclopramide.

Sec. Am. Compl. [36] ¶ 104, at pp. 20-21.

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[4]FED. R. CIV. P. 8(a) states:

> (a) Claim for Relief. A pleading that states a claim for relief must contain:
>
> > (1) a short and plain statement of the grounds for the court's jurisdiction, unless the court already has jurisdiction and the claim needs no new jurisdictional support;
> >
> > (2) a short and plain statement of the claim showing that the pleader is entitled to relief; and
> >
> > (3) a demand for the relief sought, which may include relief in the alternative or different types of relief.

FED. R. CIV. P. 8(a).

There are five elements which Plaintiffs must prove to succeed on their breach of warranty claim pursuant to section § 11-1-63(h): (1) that a "merchant" sold "goods," and that he was a merchant with respect to "goods of the kind" involved in the transaction; (2) that the goods were not merchantable at the time of the sale; (3) that Plaintiffs suffered injuries and damages as a result; (4) that the resulting injury was proximately caused in fact by the defective nature of the goods; and (5) Plaintiffs must give notice to the seller of the injury. *Watson Quality Ford, Inc. v. Casanova*, 999 So. 2d 830, 834 (Miss. 2008) (citing MISS. CODE ANN. § 11-1-63(h)).

Based upon the record before the Court, Plaintiffs have failed to carry their summary judgment burden on this claim. Plaintiffs have not proffered any evidence which tends to establish that, at the time the Pfizer Defendants placed Reglan® on the market, it was not merchantable. Plaintiffs likewise have failed to proffer sufficient competent evidence tending to show that they suffered damage as a result of Reglan®. Indeed, the record establishes that Mr. Lashley never ingested Reglan®. In view of the record evidence before this Court, summary judgment on this claim is appropriate. *See, e.g.*, *McSwain v. Sunrise Medical, Inc.*, 689 F. Supp. 2d 835, 848 (S.D. Miss. 2010) (granting summary judgment on plaintiff's breach of warranty claim under the MPLA where plaintiff had not presented any evidence that defendant made an express representation or that he relied on any information from the defendant).

b. Breach of Implied Warranty of Fitness for Particular Purpose

Plaintiffs also contend that they relied on the skill and judgment of Pfizer Defendants to select suitable medication for gastrointestinal relief.

> The Reglan/metoclopramide used by Mr. Lashley was not fit for its particular purpose because, as designed, Reglan/metoclopramide was capable of causing serious personal injuries such as those suffered by Plaintiffs during foreseeable use. Therefore, Defendants have breached the implied warranty of fitness for a particular purpose with respect to Reglan/metoclopramide.

Sec. Am. Compl. [36] ¶ 107, at p. 21.

Pfizer Defendants argue that they are "neither the manufacturers nor sellers of the drug Plaintiff ingested and thus cannot be held liable for his alleged injuries. Allowing Plaintiff to proceed with his claims would contravene the text of the MPLA and settled breach-of-warranty case law." Mem. in Support of Mot. To Dismiss [76] at p. 11.

In *Metz v. Wyeth LLC*, 830 F. Supp. 2d 1291 (M.D. Fla. 2011), the plaintiff, who ingested metoclopramide, as opposed to Reglan®, asserted breach of warranty claims against both the generic and brand-name manufacturers. The Court granted judgment as a matter of law in favor of the brand-name defendants, reasoning that:

> [t]he vast majority of courts, in Florida and elsewhere, that have addressed the issue now before the Court have consistently held that consumers may not bring claims for negligence, fraud, strict liability, misrepresentation, or breach of warranty against a brand-name pharmaceutical manufacturer when the consumers only ingested generic versions of the drug manufactured by third parties. *See, e.g., Bell v. Pfizer Inc.,* 2011 WL 904161 (E.D. Ark. March 16, 2011); *Howe v. Wyeth, Inc.,* 2010 WL 1708857 (M.D. Fla. April 26, 2010); *Levine v. Wyeth, Inc.,* 684 F. Supp. 2d 1338 (M.D. Fla.2010); *Dietrich v. Wyeth, Inc.,* No. 2009

> WL 4924722 (Fla. Cir. Ct. Dec. 21, 2009); *Sharp v. Leichus,* 2006 WL 515532 (Fla. Cir. Ct. Feb. 17, 2006), ...

