UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

TILLMAN, ET AL	*	**CIVIL ACTION**
	*	
VERSUS	*	**NO. 13-4731**
	*	
WOLDENBERG VILLAGE, INC., ET AL	*	**SECTION "L" (2)**

ORDER AND REASONS

Before the Court are seven pending motions – five motions to dismiss filed by Defendants Mylan Pharmaceuticals, Inc., Caraco Pharmaceutical Laboratories, Ltd., Wockhardt USA, LLC, Baxter Healthcare Corporation, and Taro Pharmaceuticals, U.S.A., Inc. (collectively the "generic manufacturers") (Rec. Docs. 52, 61, 65, 88, 92); one motion for judgment on the pleadings filed by Defendant Pfizer Inc. (Rec. Doc. 101); and one motion to dismiss for lack of jurisdiction filed by Defendant Jefferson Parish Hospital Service District No. 1, doing business as West Jefferson Medical Center, ("West Jefferson") (Rec. Doc. 72). The Court has reviewed the briefs and the applicable law and, having heard oral argument on four of the motions, now issues this Order and Reasons.

I. BACKGROUND

This Wrongful Death and Survival Action arises from the death of Rose Tillman, the mother of Plaintiffs Jahmal and Jirus Tillman. According to Plaintiffs, Rose Tillman died as a result of an adverse reaction to a prescription drug, phenytoin. Phenytoin sodium is an anticonvulsant drug used to treat seizures. (Rec. Doc. 61-1 at 6). In the 1950s the FDA approved a New Drug Application for phenytoin sodium under the brand name Dilantin. Defendant Pfizer Inc. designed and manufactured Dilantin. (Rec. Doc. 5 at 2). Since the 1950s,

phenytoin has been marketed in various forms, both branded and generic, by numerous companies. Plaintiffs claim that one in every ten people who take this drug have an adverse reaction to it. (Rec. Doc. 1-1 at 3).

According to Plaintiffs' complaint, on or about March 25, 2012, Rose Tillman was taken to the emergency department of West Jefferson Medical Center after suffering a stroke. There, she was treated by Doctors Frank Culicchia and Michael Puente. Plaintiffs allege that one of these doctors prescribed Dilantin or its generic version phenytoin. Plaintiffs claim that this prescription was contrary to the standard of care for this patient because the doctors should have known that it could cause dangerous side effects. Plaintiffs further allege that these two doctors failed to properly monitor Mrs. Tillman, even though she immediately showed signs of an allergic reaction to the drug in the form of a rash. Plaintiffs claim that Mrs. Tillman was then discharged from West Jefferson Medical Center and transported to Woldenberg Village in an ambulance, where she was treated by Doctor Lowentritt. Plaintiffs explain that Mrs. Tillman's rash worsened into hives, she suffered renal failure, lost mental functions and became essentially unresponsive. She was transferred back to West Jefferson Medical Center for more intensive treatment. Mrs. Tillman developed hives, blisters, bleeding and exfoliation over her entire body. On May 22, 2012, she died. Plaintiffs claim that throughout her stay at West Jefferson Medical Center and Woldenberg Village, the doctors and nurses improperly continued to administer Dilantin or phenytoin, despite Mrs. Tillman's reaction. Plaintiffs claim that this drug caused her death.

Plaintiffs filed a complaint on May 22, 2013, in which they named the hospitals, doctors, and various drug manufacturers as defendants. Plaintiffs are asking to be compensated for pain and suffering, mental anguish, loss of love and affection, loss of services, loss of support,

medical expenses and funeral expenses, all incurred as a result of their mother, Rose Tillman's death. Plaintiffs do not know which specific drug manufacturing company produced the drugs that were given to Mrs. Tillman and they do not know whether it was Dilantin or the generic form, phenytoin. Therefore, they name ten drug manufacturers who they believe manufacture phenytoin as well as Pfizer Inc., the manufacturer of Dilantin. On June 6, 2013, Defendant Pfizer, Inc. removed the case to this Court, pursuant to the Court's diversity jurisdiction. 28 U.S.C. §1332. The claims against the treating doctors and Woldenberg Village were dismissed and are proceeding instead in an administrative forum.[1] (Rec. Doc. 67).

