UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

BARBARA METZ and
DONALD METZ,

Plaintiffs,

vs. **Case No.: 8:10-CV-2658-T-27AEP**

WYETH, LLC, *et al.*,

Defendants.
_____/

ORDER

BEFORE THE COURT is Defendant Actavis Elizabeth LLC's Motion to Dismiss all Proceedings (Dkt. 43). For the reasons set forth below, the motion to dismiss will be granted without prejudice to the Plaintiffs' ability to file an amended complaint within fourteen (14) days from the date of this Order.

Introduction

Plaintiffs, Barbara Metz and Donald Metz, filed this action against Wyeth LLC ("Wyeth"), Schwarz Pharma, Inc. ("Schwarz") and Actavis Elizabeth, LLC d/b/a Purepac Pharmaceuticals ("Actavis") for injuries arising from the use of metoclopramide, marketed by Wyeth and Schwarz under the brand name Reglan. Actavis manufactured, marketed, and sold metoclopramide as a generic equivalent of Reglan.

The Complaint asserts claims against Actavis for negligence (Count I), strict liability (Count II), breach of warranties (Count III), misrepresentation and fraud (Count IV), and negligence *per se* (Count V). Tellingly, Plaintiffs allege that "[t]his case involves Defendants' failure to warn doctors and patients of information within their knowledge or possession ... ." Complaint (Dkt. 1),

¶ 32. Actavis moves to dismiss the Complaint based on the recent decision of the United States Supreme Court in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).[1]

Standard

Rule 8(a)(2) of the Federal Rules of Civil Procedure requires that a complaint provide "a short and plain statement of the claim showing that the pleader is entitled to relief," in order to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)).

Although a complaint need not include detailed factual allegations, it must contain sufficient factual allegations, which, when taken as true, "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, ___ U.S. ___, 129 S. Ct. 1937, 1949 (2009). "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.* "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." *Id.* "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint as alleged-but it has not 'show[n]'-'that the pleader is entitled to relief.'" *Id.* at 1950 (quoting Fed. R. Civ. P. 8(a)(2)). A well-pleaded complaint, however, may survive a motion to dismiss even if it appears "that recovery is very remote and unlikely." *Bell Atlantic Corp.*, 550 U.S. at 555 (quoting *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)).

---

[1] Despite broad, vague, and conclusory allegations in the Complaint alleging various alleged instances of malfeasance or misfeasance, the Plaintiffs' response in opposition to the motion to dismiss reveals that, at least with respect to their claims against Actavis, the conduct complained of is Actavis' failure to warn – including the cause of such failure (*e.g.*, lack of testing) and the manner by which Actavis failed to warn consumers and physicians. *See* Dkt. 44, p. 2.

While the Court must accept all factual allegations as true in evaluating a motion to dismiss under Rule 12(b)(6), the tenet does not apply to legal conclusions. *Ashcroft*, 129 S. Ct. at 1949. Similarly, a court may dismiss a complaint on a dispositive issue of law. *Marshall County Bd. of Educ. v. Marshall County Gas Dist.*, 992 F.2d 1171, 1174 (11th Cir. 1993).

Discussion

Actavis argues that under *Mensing*, it was required to use the same label as the branded drug and was not at liberty to communicate information inconsistent with that label. As a result, Actavis contends the Plaintiffs' claims are preempted by federal law because they all arise from Actavis' alleged knowledge of certain risks and its failure to communicate those risks to consumers, the government, and the medical community.

Plaintiffs respond that they have alleged causes of action that are not preempted by federal law. Specifically, Plaintiffs argue that because Actavis did nothing to monitor the safety of metoclopramide, it was unaware of the risks the drug posed to consumers (and, as a result, took no action to correct the problems). In addition, Plaintiffs argue that *Mensing* only involved the adequacy of a drug label, not the manner in which warnings relating to a drug were communicated. Thus, Plaintiffs argue their claims based on Actavis' failure to provide physicians with any warning relating to metoclopramide, "especially in light of changes made to the label for metoclopramide in 2004 prohibiting its long-term use," are not preempted.[2]

---

[2] Plaintiffs contend in their response to the motion to dismiss that Actavis should have sent warnings to physicians consistent with the FDA approved label and packaging materials, including communications alerting them of the changes made to the label for metoclopramide in 2004. While such a claim may fall outside the scope of federal preemption, *see Brasley-Thrash v. TEVA Pharmaceuticals USA, Inc.*, Civil Action No. 10-00031-KD-N, 2011 WL 4025734, at *3 (S.D. Ala. Sept. 12, 2011) (recognizing that claims based on generic drug manufacturer's failure to provide warnings consistent with the label and packaging materials were not preempted), the Complaint lacks any allegations relating to this label change or otherwise demonstrating a causal connection between such failure to warn and Plaintiffs' injuries. In fact, the Complaint alleges that Mrs. Metz was first prescribed metoclopramide based on her doctor's review of information published in the package inserts and/or the Physicians' Desk Reference, or otherwise disseminated by Wyeth and Schwarz ***and/or*** Actavis. Complaint, ¶ 22.