Id. at 1293.

To date, no Mississippi cases have been located which are directly on point. However, in light of the foregoing authorities, and based upon its reading of the MPLA, this Court is of the opinion that under general principles of Mississippi products liability law, the Pfizer Defendants are entitled to judgment as a matter of law on this breach of warranty claim.

Finally, to the extent any of Plaintiffs' breach of warranty claims could be construed to relate to Pfizer Defendants' providing additional warnings relating to the risks associated with long-term metoclopramide use, or the failure to stop manufacturing and marketing the generic version of metoclopramide, the Court finds that such claims are now preempted by federal law. *Mensing*, 131 S. Ct. at 2578-79; *see also Metz v. Wyeth LLC*, 2012 WL 1058870 *6 (M.D. Fla. Mar. 28, 2012).

4. Plaintiffs' Fraud Claims

Count "E" of Plaintiffs' Second Amended Complaint advances claims for misrepresentation, suppression of evidence, and fraud. Upon review, it is evident that these claims are, in essence, based upon Defendants' handling of the labeling change that occurred in 2004. Sec. Am. Compl. [36], at pp. 22-24. The Court finds that any claim based upon or relating to Defendants' failure to provide information regarding Reglan®, inadequate post-marketing testing, failure to report adverse

events, and failure to review safety issues relating to metoclopramide, cannot withstand Pfizer Defendants' Motion for Summary Judgment based on the present record. *See Mensing*, 131 S. Ct. at 2578-79; *see also Metz*, 2012 WL 1058870 *4. In summary, Pfizer Defendants are entitled to summary judgment on all of Plaintiffs' claims.

B. Watson Defendants' Motion to Dismiss

1. Applicable Legal Standard

The Court's analysis of a motion to dismiss filed under FED. R. CIV. P. 12(b)(6), is "generally confined to a review of the complaint and its proper attachments." *Lane v. Halliburton*, 529 F.3d 548, 557 (5th Cir. 2008).

> 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." A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. 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. Where a complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility of 'entitlement to relief.'"

Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (U.S. 2009) (quoting *Twombly*, 550 U.S. at 556-57, 570).

While Watson Defendants' Motion to Dismiss and accompanying Memorandum of Authorities invoke the standard applicable on a motion to dismiss under FED. R. CIV. P. 12(b)(6), their Rebuttal Memorandum references a motion for judgment on the pleadings pursuant to FED. R. CIV. P. 12(c). A motion for judgment on the pleadings is analyzed using the same standard as a motion pursuant to Rule

12(b)(6). *Jebaco, Inc. v. Harrah's Operating Co.,* 587 F. 3d 314, 318 (5th Cir. 2009) (citing *Doe v. MySpace, Inc.,* 528 F.3d 413, 418 (5th Cir. 2008)). "To avoid dismissal, a plaintiff must plead sufficient facts to 'state a claim to relief that is plausible on its face.'" *Gentilello v. Rege,* 627 F.3d 540, 544 (5th Cir. 2010) (quoting *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Gentilello*, 627 F.3d at 545 (quoting *Ashcroft v. Iqbal,* 129 S. Ct. 1937, 1949 (2009)). In conducting its analysis, the Court is of course guided by the Supreme Court's recent decision in *PLIVA, Inc. v. Mensing*, ___ U.S. ___, 131 S. Ct. 2567 (2011).

2. Preemption of Plaintiffs' Claims

Plaintiffs advance claims against the Watson Defendants for failure to warn, negligence, strict liability, breach of warranty as to merchantability, breach of warranty as to fitness for a particular purpose, misrepresentation, and fraud. Watson Defendants seek dismissal on the grounds that *Mensing* held that claims such as Plaintiffs' are now preempted by federal law. Mot. to Dismiss [73] at p. 1. In essence, Watson Defendants argue the defense of impossibility preemption.