II. PRESENT MOTIONS

The motions that are pending in this case can be grouped into three categories. Five of the motions are nearly identical and were all filed by the generic manufacturers. One motion was filed by Defendant Pfizer, Inc., the brand-name drug manufacturer. The last motion was filed by West Jefferson Medical Center. The Court will discuss each group in turn.

A. Motions to Dismiss Filed by Generic Manufacturers

Between September 24, 2013 and October 22, 2013, five of the generic drug manufacturers filed motions to dismiss. (Rec. Docs. 52, 61, 65, 88, 92). The generic manufacturers essentially make two arguments. First, they ask the Court to dismiss Plaintiffs' claims because Plaintiffs failed to allege that a specific defendant manufactured the prescription

[1]These Defendants filed motions to dismiss, arguing that pursuant to the Louisiana Medical Malpractice Act, Plaintiffs had to receive an opinion from a medical review panel before commencing the present action in court. Judge Feldman granted the motions as unopposed, but he noted that the motions appeared to have merit. Plaintiffs likely did not challenge Defendants' motions because they agreed that the present action was premature, as the administrative procedure had not yet completed. Plaintiffs confirmed this understanding during oral argument.

drug that Mrs. Tillman ingested. According to the generic manufacturers, in order to hold a defendant liable in a product-liability case, the plaintiff must identify the particular manufacturer of the product that caused the injury.

Second, the generic manufacturers claim that two recent Supreme Court decisions have made it clear that federal law preempts design-defect and failure-to-warn claims against generic prescription-drug manufacturers. They explain that there are four theories of liability for manufacturers of products: (1) manufacturing-defect, (2) design-defect, (3) failure-to-warn, (4) breach-of-express-warranty. The generic manufacturers contend that the only theories that could possibly apply in this case are design-defect and failure-to-warn. However, they argue that the Supreme Court's recent decisions in *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011) and *Pharmaceutical Company, Inc. v. Bartlett*, 133 S.Ct. 2466 (2013) preclude claims being brought against generic pharmaceutical companies on either of these two theories. According to the generic manufacturers' interpretation, the Supreme Court held in *Mensing* that federal law preempts failure-to-warn claims against generic drug manufacturers because federal law does not permit generic drug manufacturers to make any changes to the labels that are placed on the drugs. (Rec. Doc. 52-1 at 6). The generic manufacturers argue that in *Bartlett*, the Supreme Court similarly held that federal law preempts design-defect claims against generic drug manufacturers because these manufacturers are not allowed to alter the drug's design. (Rec. Doc. 52-1 at 6). Plaintiffs filed one opposition in response to three of the motions to dismiss. (Rec. Doc. 79). As to the first argument, Plaintiffs claim that they have sufficiently alleged that the generic manufacturers are the proximate cause of Mrs. Tillman's death. Plaintiffs point to paragraph 26 of their complaint, in which they state "upon information and belief, the phenytoin administered to Mrs. Tillman during her stay at Woldenberg and WJMC was manufactured and

sold by one or more of the defendant Manufacturers." Plaintiffs explain that once discovery reveals which manufacturer made the drug that was ingested by Mrs. Tillman, the rest of the defendants will be voluntarily dismissed. In response to the generic manufacturers' second argument, Plaintiffs agree with their interpretation and application of the two recent Supreme Court decisions, *Mensing* and *Bartlett*. However, Plaintiffs argue that these decisions are "manifestly unfair and legally incorrect, especially as applied in this case." (Rec. Doc. 79 at 2).

1. Standard

The Federal Rules of Civil Procedure permit a defendant to seek a dismissal of a complaint based on the "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). A district court must construe facts in the light most favorable to the nonmoving party. The court must accept as true all factual allegations contained in the complaint. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "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." *Id.* (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). Dismissal is appropriate only if the complaint fails to plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp.* 550 U.S. at 570.

2. Liability of Generic Drug Manufacturers

The Louisiana Products Liability Act, the substantive law that applicable in this case, states that "the manufacturer of a product shall be liable to a claimant for damage proximately caused by a characteristic of the product that renders the product unreasonably dangerous...." La. Rev. Stat. § 9:2800.54. Pursuant to this Act, there are four exclusive theories of liability.

The Act states:

> A product is unreasonably dangerous if and only if: (1) The product is unreasonably dangerous in construction or composition... (2) The product is unreasonably dangerous in design... (3) The product is unreasonably dangerous because an adequate warning about the product has not been provided... (4) The product is unreasonably dangerous because it does not form to an express warranty of the manufacturer...."

