UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

JOSHUA A. WHITENER, SR., ET AL.	**CIVIL ACTION**
VERSUS	**NUMBER 10-1552**
PLIVA, INC., ET AL.	**SECTION "L" (4)**

ORDER & REASONS

Before the Court is a Joint Motion to Dismiss (Rec. Doc. 135) filed by Defendants PLIVA, Inc., Barr Laboratories, Inc., and Teva Pharmaceuticals USA, Inc. The Court has reviewed the briefs and the applicable law and now issues this Order and Reasons.

I. BACKGROUND

This pharmaceutical products liability action arises out of congenital injuries to Lucas Whitener, son of Plaintiffs Joshua A. Whitener, Sr., and Lindsey C. Whitener, as well as injuries to Mrs. Whitener, allegedly caused by the anti-emetic drug metoclopramide. Plaintiffs allege that while Mrs. 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 FDA-approved label for Reglan did not include prescription to pregnant women for morning sickness as an indication.

Plaintiffs filed suit in the 40th Judicial District Court for the Parish of St. John the Baptist against a variety of pharmaceutical entities alleged to have designed, manufactured, marketed, or sold metoclopramide, as well as the doctor and clinic. (Petition at ¶ 2.) The claims against the doctor and clinic were jointly dismissed in state court on grounds of prematurity (Rec. Doc. 1-3 at 39) and the pharmaceutical Defendants removed to this Court.

The Court previously granted a motion for judgment on the pleadings filed by the

Defendants who have appeared in the case. (Rec. Doc. 130). In that Order and Reasons, the Court addressed the Supreme Court's recent opinion in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). *Mensing* holds that federal law "preempts any [state-law] claims that Defendants should have provided more or different warnings than those contained in the label and materials approved by the FDA" with respect to a generic drug. (Rec. Doc. 130 at 9). However, the Court granted Plaintiffs leave to amend their pleadings to attempt to assert a non-preempted state-law claim predicated on "alleged promotion of metoclopramide for off-label purposes in violation of federal law." *Id.* . As the Court observed, "if Plaintiffs are attempting to allege that the Defendants promoted or marketed the drug in a manner *inconsistent* with the label or marketed it for an off-label purpose in violation of federal rules and regulations ... the briefing is insufficient at this time for the Court to conclude that such a claim fails as a matter of law." *Id.* at 8-9. Specifically, the Court instructed that:

> If Plaintiffs wish to pursue such a claim they should plead sufficient factual content regarding what marketing or promotional representations were made, by which Defendants, to whom, and how those statements violated applicable federal law.

Id.

Plaintiffs have filed an amended complaint. (Rec. Doc. 131). In that pleading, they allege that Defendants manufactured or distributed metoclopramide knowing or intending that it would be prescribed off-label to treat morning sickness. (*Id.* at ¶ 3a-b, ¶ 7). According to the amended complaint, the Defendants knew that doctors frequently prescribed generic metoclopramide off-label to pregnant women to treat morning sickness. Further, Defendants maintained sales relationships with OBGYN clinics through the legitimate marketing of other drugs. Therefore, Plaintiffs draw the inference that discovery will reveal that Defendants were

promoting metoclopramide off-label to doctors for prescription to pregnant women.

II. PRESENT MOTION

Defendants have filed a joint motion to dismiss the amended complaint. (Rec. Doc. 135). They argue that Plaintiffs' amended complaint fails to plead with the requisite factual specificity that any Defendant promoted metoclopramide for off-label use in violation of federal law. Likewise, Defendants contend that the amended complaint persists in attempting to assert a claim predicated on a failure to warn that is preempted by *Mensing*. In response, Plaintiffs argue that they have pleaded enough facts to state a plausible claim that Defendants violated federal regulations by promoting metoclopramide for off-label uses in violation of federal law, rather than consistent with it, and failing to warn of the risks associated with that off-label use, and that Defendants' conduct resulted in metoclopramide being prescribed to Mrs. Whitener.

III. LAW & ANALYSIS

A. Standard on Motions to Dismiss

In assessing a motion to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), "all well-pleaded facts are viewed in the light most favorable to the plaintiff, but plaintiffs must allege facts that support the elements of the cause of action in order to make out a valid claim." *City of Clinton v. Pilgrim's Pride Corp.*, 632 F.3d 148, 152-53 (5th Cir. 2010). "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." *Id.* (quoting *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009)). The court "do[es] not accept as true conclusory allegations, unwarranted factual

inferences, or legal conclusions." *Plotkin v. IP Axess Inc.*, 407 F.3d 690, 696 (5th Cir. 2005).

B. Analysis

In their amended complaint, Plaintiffs attempt to articulate a cause of action predicated on Defendants' alleged violation of federal regulations through active promotion of metoclopramide for prescription to treat morning sickness and failing to warn of the risks of that off-label use. With respect to this potential theory of liability, there are two issues: whether Plaintiffs have adequately pleaded factual material stating a claim for off-label promotion, and whether such a claim is legally viable. The Court will address each issue in turn.

1) Sufficiency of the Factual Pleadings

First, with respect to the factual pleadings, Plaintiffs allege that Defendants knew that metoclopramide was prescribed to women for morning sickness, which was not a purpose approved by the FDA. Plaintiffs allege that Defendants legitimately marketed other products to doctors, to OB/GYNs in particular, and to Plaintiff's physician specifically. Combining the fact of off-label prescription with the fact of Defendants' marketing apparatus, Plaintiffs allege that Defendants used legitimate marketing channels "and the access and relationships developed thereby to promote sales of their entire product line, including sales of metoclopramide for the treatment of morning sickness and/or nausea." (Rec. Doc. 131 at ¶ 10).[1] Plaintiffs also allege specific facts suggesting contact between the physician who prescribed metoclopramide to Mrs.

