UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

JOSHUA A. WHITENER, ET AL.	CIVIL ACTION
VERSUS	NO. 10-1552
PLIVA, INC., ET AL.	SECTION "L" (4)

ORDER & REASONS

Before the Court are motions for summary judgment by Defendants PLIVA, Inc., Barr Laboratories, Inc., Teva Pharmaceuticals USA, Inc., Alaven Pharmaceutical, LLC, and Schwarz Pharma, Inc., now known as UCB, Inc. (collectively the "pharmaceutical entities"). (Rec. Docs. 175, 233, 258). The Court has considered the applicable law and the parties' memoranda, and after having heard oral argument on one of the motions, now issues this order.

I. BACKGROUND

This pharmaceutical products liability action arises out of congenital injuries to Lucas Whitener, son of Plaintiffs Joshua Whitener, Sr. and Lindsey Whitener, as well as injuries to Ms. Whitener, allegedly caused by the anti-emetic drug metoclopramide. The Whiteners allege that while Ms. Whitener was pregnant with Lucas, she was prescribed metoclopramide to treat nausea and morning sickness. Metoclopramide is the generic form of the brand-name drug Reglan.

The Whiteners filed suit in the 40th Judicial District Court for the Parish of St. John the Baptist against a variety of pharmaceutical entities, who allegedly designed, manufactured, marketed, or sold metoclopramide, as well as her treating doctor and clinic. The claims against the doctor and clinic were dismissed in state court on grounds of prematurity (Rec. Doc. 1-3 at 39), and the pharmaceutical entities removed to this Court. (Rec. Doc. 1).

The Court previously granted a motion for judgment on the pleadings filed by the pharmaceutical entities, but allowed the Whiteners leave to amend their pleadings to attempt to assert a non-preempted state law claim. (Rec. Doc. 130). The Whiteners then filed an amended complaint. (Rec. Doc. 131). In the amended complaint, they allege that the pharmaceutical entities manufactured or distributed metoclopramide knowing or intending that it would be prescribed to treat morning sickness, an off-label use. Further, the Whiteners allege that because the pharmaceutical entities maintained sales relationships with obstetrics and gynecology doctors and clinics to legitimately market other drugs, it may be inferred that they employed those relationships to promote metoclopramide for off-label use.

After the amended complaint had been filed, the pharmaceutical entities filed a joint motion to dismiss it. (Rec. Doc. 135). They argued that the Whiteners failed to plead with the requisite factual specificity that any of the pharmaceutical entities promoted metoclopramide for off-label use in violation of federal law. Likewise, they contended that the amended complaint persists in attempting to assert a claim predicated on a failure-to-warn theory that is preempted. In response, the Whiteners argued that their amended complaint contains enough facts to state a plausible claim that the pharmaceutical entities violated federal regulations by promoting metoclopramide for off-label use in violation of federal law and by failing to warn of the risks associated with that off-label use, and that their conduct resulted in metoclopramide being prescribed to Ms. Whitener.

On June 4, 2012, this Court issued an order denying the pharmaceutical entities' motion to dismiss. (Rec. Doc. 145). With respect to the factual sufficiency of the pleading, it held that the Whiteners "ha[d] (barely) pleaded enough facts to raise a reasonable expectation that discovery will reveal evidence of such conduct." *Id.* at 5 (internal quotation marks omitted). With

respect to preemption, the Court noted that they "ha[d] not clearly articulated the legal foundation of their claims" and that the off-label prescription "makes no apparent difference in the *Mensing* preemption analysis." *Id.* at 6. The Court then stated:

> Even if a generic manufacturer knows that its product is prescribed for some other purpose, that manufacturer has no mechanism to unilaterally provide any additional warnings relevant to the off-label use; that inability is the crux of the *Mensing* opinion. . . . The harder question . . . is whether the *Mensing* analysis changes if a generic defendant *actively promotes* the drug for off-label use in violation of federal law. [T]here is something troubling about permitting a generic defendant to violate federal law by actively and aggressively promoting a drug for a purpose not contemplated by the label approved by the FDA while also hiding behind an inability to provide warnings connected to that off-label use because it cannot change the approved label.

Id. at 6-7. On this basis, as well as the fact that the parties had not cited a case directly addressing the issue, the Court stated that it was "hesitant to hold as a matter of law that there is not a kernel of a viable claim somewhere in [the Whiteners'] allegations." *Id.* at 7. The Court denied the pharmaceutical entities' motion, but noted that it may prove necessary to revisit the issue.