La. Rev. Stat. § 9:2800.54(B). The thrust of Plaintiffs' complaint against the generic manufacturer is a design defect claim. In their complaint, Plaintiffs state that "[p]henytoin is a defective drug because one in every ten persons who takes it has an adverse reaction in the form of a rash of varying degrees of severity." (Rec. Doc. 1-1 at 3). Plaintiffs do not claim that the particular drug that was ingested by Mrs. Tillman was manufactured improperly or that she was not adequately warned about the side effects. Rather, they claim that the design of the drug is defective because of these side effects. However, as the generic manufacturers point out, the Supreme Court in *Bartlett* held that "state-law design-defect claims...that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling." *Bartlett*, 133 S.Ct. at 2478. Plaintiffs admitted to the Court in their opposition as well as during oral argument, that this Supreme Court decision does apply in this case. However, Plaintiffs argue that the law should be changed because of its unfair consequences.

While the Court sympathizes with the position that Plaintiffs find themselves in, it is beyond this Court's authority to do anything but apply the established Supreme Court precedent. For this reason, the Court finds that Plaintiffs' claims against the generic manufacturers are pre-empted and voided by federal law. Accordingly, the generic manufacturers' motions to dismiss

are granted.

B. Motion for Judgment on the Pleadings Filed by Defendant Pfizer Inc.

Defendant Pfizer Inc. ("Pfizer") filed a motion for judgment on the pleadings. (Rec. Doc. 101). Pfizer argues that the Plaintiffs' complaint sets forth no valid claim under the Louisiana Product Liability Act ("LPLA"). First, Pfizer points to the Plaintiffs' complaint which says that Mrs. Tillman died "as a direct and proximate result of an adverse reaction to the prescription drug, phenytoin (marketed as the generic for Dilantic)." Since Pfizer does not manufacture phenytoin, it argues that it cannot be held liable under the LPLA. Second, Pfizer claims that Plaintiffs do not allege sufficient factual allegations to support the elements of a claim under LPLA. Pfizer describes the four theories of liability under the LPLA--(1) defect in construction or composition, (2) defect in design, (3) inadequate warning, (4) failure to comply with an express warranty. Pfizer analyzes each of these four theories in more detail, and alleges that Plaintiffs have failed to provide sufficient factual allegations to meet any of these four theories. Lastly, Pfizer argues that if Plaintiffs are asserting non-LPLA claims, they should be dismissed because Louisiana law disallows all theories of recovery against a manufacturer other than those set forth in the LPLA.

In opposition, Plaintiffs argue that their complaint includes specific allegations that are sufficient to meet the requirements for a design defect claim under the Louisiana Products Liability Act.[2] Second, Plaintiffs argue that the Federal Rules of Civil Procedure do not require

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[2]Specifically, Plaintiffs point to four paragraphs in their complaint which state:

> 8. Phenytoin is a defective drug because one in every ten persons who takes it has an adverse reaction in the form of a rash of varying degrees of severity.
>
> 9. Phenytoin is also known to produce a reaction, which is the most sever form of this rash, known as Stevens Johnson Syndrome ("SJS") and / or

that a claimant mention a specific statute in his complaint.

1. Standard

The Federal Rules of Civil Procedure allow a Court to enter a judgment on the pleadings. Fed. R. Civ. P. 12(c). The Court should evaluate a motion under Rule 12(c) using the same standard as a motion to dismiss under Rule 12(b)(6). *Gentilello v. Rege*, 627 F.3d 540, 544 (5th Cir. 2010). "As with a Rule 12(b)(6) motion to dismiss, the question is whether, viewed in the light most favorable to the plaintiffs, the complaint states a valid claim for relief." *Lott v. Edenfield*, No. 12-10844, 2013 WL 5495563, at *2. "To avoid dismissal, a plaintiff must plead sufficient facts to 'state a claim to relief that is plausible on its fact.'" *Gentilello v. Rege*, 627 F.3d 540 (5th Cir. 2010). "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." *Id.* "We do not accept as true conclusory allegations, unwarranted factual inference, or legal conclusions." *Id.* (quoting *Plotkin v. IP Axess Inc.*, 407 F.3d 690, 696 (5th Cir. 2005)).

