UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

MONROE DIVISION

PENNY MORRIS AND JOHN MORRIS	**CIVIL ACTION NO. 09-0854**
VERSUS	**JUDGE ROBERT G. JAMES**
WYETH, INC., ET AL.	**MAG. JUDGE KAREN L. HAYES**

RULING

Plaintiffs Penny and John Morris brought this action against Defendants Wyeth, Inc. ("Wyeth") and Schwarz Pharma, Inc. ("Schwarz"), among others, alleging that Mrs. Morris suffered injuries as a result of her ingestion of the prescription drug, metoclopramide. Plaintiffs have stipulated that Mrs. Morris did not ingest the brand-name version of metoclopramide manufactured and/or distributed by Wyeth or Schwarz. However, Plaintiffs contend that Wyeth and Schwarz are liable for the warnings and information distributed by the generic metoclopramide manufacturers whose product Mrs. Morris did ingest.

Pending before the Court is a Motion for Summary Judgment [Doc. No. 57] filed by Wyeth and Schwarz. For the following reasons, Wyeth and Schwarz's Motion for Summary Judgment is GRANTED, and Plaintiffs' claims against these Defendants are DISMISSED WITH PREJUDICE for failure to state a claim as a matter of law.

I. Facts and Procedural History

Metoclopramide is a prescription drug approved by the U.S. Food and Drug Administration ("FDA") to treat, among other conditions, gastroesophageal reflux disease and diabetic gastroparesis.

Metoclopramide is available in generic and brand formulation. The brand formulation is known by the trade name Reglan.

Since the mid-1980s, several companies have manufactured and distributed generic metoclopramide.

From approximately 1989 through late December 2001, Wyeth manufactured and distributed Reglan tablets. In late December 2001, Schwarz acquired the rights to Reglan tablets and manufactured and distributed the tablets until February 2008.

On May 22, 2009, Plaintiffs filed this lawsuit, alleging that Mrs. Morris ingested metoclopramide tables from early 2006 through July 2008, and, allegedly, as a result, developed tardive dyskinesia, a neurological condition causing involuntary movements and other symptoms. Plaintiffs asserted claims against Wyeth and Schwarz of negligent misrepresentation, fraudulent misrepresentation, breach of implied warranty, and violations of the Louisiana Unfair Trade Practices and Consumer Protection Law ("LUTPA").

On August 7, 2009, Plaintiffs filed a stipulation [Doc. No. 43], admitting that Mrs. Morris ingested only generic metoclopramide and that she did not ingest any metoclopramide, whether generic or brand name, manufactured by Wyeth or Schwarz. Plaintiffs further confirmed that their "causes of action against Wyeth [and] Schwarz . . . are not based upon the claim that Wyeth [or] Schwarz . . . manufactured or sold the Reglan metoclopramide ingested by Penny Morris." [Doc. No. 43].

On August 19, 2009, Wyeth and Schwarz filed the pending Motion for Summary Judgment [Doc. No. 57].

On September 3, 2009, Plaintiffs filed a Memorandum in Opposition to the Motion for

Summary Judgment [Doc. No. 71].

On September 18, 2009, with leave of Court, Wyeth and Schwarz filed a Reply memorandum in support of their Motion for Summary Judgment [Doc. No. 76].

In the meantime, however, Magistrate Judge Karen L. Hayes issued several orders regarding another Defendant, Alaven Pharmaceuticals, LLC ("Alaven"). Magistrate Judge Hayes was unable to tell from the documents submitted whether Alaven had any members who were domicilaries of Louisiana at the time the lawsuit was filed. The Court deferred ruling on Wyeth and Schwarz's Motion for Summary Judgment until it could be determined if the Court had subject matter jurisdiction.

On October 23, 2009, Plaintiffs filed a voluntary Motion to Dismiss their claims against Alaven, which was consented to by Alaven. Plaintiffs' claims against Alaven were dismissed without prejudice on October 27, 2009. [Doc. No. 96].[1] With the dismissal of Alaven, it is clear that the Court has subject matter jurisdiction in this matter.

On November 6, 2009, Plaintiffs filed a Third Amended Complaint [Doc. No. 103] and stated in paragraph 3.06 that the drugs ingested by Mrs. Morris were manufactured by Pliva USA, Inc. ("Pliva") and Teva Pharmaceuticals USA, Inc. ("Teva"). *See also* [Doc. No. 101 (notice of product identification, identifying Pliva and Teva as the manufacturers of the metoclopramide Mrs. Morris ingested)].