> In *Mensing,* the Supreme Court held that Food and Drug Administration ("FDA") regulations that prevent generic manufacturers from changing warning labels absent FDA approval or changes by brand name manufacturers resulted in an impossibility, or conflict, preemption of state law failure to warn claims against generic manufacturers because the manufacturers are unable to comply with both their federal regulatory duty and state law duty to warn.

Morris v. Wyeth, Inc., 2012 WL 601455 (W.D. La. Feb. 23, 2012).

Watson Defendants' burden of establishing the affirmative defense of impossibility preemption is a "demanding" one. *Mensing*, 131 S. Ct. at 2587; *see also Wyeth v. Levine,* 555 U.S. 555, 573 (2009). This Court, in applying Supreme Court precedent, will "find preemption where it is impossible for a private party to comply with both state and federal law, *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372-373 (2000)(quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143 (1963)), and where . . . '[the challenged state law] stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Crosby*, 530 U.S. at 373 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). In this case, Watson Defendants must "demonstrate an inevitable collision between the two schemes of regulation, despite the dissimilarity of the standards." *Florida Lime & Avocado Growers,* 373 U.S. at 143.

a. Failure to Warn Claims

Plaintiffs submit that because Watson Defendants: 1) failed to keep apprised of the developing problems associated with the long-term use of metoclopramide; 2) introduced a prescription drug containing misleading and false information into the stream of commerce; 3) failed to provide any warning to the medical community and the community at large; and 4) failed to warn individuals taking metoclopramide of the dangers associated with long-term use, the *Mensing* decision is inapplicable to their claims here. According to Plaintiffs:

> [w]hat was not considered in *Mensing* was the extent to which a generic manufacturer could be held liable for *selling* an unreasonably dangerous product, for accompanying its product with *false information* about potential risks associated with metoclopramide, and for *concealing* important safety information from the FDA, consumers, and the medical community [emphasis in original].

Pls.' Mem. Br. in Support of Resp. to Mot. to Dismiss [96] at p. 11.

However, the Supreme Court has reasoned that, even if generic manufacturers were required to propose stronger warning labels to the FDA, "the question for impossibility is whether the private party could independently do under federal law what state law requires of it." *Mensing*, 131 S. Ct. at 2579. In this case, generic manufacturers would violate federal law if they unilaterally changed warning labels or sent additional warnings to the medical community. In short, "[t]he only action the Manufacturers could independently take—asking for the FDA's help—is not a matter of state-law concern." *Id.* at 2581.

Based on the foregoing, this Court is of the opinion that *Mensing* dictates that Plaintiffs' failure to warn claims are preempted by federal law.

b. Breach of Warranty Claims

Plaintiffs next contend that Watson Defendants, as producers, merchants, and marketers of the drug metoclopramide, impliedly warranted to the public that it was safe to ingest for its intended and particular purpose. Sec. Am. Compl. [36], ¶¶ 103-108, at pp. 19-20. They further maintain that Defendants, in breaching this warranty, caused them to sustain serious and permanent injury. *Id.*

Watson Defendants argue that Plaintiffs' claims, "no matter how characterized, relate to allegedly inadequate warnings." Mem. in Support of Mot. To Dismiss [74] at p. 12. In support of this argument, Defendants rely on *Windham v. Wyeth Laboratories, Inc.*, 786 F. Supp. 607 (S.D. Miss. 1992). In *Windham*, the Court considered the plaintiffs' breach of warranty, strict liability, and negligent development, design, manufacture, and marketing claims, and concluded that all such claims "relate primarily to the issue of the adequacy of Wyeth's warning." *Windham*, 786 F. Supp. at 607. In sum, Watson Defendants submit that because Plaintiffs' failure to warn claims are preempted by *Mensing*, and because consideration of Plaintiffs' breach of warranty claims merge into consideration of a failure to warn to claim, Plaintiffs' breach of warranty claims are likewise preempted.