The parties then submitted separate motions for reconsideration of the Court's orders described above. (Rec. Docs. 151, 155). Both motions were denied on September 10, 2012. (Rec. Doc. 160). There was no further activity in the case until a telephone status conference on June 19, 2013. (Rec. Doc. 165). During that conference, the Court overruled the pharmaceutical entities' objections to providing initial disclosures, while allowing them to preserve their right to contest personal jurisdiction. (Rec. Doc. 162, 165). The Court also instructed the parties that any further amended complaints were due on August 3, 2013. (Rec. Doc. 165).

After several deficient attempts to move for leave to file a second amended complaint, the Whiteners succeeded on August 7, 2013. (Rec. Doc. 167). The motion was initially opposed by the pharmaceutical entities, but the parties conferred and the Whiteners then submitted an

unopposed and revised second amended complaint on September 9, 2013, which was entered into the record the following day. (Rec. Doc. 181).

PLIVA, Barr Laboratories, and Teva Pharmaceuticals then filed a motion for summary judgment, (Rec. Doc. 175), on which the Court heard oral argument on October 16, 2013. However, the Court delayed its decision on that motion after Alaven Pharmaceutical filed its motion for summary judgment on November 1, 2013, and Schwarz Pharma filed a nearly identical motion on March 18, 2011 (Rec. Doc. 258). Each of these motions is now before the Court.[1]

II. PRESENT MOTIONS

A. PLIVA, Barr Laboratories, and Teva Pharmaceutical's Motion

PLIVA, Barr Laboratories, and Teva Pharmaceuticals move for summary judgment on the basis that there is no causal relationship between their alleged promotion of metoclopramide and the decision by Ms. Whitener's treating physician, Dr. John McCrossen, to prescribe the drug to her.[2] (Rec. Doc. 175). Unlike Alaven Pharmaceutical and Schwarz Pharma, whose motions are discussed below, PLIVA, Barr Laboratories, and Teva Pharmaceuticals were generic

[1] On March 25, 2014, the Whiteners filed a motion for leave to file a third amending and supplemental complaint, which is set for submission on April 9, 2014. (Rec. Doc. 261). The proposed complaint reasserts allegations against non-diverse defendants, including her treating physican, who had previously been dismissed prior to removal due to prematurity.

[2] PLIVA, Barr Laboratories, and Teva Pharmaceuticals note:

> Defendants Barr Pharmaceuticals, Inc.; Watson Pharmaceuticals, Inc.; and PLIVA Hrvatska d.o.o. (incorrectly identified in plaintiff's Amending Complaint as PLIVA Pharmaceuticals, Inc.) do not formally join in this motion to dismiss because they have asserted personal jurisdiction defenses upon which they will seek dismissal, if necessary. However, plaintiffs have alleged those entities also were manufacturers and/or distributors of generic metoclopramide, and the grounds for summary judgment asserted by Generic Defendants in this motion apply equally to those other defendants and require dismissal of plaintiffs' lawsuit against all defendants.

(Rec. Doc. 175 at 1 n.1). Thus, the Court's resolution of that motion is equally applicable to Barr Pharmaceuticals, LLC., erroneously named Barr Pharmaceuticals, LLC, Watson Pharmaceuticals, Inc., and PLIVA Hrvatska, d.o.o.

manufacturers of the actual product that Ms. Whitener consumed. They rely on a deposition of Dr. McCrossen that was taken in another case and that was produced during early discovery in this case. According to the pharmaceutical entities, the deposition indicates that Dr. McCrossen had no contact with them but instead relied solely on his own clinical experience and judgment in prescribing metoclopramide.

In response, the Whiteners posit a number of arguments. (Rec. Doc. 214-2). First, they contend that the pharmaceutical entities' statement of uncontested facts does not meet the requirements of Federal Rule of Civil Procedure 56 or Local Rule 56.1 because it lists testimony rather than providing an actual statement of uncontested material facts. Second, they argue that the pharmaceutical entities have acted in bad faith by basing their motion solely upon a deposition that was provided by the Whiteners as an initial disclosure while simultaneously refusing to provide similar initial disclosures. Third, they state that the pharmaceutical entities have misrepresented the significance of Dr. McCrossen's deposition. Fourth, they argue that pharmaceutical entities have misrepresented the scope of activities constituting the promotion of off-label use. Specifically, they note that the entities have "rested their motion primarily on the idea that direct, face-to-face promotion . . . is the only activity that could constitute their 'actively and aggressively promoting a drug for a purpose not contemplated by the label approved by the FDA.'" (Rec. Doc. 214-2 at 5 (internal quotation marks omitted)). They also indicate that they "will show that even publically available information reveals that [the pharmaceutical entities'] off-label promotion (misbranding) was a proximate cause of the prescription of metoclopramide to Ms. Whitener." (*Id.* at 8). Fifth, the Whiteners' argue that, based on publicly available information alone, the extent of the pharmaceutical entities' influence over prescribing practices demonstrates that Dr. McCrossen was influenced by their activities. Last, they indicate that there