2. Liability of Pfizer Inc. Under the Louisiana Product Liability Act

The Louisiana Products Liability Act ("LPLA") states that "the manufacturer of a product shall be liable to a claimant for damage proximately caused by a characteristic of the product that renders the product unreasonably dangerous..." La. Rev. Stat. § 9:2800.54. The Act

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> Toxic Epidermal Necrolysis ("TEN"), which kills approximately fifteen percent of those afflicted by it.
> 10. Phenytoin is known to be most dangerous to African Americans who are more likely to experience allergic reactions than those of other ethnic origins....
> 11. There are other drugs available with fewer and less harmful side effects than phenytoin, yet the Manufacturers continue to produce, market, and sell phenytoin, knowing of its dangerous side effects.

defines "manufacturer" as "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." La. Rev. Stat. § 9:2800.53(1).

Plaintiffs allege that "Mrs. Tillman died as a direct and proximate result of her adverse reaction to phenytoin." (Rec. Doc. 1-1 at 6). In their briefings to the Court, Plaintiffs explain that "in light of the fact that virtually every private medical insurer as well as government sponsored insurance pays only for generics where available, it is a safe assumption that the drug that Mrs. Tillman received was one of the generics." (Rec. Doc. 79 at 2). Counsel for Plaintiffs repeated this statement during oral argument as well.

In light of Plaintiffs' admission, Plaintiffs fail to plead sufficient facts to state a claim to relief against Pfizer Inc. under the LPLA. In order to state a claim for relief under the LPLA, a plaintiff must establish that the defendant is the manufacturer of the product. *See Ayo v. Triplex, Inc.*, 457 Fed.Appx. 382, 385 (2012) (quoting *Jack v. Alberto-Culver USA, Inc.*, 2006-1883, p. 4 (La. 2/22/07)). Pfizer Inc. did not manufacture or market the generic form the drug, phenytoin. Therefore, Pfizer Inc. cannot be held liable under the LPLA for the damage that was caused by the generic version of the drug.

3. Liability of Pfizer Inc.Under Non-LPLA Claim

The Court does not find that Plaintiffs have stated a claim for relief under any non-LPLA theories of liability. As stated previously, the thrust of Plaintiffs' complaint against the drug manufacturers is a design-defect claim. This is apparent from the complaint which discusses the well-known side effects of phenytoin. This is also apparent from Plaintiffs' opposition to the present motion. Plaintiffs' sole argument against a judgment on the pleadings is that they have

put forth sufficient facts to state a design defect claim under the LPLA. (Rec. Doc. 111 at 2). Furthermore, at oral argument, counsel for Plaintiffs conceded that they are not pursuing any non-LPLA claims. For this reason, the Court finds that there are no viable non-LPLA claims in this case.

C. Motion to Dismiss Filed by West Jefferson

On October 8, 2013, Defendant West Jefferson filed a motion to dismiss for lack of subject matter jurisdiction. (Rec. Doc 72). West Jefferson claims that the Louisiana Medical Malpractice Act, La. R.S. 40:1299.41, provides a set of administrative procedures that must be completed in a medical malpractice case before the commencement of a court action. West Jefferson argues that this court does not have subject mater jurisdiction over the claim until the administrative procedures are completed. Here, the claim has been submitted to a malpractice review panel, but the procedures have not yet been completed. Therefore, West Jefferson asks the Court to dismiss the claims against it.

This motion is currently unopposed by Plaintiffs. Furthermore, during oral argument, Plaintiffs admitted to the Court that the administrative procedure has not been completed. Therefore, West Jefferson's unopposed motion to dismiss is granted.

III. CONCLUSION

For the foregoing reasons, **IT IS ORDERED** that the generic manufacturers' motions to dismiss (Rec. Docs. 52, 61, 65, 88, 92) are **GRANTED**.

IT IS FURTHER ORDERED that Defendant Pfizer Inc.'s motion for judgment on the pleadings (Rec. Doc. 101) is **GRANTED**.

IT IS FURTHER ORDERED that the motion to dismiss for lack of jurisdiction filed by Defendant Jefferson Parish Hospital Service District No. 1, doing business as West Jefferson Medical Center, (Rec. Doc. 72) is **GRANTED**.

New Orleans, Louisiana, this 27th day of November, 2013.

UNITED STATES DISTRICT JUDGE