[1]They also allege "upon information and belief" that "Defendants have marketed and promoted metoclopramide to OBGYNs for off-label purposes through their purposeful development of relationships between sales representatives and OBGYN clinics, through bonus, reward and commission structures that encourage volume of sales per territory, through the promotion of Defendants' companies and entire product lines without drawing appropriate limitations, and/or through associations such as the American College of Obstetricians and Gynecologists." (Rec. Doc. 131 at ¶ 9).

Whitener, and sales representatives for Defendants. As background, Plaintiffs discuss the job descriptions of pharmaceutical sales representatives as well as reports of general misconduct throughout the pharmaceutical industry by sales representatives. *Id.* at ¶¶ 17-18.

The Court has reviewed the amended complaint and Defendants' arguments regarding the sufficiency of the factual pleadings with respect to Federal Rule of Civil Procedure 8. Although Plaintiffs have not strictly complied with the Court's prior guidance and do not allege any specific communications between any particular Defendant and Plaintiffs' physician, they have articulated a method of how Defendants promoted metoclopramide to their physician for off-label purposes. The Court's role at this stage of the proceeding is "to determine whether the plaintiff has stated a legally cognizable claim that is plausible, not to evaluate the plaintiff's likelihood of success." *Doe ex rel. Magee v. Covington Cnty. Sch. Dist. ex rel. Keys*, 675 F.3d 849, 854 (5th Cir. 2012) (quotation omitted). Plaintiffs have (barely) pleaded "'enough facts to raise a reasonable expectation that discovery will reveal evidence'" of such conduct. *See In re S. Scrap Material Co., LLC*, 541 F.3d 584, 587 (5th Cir. 2008) (quoting *Twombly*, 550 U.S. at 556). Whether the factual allegations can be supported by evidence or whether the legal theory is viable may well be appropriate for a subsequent motion for summary judgment. But in the present posture, dismissal pursuant to Rule 12(b)(6) is not appropriate.

2) Sufficiency of the Legal Argument

The second issue is whether Plaintiffs' allegations of off-label promotion of metoclopramide state a legally cognizable, non-preempted claim. Defendants have mainly confined their arguments to the factual specificity of the pleadings and do not analyze the legal sufficiency of the allegations in any particular depth. To the extent that they reach the legal sufficiency of those allegations, Defendants argue that Plaintiffs have cited only federal

regulations that relate to labeling and a duty to warn, which do not survive preemption after *Mensing*.

Admittedly, Plaintiffs have not clearly articulated the legal foundation of their claims or explained why the circumstance of off-label promotion makes a difference in the *Mensing* preemption analysis. They cite two federal regulations in their amended complaint and briefing. First, Plaintiffs cite 21 C.F.R. § 201.128, which states that if a pharmaceutical manufacturer "knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accord with such other uses to which" it is put. Second, Plaintiffs cite 21 C.F.R. § 201.57, which dictates "information [that] must appear in all prescription drug labeling." Plaintiffs allege that Defendants failed to comply with these regulations because they did not amend their metoclopramide labels or otherwise include additional warning information regarding prescription to pregnant women, and are therefore liable.

The fact that metoclopramide was prescribed off-label to Plaintiffs makes no apparent difference in the *Mensing* preemption analysis. A physician has leeway to prescribe a drug off-label. 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. *See Mensing*, 131 S. Ct. at 2577 ("Federal drug regulations, as interpreted by the FDA, prevented the Manufacturers from independently changing their generic drugs' safety labels."). It is not the case, as Plaintiffs seem to argue, that a generic manufacturer that know that its drug is being prescribed off-label must provide additional warnings. If that were the case, we would have a

regulatory scheme in which labels are in constant flux based on a generic manufacturers' knowledge of what off-label purposes its drugs are being put to, and its efforts to bring labelling in line to warn regarding those developing uses. That is not the law, and Plaintiffs cite nothing remotely supporting the proposition. Thus, the mere fact that generic drugs are eventually prescribed off-label does not avoid preemption.

The harder question, and one that Plaintiffs do not clearly address, is whether the *Mensing* analysis changes if a generic defendant *actively promotes* the drug for off-label use in violation of federal law. In that situation, the generic manufacturer still has no ability to change the label in compliance with federal law, and to that extent *Mensing* would seem to control. But there 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.

Preemption occurs "where it is impossible for a private party to comply with both state and federal requirements." *Mensing*, 131 S. Ct. at 2577 (quotation omitted). If a generic pharmaceutical manufacturer has failed to comply with federal requirements from the outset by marketing a drug off-label, it may be appropriate for liability to be imposed for failing to warn of risks associated with the off-label purpose which the manufacturer should not have been promoting in the first place. At any rate, the parties have not cited a case on point addressing post-*Mensing* liability for off-label promotion of a generic drug. Given the present state of the briefing, the Court is hesitant to hold as a matter of law that there is not a kernel of a viable claim somewhere in Plaintiffs' allegations. Accordingly, Defendants' motion to dismiss is denied at this time. It may well be appropriate to revisit these legal issues at a later time.

IV. CONCLUSION

Accordingly, for the foregoing reasons, Defendants' motion to dismiss (Rec. Doc. 135) is is DENIED at this time.

New Orleans, Louisiana, this 4th day of June, 2012.

UNITED STATES DISTRICT JUDGE