The Motion for Summary Judgment is now ripe for review.

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[1]Alaven had its own Motion to Dismiss [Doc. No. 20], which was pending at the time, but was mooted by the dismissal of Plaintiffs' claims.

II. Law and Analysis

A. Summary Judgments

Summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c)(2). The moving party bears the initial burden of informing the court of the basis for its motion by identifying portions of the record which highlight the absence of genuine issues of material fact. *Topalian v. Ehrmann*, 954 F.2d 1125, 1132 (5th Cir. 1992). A fact is "material" if proof of its existence or nonexistence would affect the outcome of the lawsuit under applicable law in the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute about a material fact is "genuine" if the evidence is such that a reasonable fact finder could render a verdict for the nonmoving party. *Id.*

If the moving party can meet the initial burden, the burden then shifts to the nonmoving party to establish the existence of a genuine issue of material fact for trial. *Norman v. Apache Corp.*, 19 F.3d 1017, 1023 (5th Cir. 1994). The nonmoving party must show more than "some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). In evaluating the evidence tendered by the parties, the court must accept the evidence of the nonmovant as credible and draw all justifiable inferences in its favor. *Anderson*, 477 U.S. at 255.

B. Louisiana Products Liability Act

The Louisiana Products Liability Act, La. Rev. Stat. 9:2800.51, *et seq.* ("LPLA"), "establishes the exclusive theories of liability for manufacturers for damage caused by their products. A claimant may not recover from a manufacturer for damage caused by a product on the basis of any

theory of liability that is not set forth in [the LPLA]." *See* LA. REV. STAT. 9:2800.52. Under the LPLA, a plaintiff asserting liability against any defendant must prove that the defendant was a manufacturer or seller of the product at issue as defined by statute.[2] *See Stanley v. Wyeth, Inc.*, 07-2080 (La. App. 1 Cir. 2008); 991 So.2d 31, 33 n.2 ("Under the LPLA the first element that must be proven by the claimant is that the defendant is the manufacturer of the product causing plaintiff's

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[2]Under the LPLA, a "Manufacturer" is defined as:

> (1) . . . a person or entity who is in the business of manufacturing a product for placement into trade or commerce. "Manufacturing a product" means producing, making, fabricating, constructing, designing, remanufacturing, reconditioning or refurbishing a product. "Manufacturer" also means:
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> (a) A person or entity who labels a product as his own or who otherwise holds himself out to be the manufacturer of the product.
>
> (b) A seller of a product who exercises control over or influences a characteristic of the design, construction or quality of the product that causes damage.
>
> (c) A manufacturer of a product who incorporates into the product a component or part manufactured by another manufacturer.
>
> (d) A seller of a product of an alien manufacturer if the seller is in the business of importing or distributing the product for resale and the seller is the alter ego of the alien manufacturer . . . .

LA. REV. STAT. 9:2800.53.

A "Seller" is "a person or entity who is not a manufacturer and who is in the business of conveying title to or possession of a product to another person or entity in exchange for anything of value." LA. REV. STAT. 9:2800.53. However, a seller who did not manufacture the product does not incur liability under the LPLA unless he vouched for the product as his own. *Slaid v. Evergreen Indem., Ltd.*, 32,363 (La. App. 2 Cir. 10/27/99); 745 So.2d 793, 797; *see also Jenkins v. Int'l Paper Co.*, 41,566 (La. App. 2 Cir. 11/15/06); 945 So.2d 144, 147 (citing same). The non-manufacturing seller is responsible for damages in tort "only if he knew or should have known that the product sold was defective, and failed to declare it." *Slaid*, 745 So.2d at 797 (internal quotation marks and citations omitted).

harm."). A plaintiff must also show that her damage was "proximately caused by a characteristic of the product that renders the product unreasonably dangerous when such damage arose from a reasonably anticipated use of the product by the claimant or another person or entity." LA. REV. STAT. 9:2800.54. A product may be proven to be unreasonably dangerous in construction, design, because an adequate warning was not provided, or because it failed to comply with an express warranty. *Id.*