are genuine disputes as to the material facts that preclude summary judgment and that further discovery is warrented.

The PLIVA, Barr Laboratories, and Teva Pharmaceuticals reply. (Rec. Doc. 224). First, they argue that more recent evidence demonstrates that Teva Pharmaceuticals did not produce any of the metoclopramide that Ms. Whitener used. Second, they contend that their motion is not procedurally deficient merely because it cites the deposition. Third, they reemphasize that "the dispositive fact remains: Dr. McCrossen's testimony conclusively demonstrates that [the Whiteners] cannot establish proximate causation." (*Id.* at 2). Fourth, they dispute the contention that they influenced any medical publication upon which Dr. McCrossen may have relied. Further, even if such an influence could be demonstrated, they contend that Dr. McCrossen's deposition conclusively states that he did not rely on anything but his own experience and judgment. Fifth, the pharmaceutical entities state that the Whiteners have not provided any evidence that the entities participated in any of the annual American Congress of Obstetricians and Gynecologists' ("ACOG") meetings that Dr. McCrossen had attended nor that they discussed metoclopramide with him. Sixth, they seek to discredit the Whiteners' theory regarding their relationship with researchers, ACOG, and others as an unreasonable inference unsupported by fact. Seventh, they note that the Whiteners' contention that the relevant inquiry relates to the intent of the person responsible for labeling is flawed because generic manufactures are not responsible for the labeling. Last, they contend that additional discovery is unnecessary because the Whiteners are unable to demonstrate that such discovery will establish any genuine issue of material fact.

B. Alaven Pharmacutical's & Schwarz Pharma's Motions

Alaven Pharmaceutical and Schwarz Pharma also move for summary judgment on the basis that they did not distribute or sell the drugs Ms. Whitener used and because they did not

manufacture the drugs Ms. Whitener ingested. (Rec. Docs. 233, 258). The Whiteners respond that these pharmaceutical entities are independently liable for fraud or misrepresentation and that their promotion of the drug to Dr. McCrossen caused him to prescribe it to Ms. Whitener. (Rec. Docs. 251, 259). Further, they argue that there is a genuine issue of material fact as to whose drugs Ms. Whitener consumed while she was in the hospital. They reply that the Whiteners have misstated the applicable law and that their procedural and substantive arguments are otherwise meritless. (Rec. Docs. 257, 260-2).

III. LAW & ANALYSIS

A. Law

Summary judgment is appropriate if the moving party can show "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). "Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which the party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The moving party bears the initial burden of "informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Id.* The moving party is entitled to summary judgment if the nonmoving party "has failed to make a sufficient showing on an essential element of [their] case...." *Id.* at 323. A court should "resolve factual controversies in favor of the non-moving party, but only when there is an actual controversy, that is, when both parties have submitted evidence of contradictory facts. *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994). "[I]n the absence of any proof," a court should not "assume that the nonmoving party could or would prove the necessary facts." *Id.* "The mere existence of a scintilla of evidence in support of the plaintiff's position will

be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 253 (1986). Furthermore, "[t]he non-movant cannot avoid summary judgment . . . by merely making 'conclusory allegations' or 'unsubstantiated assertions.'" *Calbillo v. Cavender Oldsmobile, Inc.*, 288 F.3d 721, 725 (5th Cir. 2002) (quoting *Little*, 37 F.3d at 1075). In deciding a summary judgment motion, the court reviews the facts drawing all reasonable inferences in the light most favorable to the non-movant. *Id.* at 255.