In *Mensing*, consumers sued generic manufacturers of metoclopramide alleging that the generic manufacturers violated state tort law (specifically, that of Minnesota and Louisiana) by failing to provide adequate warnings to consumers, the federal government, and the medical community. The consumers alleged that "despite mounting evidence that long term metoclopramide use carries a risk of tardive dyskinesia far greater than that indicated on the label," none of the manufacturers had changed their labels to adequately warn of the danger. *Mensing*, 131 S. Ct. at 2573. Moreover, similar to the Plaintiffs' allegations in this case, the consumers in *Mensing* alleged that the manufacturers ignored scientific and medical literature establishing a higher risk of developing tardive dyskinesia, failed to request that the U.S. Food and Drug Administration (the "FDA") approve a revised label, and failed to report safety information directly to the medical community. *See Demahy v. Actavis, Inc.*, 593 F.3d 428, 430 (5th Cir. 2010); *Mensing v. Wyeth, Inc.*, 562 F.Supp.2d 1056, 1058 (D. Minn. 2008).

The manufacturers argued that because federal law required them to use the same safety and efficacy labeling as their brand-name counterparts, it was impossible to simultaneously comply with both federal law and a state tort-law duty that required them to use a different label. The Court agreed and held that federal law preempted the consumers' state law claims. *Mensing*, 131 S. Ct. at 2581. The Court based its conclusion on the fact that the manufacturers could not unilaterally strengthen their warning labels nor could they send additional warnings to prescribing physicians and other healthcare professionals advising of new information and increased risks. *Id.* at 2575-76. The Court further held that complete preemption existed even assuming that the manufacturers had a duty

to propose stronger warning labels to the FDA if they believed such warnings were needed. *Id.* at 2577.[3]

A review of the allegations in the Complaint establish that the majority, if not all, of Plaintiffs' claims are subject to federal preemption under *Mensing*. To the extent Plaintiffs argue that they have alleged claims falling outside the scope of federal preemption, the Complaint lacks factual allegations establishing that such claims are plausible on their face as required by *Twombly* and *Ashcroft.*

Negligence (Count I)

The Complaint alleges that "Defendants failed to exercise reasonable care in the design of [metoclopramide] ... [and] in the marketing of [metoclopramide] because they failed to warn that, as designed, [metoclopramide] was capable of causing serious personal injuries ... ." Complaint, ¶ 97. Specifically, the Complaint alleges Actavis was negligent because it failed to (1) exercise due care in developing, testing, designing, and manufacturing metoclopramide, (2) accompany the product with adequate warnings, (3) provide warnings, (4) conduct adequate pre-clinical and clinical testing and post-marketing surveillance, (5) provide adequate training and information to medical care providers, and (6) adequately warn consumers and medical providers. Complaint, ¶ 98.

---

[3] The consumers in *Mensing* expressly denied that their state law tort claims were based on the manufacturers' alleged failure to ask the FDA for assistance in changing the labels. *Mensing*, 131 S. Ct. at 2578. The Court hinted that this was because federal law preempted state tort-law claims based on the failure of a manufacturer to properly communicate with the FDA. *Id.* (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001)). More importantly, the Court ultimately concluded that "[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 (emphasis added). The same reasoning likely bars Plaintiffs' claims in this case to the extent they are based on Actavis' failure to notify the FDA of alleged risks associated with metoclopramide. Even if such claims were not preempted, however, the allegations in the Complaint do not establish that the failure of Actavis to petition the FDA to change the labeling requirements for metoclopramide was a proximate cause of the Plaintiffs' damages (*e.g.*, the Complaint does not allege that had Actavis timely notified the FDA and requested a labeling change that the FDA would have approved such a request).

Plaintiffs' also allege that Defendants were negligent in representing to physicians that metoclopramide was safe and effective for use. *Id.*

The Complaint contains no allegations suggesting that Actavis, as opposed to Wyeth or Schwarz designed metoclopramide, the nature of the alleged design defect, or how a design defect attributable to the metoclopramide sold by Actavis caused Plaintiffs' injuries. Similarly, given the limitation on the information Actavis could distribute to the medical community or general public in light of federal law, Plaintiffs have not alleged or established that Actavis' failure to conduct testing was the proximate cause of their injuries.[4] To the extent Count I purports to hold Actavis liable for failing to notify the FDA of risks associated with metoclopramide, the Complaint lacks factual allegations sufficient to establish that (even assuming such a duty), Actavis' failure to notify the FDA was a proximate cause of the Plaintiffs' injuries. Thus, Plaintiffs' negligence claim as to Actavis is essentially based on a failure to warn and, as alleged, is preempted by federal law.