It is undisputed that Plaintiffs' claims against Defendants Pliva and Teva arise under the LPLA on the basis that she ingested generic metoclopramide manufactured by these Defendants. It is also stipulated by Plaintiffs that Mrs. Morris did not ingest metoclopramide manufactured or distributed by Wyeth or Schwarz. Wyeth and Schwarz contend that, because the LPLA provides the exclusive remedy for Plaintiffs' claims and Plaintiffs admit that Wyeth and Schwarz are not manufacturers under the Act, they are entitled to summary judgment. Plaintiffs respond that Wyeth and Schwarz are not liable as manufacturers or sellers under the LPLA, but are liable under "other areas of law" for negligent misrepresentation, fraudulent misrepresentation, breach of implied warranty, and violations of the LUTPA. [Doc. No. 71, Statement of Contested Material Facts Nos. 1 & 8] for the following reasons:

- Defendants Wyeth and Schwarz authored an inaccurate and misleading label for [their] metoclopramide products, which [they] disseminated to physicians and the general public;

- Defendants Wyeth and Schwarz were aware that the misinformation present in their metoclopramide labeling would be relied upon by physicians when prescribing metoclopramide;

- Penny Morris' prescribing physician relied on the inaccurate representations contained in the metoclopramide labeling authored and disseminated by Wyeth and Schwarz; and

- Penny Morris developed tardive dyskineasia as a direct result of Wyeth['s] and Schwarz's failure to provide an adequate and accurate warning about the risk of developing tardive dyskinesia with prolonged use of metoclopramide.

[Doc. No. 71, Statement of Contested Facts, ¶¶ 11-14]. Plaintiffs allege that Wyeth and Schwarz were aware that generic manufacturers could rely on the information and warnings used in their new drug application to the FDA and that, additionally, as the manufacturers of the reference listed drug for metoclopramide, Wyeth and Schwarz "became responsible for the accuracy and sufficiency of the package insert for all metoclopramide drugs, without regard to who manufactured them." [Doc. No. 71, p. 3 (emphasis in original)].

In *Tarver v. Wyeth*, No. Civ. A. 3-04-2036, 2005 WL 4052382 (W.D. La. June 7, 2005), this Court considered and rejected Plaintiffs' arguments. In that case, the plaintiff, Patricia Tarver, had also ingested the generic form of metoclopramide and also developed tardive dyskinesia. She asserted that Schwarz, as the manufacturer of the brand name form of metoclopramide, "had a duty to warn all users of the drug, including the users of its generic competitors' products, of the drug's dangers." *Id.* at *1. In a report and recommendation adopted by the Court, Magistrate Judge James D. Kirk stated as follows:

> In Louisiana, the LPLA provides the exclusive theories of liability of manufacturers for damage caused by their products. La. R.S. 9:2800.52. A claimant may not recover on the basis of any theory not set forth in the LPLA. *Jefferson v. Lead Indus. Assoc., Inc.* 106 F.3d 1245, 1250-51 (5th Cir. 1997). To maintain an action under any of the theories, a plaintiff must establish that the defendant is the manufacturer of the product. *Stahl v. Novartis Pharmaceuticals Corp.*, 283 F.3d 254, 260-261 (5th Cir. 2002).
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> Here, plaintiff attempts to hold liable a company who is not the manufacturer of the product by asserting that it had a duty to warn of the product's dangers. Plaintiffs argue that generic manufacturers "have taken the position" in past litigation, that they are prohibited by the Food and Drug Administration (FDA) from changing the

> warnings created by the brand-name manufacturer. They argue that, if that is so, there would be no liability against the generic manufacturer for failure to warn and, if liability is not imposed on the brand-name manufacturer, an injured plaintiff would have no recourse.
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> First, if the generic manufacturers have taken that position, it is not clear to the court that they are correct, for 21 C.F.R. 314.94(a)(8) expressly provides for changing the labeling, with certain limitations. However, the court need not and does not decide that issue now, without the benefit of thorough briefs by the parties on that issue. However, even if plaintiff is without a remedy, that is an issue for the FDA or, in this case, the Louisiana legislature, not the courts. The law is clear that Louisiana imposes on a manufacturer no duty to warn of the dangers of another company's product. *Fricke v. Owens-Corning Fiberglass Corp.*, 618 So.2d 473 (La. App.1993); *Roberts v. Bioplastics*, 93-2967, 2000 WL 34487072 (E.D.La., 2000). The fact that the defendant here is a pharmaceutical manufacturer subject to government regulations, as plaintiff argues distinguishes this case, is irrelevant.
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> In a very well-written, thorough, and thought provoking brief, plaintiffs' counsel makes persuasive public policy arguments, and, citing the Restatement of Torts, argues that a negligent misrepresentation claim should be recognized in Louisiana based upon foreseeability and duty-risk analysis. Plaintiffs' counsel suggests that this is not a products claim subject to the limitations of the LPLA but is a negligent misrepresentation claim.
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> The claim in this case is that plaintiff was injured by a product which should not have injured her. It is, therefore, a products liability case, regardless of who are the defendants. It is, therefore, subject to the LPLA and its exclusive theories of liability. Plaintiffs' claims against Schwarz, who neither manufactured nor sold the drug plaintiff took, should be dismissed.