Plaintiffs' warranty claims mirror those asserted by the plaintiffs against the generic manufacturer and considered in *Metz v. Wyeth*, 2012 WL 1058870 (M.D. Fl. Mar. 28, 2012). *Metz* concluded that:

> [u]nder *Mensing,* Plaintiffs' implied warranty claim is also preempted by the FDCA to the extent it stems from Actavis' failure to provide additional warnings relating to the risks associated with long-term metoclopramide use or Actavis' failure to stop manufacturing and marketing the generic version of metodopramide.

Metz, 2012 WL 1058870, *5.

Having considered the record and the foregoing authorities, the Court is of the opinion that *Mensing* likewise preempts Plaintiffs' breach of warranty claims against the Watson Defendants in this case.

c. Defective Design and Dangerous Product Claims

Plaintiffs claim that:

> Defendants owed a duty to the general public and specifically to Plaintiffs to exercise reasonable care in the design, study, development, manufacture, promotion, sale, marketing and distribution of their prescription medications, including the Reglan/metoclopramide at issue in this lawsuit. Defendants failed to exercise reasonable care in the design of Reglan/metoclopramide because as designed, it was capable of causing serious personal injuries such as those suffered by Mr. Lashley during foreseeable use.

Sec. Am. Compl. [36], at p. 17.

Under Mississippi law:

> [a] product is not defective in design or formulation if the harm for which the claimant seeks to recover compensatory damages was caused by an inherent characteristic of the product which is a generic aspect of the product that cannot be eliminated without substantially compromising the product's usefulness or desirability and which is recognized by the ordinary person with the ordinary knowledge common to the community.

MISS. CODE ANN. § 11-1-63 (b).

In this case there is no dispute that warnings, including package inserts, were present. Because Watson Defendants could not have altered their package inserts without FDA approval, Plaintiffs' claim based upon defective design is preempted by federal law. *See Johnson v. Teva Pharmaceuticals USA, Inc.*, 2012 WL 1866839, *5 (W.D. La. May 21, 2012)(citing *Mensing,* 131 S. Ct. at 2578). The Court further finds that Plaintiffs' mere recital of the elements of these claims,

without additional supporting factual allegations, fails to satisfy the pleading requirements of Rule 8(a). *Morris v. Wyeth*, 3:09cv854, 2011 LEXIS 121052, at *8 (W.D. La. Oct. 19, 2011)(breach of warranty claims dismissed as preempted by *Mensing*). These claims should be dismissed.

III. CONCLUSION

With regard to the Motion for Summary Judgment filed by Pfizer Defendants, the Court finds insufficient evidence has been proffered to establish genuine issues of material fact as to Plaintiffs' claims. Pfizer Defendants are therefore entitled to judgment as a matter of law. The Court further finds that because Plaintiffs' claims against Watson Defendants are preempted, Watson Defendants are entitled to dismissal.

IT IS, THEREFORE, ORDERED AND ADJUDGED that, for the reasons stated herein, the Motion [75] for Summary Judgment filed pursuant to FED. R. CIV. P. 56, on behalf of Defendants Pfizer, Inc., Wyeth, LLC, and Schwarz Pharma, Inc., is **GRANTED.**

IT IS, FURTHER, ORDERED AND ADJUDGED that, for the reasons stated herein, the Motion [73] to Dismiss filed pursuant to FED. R. CIV. P. 12(b)(6) and 12(c), on behalf of Defendants Watson Pharma, Inc. and Watson Laboratories, Inc., is **GRANTED.**

IT IS, FURTHER, ORDERED AND ADJUDGED that, for the reasons stated herein, the Motion [71] for Summary Judgment filed pursuant to FED. R. CIV.

P. 56, on behalf of Defendants Watson Pharma, Inc., and Watson Laboratories, Inc., is **DENIED AS MOOT.**

SO ORDERED AND ADJUDGED, this the 27th day of June, 2012.

s/ Halil Suleyman Ozerden
HALIL SULEYMAN OZERDEN
UNITED STATES DISTRICT JUDGE