Strict Liability (Count II)

The Complaint alleges that metoclopramide was unreasonably defective in design and that the Defendants' failure to warn consumers and/or the medical community rendered metoclopramide unreasonably dangerous and defective as marketed. Complaint, ¶ 103. The Complaint contains no allegations suggesting that Actavis, as opposed to Wyeth or Schwarz designed metoclopramide, the nature of the alleged design defect, or how a design defect attributable to the metoclopramide sold

[4] Moreover, to the extent Plaintiffs seek to assert a claim based on negligent design or testing, there are no allegations in the Complaint suggesting that their claim is a "parallel" claim as required to avoid federal preemption. *See Yost v. Stryker Corp.*, No. 2:09-cv-28-FtM-29DNF, 2010 WL 1141586, at *3 (M.D. Fla. March 23, 2010).

by Actavis caused Plaintiffs' injuries.[5] Thus, Plaintiffs' strict liability claim as to Actavis is essentially based on a failure to warn and, as alleged, is preempted by federal law.

Breach of Warranties (Count III)

The Complaint alleges that "Defendants expressly and impliedly warranted that [metoclopramide was] not unreasonably dangerous and instead [was] merchantable and fit for its intended use ... ." Complaint, ¶ 107. Thus, Plaintiffs breach of warranty claim, as alleged, falls directly within the scope of *Mensing* because it is based on Actavis' express or implied representations relating to metoclopramide – representations governed by the FDA.[6]

Misrepresentation and Fraud (Count IV)

The Complaint alleges that Defendants made material misrepresentations and omissions relating to the safety of metoclopramide and committed "constructive fraud" by breaching "one or more legal or equitable duties." Complaint, ¶¶ 109-112. Plaintiffs' claim for misrepresentation and fraud, as alleged, falls directly within the scope of *Mensing* because it is based on Actavis' purported failure to adequately warn consumers and the medical community as to the risks associated with metoclopramide. To the extent Count IV purports to hold Actavis liable for failing to notify the FDA of risks associated with metoclopramide, the Complaint lacks factual allegations sufficient to

---

[5] Unlike in a traditional strict liability action where a distributor, in addition to the manufacturer, may be liable for defects in a product, Actavis is not a distributor of metoclopramide manufactured by *Wyeth* or *Shwarz*, but rather is alleged to sell metoclopramide it itself manufactured. Moreover, to the extent Plaintiffs seek to assert a claim that the product was defective due to a design defect, there are no allegations in the Complaint suggesting that their claim is a "parallel" claim as required to avoid federal preemption. *See Yost,* 2010 WL 1141586, at *2.

[6] To the extent Plaintiffs seeks to recover under a warranty unrelated to the label and packaging materials, the Complaint fails to allege a specific statement or statements creating an express warranty. *See Yost*, 2010 WL 1141586, at *3 (M.D. Fla. March 23, 2010). Moreover, to the extent Plaintiffs seek to assert a claim based on the "unreasonably dangerous" nature of metoclopramide, there are no allegations in the Complaint suggesting that their claim is a "parallel" claim as required to avoid federal preemption. *Id.*

establish that (even assuming such a duty), Actavis' failure to notify the FDA was a proximate cause of the Plaintiffs' injuries.

Negligence Per Se (Count V)

The Complaint alleges that "[t]he product label and package insert for [metoclopramide] is misbranded within the meaning of 21 U.S.C. § 352(a) and (f) because it was false and misleading and failed to give adequate warnings and directions for use by physicians ... [and] the Defendants each had a statutory duty under 21 U.S.C. § 352(a) and (f) not to misbrand [metoclopramide]." Complaint, ¶ 116. In addition, Plaintiffs allege that Defendants knew or should have known that metoclopramide was proscribed for long-term use resulting in such use becoming an "intended use" and were therefore required to provide adequate labeling warning about the dangers associated with long-term use. *Id.* Count V falls directly within the scope of *Mensing* because it is based on Actavis' purported failure to provide an adequate label and package insert for metoclopramide.

Conclusion

Plaintiffs' claims as alleged in the Complaint are either preempted by federal law under *Mensing* or fail to state claims upon which relief may be granted. *See Ashcroft*, 129 S. Ct. at 1949-50. While the Court is doubtful that Plaintiffs can amend the Complaint to allege facts plausibly establishing that their injuries were proximately caused by conduct of Actavis that fell outside the scope of federal preemption, Plaintiffs will be given an opportunity to file an amended complaint.

Accordingly, it is **ORDERED AND ADJUDGED** that Defendant Actavis Elizabeth, LLC's Motion to Dismiss all Proceedings (Dkt. 43) is **GRANTED**. The Complaint is **DISMISSED**

without prejudice to Plaintiffs' ability to file an amended complaint within **fourteen (14) days** from the date of this Order.

DONE AND ORDERED in chambers this 19th day of October, 2011.

JAMES D. WHITTEMORE
United States District Judge

Copies to:
Counsel of Record