Id. at *2-3.

In the ensuing four and one-half years since *Tarver*, the Court finds no basis to alter its opinion. Plaintiffs argue that they are not attempting to hold Wyeth and Schwarz liable as manufacturers and thus their claims are outside the LPLA, but, no matter their theories, Plaintiffs *are* attempting to hold Wyeth and Schwarz liable for warnings associated with their product, a product that was not ingested by Mrs. Morris. The Louisiana Legislature has chosen to make the LPLA the exclusive source of liability to be used against manufacturers for damages caused by their

products and the warnings associated with those products. *See Jefferson*, 106 F.3d at 1251 (finding that "neither negligence, strict liability, nor breach of express warranty is any longer viable as an independent theory of recovery against a manufacturer" and also affirming the district court's dismissal of the plaintiff's claims of fraud by misrepresentation.); *Bladen v. C.B. Fleet Holding Co.*, 487 F. Supp.2d 759, 767 (W.D. La. 2007) ("The legislature, with full knowledge of the LUTPA, unquestionably enacted the LPLA statutory declaration of exclusive liability in the LPLA and made no exception for the LUTPA" despite expressly exempting a claim for redhibition, demonstrating "the legislature's intent to make the LPLA the sole vehicle for a suit against a 'manufacturer.'"). As Plaintiffs admit that Mrs. Morris did not ingest products manufactured and/or sold by Wyeth and Schwarz, they have no cause of action against these Defendants.

The Court has considered whether the Supreme Court's decision in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), has changed the landscape of the law. However, *Levine* held only that the FDA's approval of a branded drug's labeling does not preempt a plaintiff's state law failure-to-warn tort claim against the manufacturer of the branded drug. *Levine* certainly does not stand for the proposition that the brand-name manufacturer of a drug may be held liable under the law of Louisiana for the warning provided by a generic manufacturer.[3] The Court finds, even after review

[3]*Levine* did not address generic drugs and if or how its analysis might apply to claims against generic drug makers. The Court is aware that generic drug manufacturers continue to argue that failure to warn claims against them are preempted because they are bound by FDA regulation to conform their labels to that of the brand-name drug. *See Stancel v. Teva Pharmaceuticals USA*, 620 F. Supp.2d 899 (N.D. Ill. 2009) (explaining the abbreviated new drug application ("ANDA") procedure used by generic drug producers which requires the generic manufacturer to show that the initial labeling of the generic drug conform to that of the reference-listed drug); *see also Demahy v. Wyeth Inc.*, 586 F.Supp.2d 642 (E.D. La. 2008) (concluding that a plaintiff's state failure-to-warn claims against a generic drug manufacturer are not preempted by federal law, relying in part on 21 C.F.R. § 314.70, which the court interpreted as permitting an "approved applicant" to submit a supplement to its labeling "to reflect newly

of *Levine*, that the LPLA provides Plaintiffs' exclusive remedy, and they have no cause of action against Wyeth and Schwarz.

III. Conclusion

For the foregoing reasons, the Motion for Summary Judgment filed by Wyeth and Schwarz [Doc. No. 57] is GRANTED, and Plaintiffs' claims against these Defendants are DISMISSED WITH PREJUDICE.

MONROE, LOUISIANA, this 23 day of November, 2009.

ROBERT G. JAMES
UNITED STATES DISTRICT JUDGE

acquired information" to add or strengthen a warning). However, as in *Tarver*, that issue is not before the Court in this motion. *See* [Doc. No. 82, Pliva and Teva's discussion of the relevant law, but noting that the issue is not currently before the Court]. The Court recognizes the inequity that may result if a plaintiff who was harmed by a generic drug is preempted from obtaining damages from the generic manufacturer on the basis of its failure to warn, but also has no cause of action against the name-brand manufacturer who prepared the warning used by the generic manufacturer. Nevertheless, these are two separate legal issues, and the Court cannot render a finding of liability against Wyeth and Schwarz based on the possibility that the generic manufacturers, Teva and Pliva, may or may not have a preemption defense to Plaintiffs' failure-to-warn claim.