B. Analysis

As discussed above, the Whiteners bring claims against a number of pharmaceutical entities who manufactured metoclopramide, including those whose product Ms. Whitener ingested and those whose product she did not. First, it is necessary to consider the claims against those whose product Ms. Whitener consumed, namely PLIVA, Barr Laboratories, and Teva Pharmaceuticals.[3]

The Louisiana Products Liability Act ("LPLA") "establishes the exclusive theories of liability for manufacturers for damage caused by their products." LA. REV. STAT. § 9:2800.52. Accordingly, "[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 [it]." *Id.* "Under the LPLA, recovery is not available against a manufacturer if the manufacturer did not produce the offending product." *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 182 (5th Cir. 2012).

Under the LPLA, "a plaintiff must establish four elements: (1) that the defendant is a manufacturer of the product; (2) that the claimant's damage was proximately caused by a characteristic of the product; (3) that this characteristic made the product 'unreasonably

[3] In their reply, it is noted that Teva Pharmacuticals did not manufacture the product Ms. Whitener consumed. To the extent this is true, the claims against it are considered with those of Alaven Pharmaceutical and Schwarz Pharma. Either way, the claims against it must be dismissed.

dangerous'; and (4) that the claimant's damage arose from a reasonably anticipated use of the product by the claimant or someone else." *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 260–61 (5th Cir. 2002) (citing LA. REV. STAT. § 9:2800.54).

Further, "Louisiana applies the 'learned intermediary doctrine' to [LPLA] claims involving prescription drugs." *Id.* at 265. "Under this doctrine, a drug manufacturer discharges its duty to consumers by reasonably informing prescribing physicians of the dangers of harm from a drug." *Id.* To prevail, the following elements must be demonstrated: first, "that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product that was not otherwise known to the physician," and second, "that this failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury." *Id.* at 265–66.

It is now well-established that generic drug manufacturers are not permitted to alter the labels of those drugs. However, "there is something troubling about permitting a [generic drug manufacturer] to violate federal law by actively and aggressively promoting a drug for a purpose not contemplated by the label approved by the FDA while also hiding behind an inability to provide warnings connected to that off-label use because it cannot change the approved label." (Rec. Doc. 147 at 7). Accordingly, it is necessary to consider whether such promotion constitutes a failure to warn.

Here, the question is whether Dr. McCrossen relied on the alleged promotion of the drug by the pharmaceutical entities in prescribing it to Ms. Whitener. Stated differently, the pharmaceutical entities will be entitled to summary judgment if the record taken as a whole could not lead a rational trier of fact to find that, but for their promotion of the drug, the treating doctor would not have prescribed it. *See Allgood v. GlaxoSmithKline PLC*, 06-3506, 2008 WL 483574, at *4 (E.D. La. Feb. 20, 2008) (Fallon, J.).

Having very closely reviewed Dr. McCrossen's deposition, it is clear that his decision to prescribe the drug to Ms. Whitener was made independently of any alleged conduct by the pharmaceutical entities.[4] Specifically, Dr. McCrossen indicates that he did not have any contact with any of the pharmaceutical entities named in this action nor their representatives with regard to the drug. In fact, he stated that "[n]o one has specifically talked to me from [any] company about Reglan or Metoclopramide." (Rec. Doc. 175-3 at 29). Samples of the drug were never left at his office or, to his knowledge, provided to anyone else in his office. Further, he did not reference any other materials in prescribing the drug to Ms. Whitener. For instance, he remarked that "ACOG does not determine a course of treatment; [it] just make[s] recommendations" about what a doctor should prescribe. (*Id*. at 16). Instead, "[i]t's up to the clinical discretion and judgment of the physician, based on the given situation." (*Id*.).

He states unambiguously that his decision to prescribe the drug to Ms. Whitener was only based on his own experience. Beginning when he was a first-year resident, he had been using the drug to treat "[n]ausa and vomiting in pregnancy, particularly the first trimester, but, really, at any point in pregnancy" because "it's effective." (*Id*. at 15).

He explains:

> Q: Do you think it's your judgment? You said that's what "I base my judgment on" in deciding to prescribe Metoclopramide. Do you think it's your judgment to balance the risks and benefits of the medicine?
>
> A: I think it's my clinical decision to make decisions about the best treatment for patients, and part of clinical decision-making is using judgment.

[4] The Whitners have expressed some concern that the deposition of Dr. McCrossen has been misinterpreted or that his statements have been taken out of context. During oral argument, the Court requested that the entire deposition of Dr. McCrossen be provided for in camera review. The Court has perused the entire deposition, and sees no reason to consider the designations provided as exhibits to the papers as aberrations or misrepresentations.

> So, again, when patients have nausea and vomiting and need a medication . . . [,] in my clinical decision-making, I feel like it's safe to use to control the problem.

(*Id*. at 26-27).

He also indicated that it did not matter that metoclopramide had not been approved by the FDA for use in treating pregnant women, because "I don't rely on the FDA to make those decisions" and "[i]t's a clinical decision and a professional decision based on guidelines from the people that practice my sort of medicine." (*Id*. at 21). Instead, what matters is that he use "a medication that helps a problem." (*Id*. at 23).

Based on the above testimony, it seems clear to the Court that Dr. McCrossen relied principally on his own experience, and that even knowing everything he knows today, he would have still prescribed metoclopramide to Ms. Whitener. The Whiteners allege complex theories regarding the manner in which the pharmaceutical companies promoted the drug, however these remain mere assertions that are supported by scant, if any, testimony and evidence. However, even if these allegations were substantiated, Dr. McCrossen's testimony makes clear that the decision to prescribe the drug to Ms. Whitener was his own. The Whiteners have not presented anything that creates a genuine dispute with regard to this material fact. Accordingly, the Whiteners have failed to establish any causal relationship between the alleged activities of the pharmaceutical entities who manufactured the product Ms. Whitener ingested and Ms. Whitener's injury. Without any such relationship, their remaining claim against the Barr, PLIVA, and Teva must be dismissed.

Next, it is necessary to consider whether the claims against Alaven Pharmaceutical and Schwarz Pharma, both of whom manufactured metoclopramide but neither of whom manufactured the metoclopramide ingested by Ms. Whitener. As noted above, the LPLA

"establishes the exclusive theories of liability for manufacturers for damage caused by their products." LA. REV. STAT. § 9:2800.52. Accordingly, [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 [it]." *Id.* "Under the LPLA, recovery is not available against a manufacturer if the manufacturer did not produce the offending product." *Demahy*, 702 F.3d at 182. Name-brand drug manufacturers "are, indeed, manufacturers—and were they not, there would be no relationship on which to presume liability (since they did not design the drug)." *Lashley v. Pfizer, Inc.*, Nos. 12–60861, 12–41148, 2014 WL 661058, at *4 (5th Cir. Feb. 21, 2014). Accordingly, a drug manufacturer may not be held liable where a plaintiff has not been injured from ingesting a another drug manufacturer's drug. Here, neither Alaven Pharmaceutical nor Schwarz Pharma can be liable under the LPLA because they did not manufacture the metoclopramide taken by Ms. Whitener.

Likewise, the Whiteners are unable to sustain any claim against them under tort law. As the Fifth Circuit has noted, "[t]he vast majority of decisions have held that the LPLA broadly applies to all suits involving injuries from products, and these decisions rejected the argument that common law tort claims can still be brought for injuries stemming from products . . . ." *Id*. at 183 n.4. Further, even if the LPLA did not apply, under Louisiana law "there is no duty of care owed by name-brand manufacturers to consumers of generic products." *Id.* Here, the LPLA's language clearly bars any state law tort claim, and even if it did not, such a tort claim would not be cognizable. For these reasons, all claims against these pharmaceutical entities do not survive.

Further, any fraud claim is likewise unsupportable. Even if Alaven Pharmaceutical and Schwarz Pharma had engaged in fraud or misrepresentation regarding the safety of the drug, there is no causal relationship between their acts or omissions and Ms. Whitener's injury. As

noted above, Dr. McCrossen unambiguously stated that he made his decision to prescribe the drug to Ms. Whitener based on his own experience, not based on any external influence—including any FDA classification or recommendation.

IV. CONCLUSION

For these reasons, **IT IS ORDERED** that the pharmaceutical entities' motions for summary judgment (Rec. Docs. 175, 233, 258) are **GRANTED** and that the claims against PLIVA, Inc., Barr Laboratories, Inc., Teva Pharmaceuticals, Alaven Pharmaceutical, and Schwarz Pharma, Inc., now known as UCB, Inc., Barr Pharmaceuticals, erroneously named Barr Pharmaceuticals, Inc., Watson Pharmaceuticals, Inc., and PLIVA Hrvatska are **DISMISSED**.

IT IS FURTHER ORDERED that PLIVA, Inc., Barr Laboratories, Inc., Teva Pharmaceuticals' objections to Magistrate Judge Roby's order (Rec. Doc. 249) are **DENIED AS MOOT**.

New Orleans, Louisiana, this 27th day of March, 2014.

UNITED STATES DISTRICT JUDGE