IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA

SUSAN SCHROCK, and STEVE SCHROCK,	)	
Plaintiffs,	)	
v.	)	Case No. CIV-08-453-M
PLIVA USA, INC., and QUALITEST PHARMACEUTICAL, INC.,	)	
Defendants.	)	

ORDER

Before the Court is defendant Qualitiest Pharmaceuticals, Inc.'s ("Qualitiest") Motion to Dismiss, or in the Alternative, Motion for Continuance, filed October 27, 2011. On November 17, 2011, plaintiffs filed their response, and on November 22, 2011, Qualitiest filed its reply. Based upon the parties' submissions, the Court makes its determination.

I. Introduction

Qualitest was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and selling of Reglan/metoclopramide ("metoclopramide"). Qualitest submitted an Abbreviated New Drug Application to the Food and Drug Administration ("FDA"), requesting permission to manufacture, market, and distribute the generic metoclopramide.

Plaintiff alleges that Qualitest failed to investigate the accuracy of its metoclopramide drug labels and relied upon the name brand manufacture and listed drug companies to review the medical literature for its metoclopramide. Plaintiff further alleges that the package insert for the metoclopramide understated the risk of acute and long-term side effects of ingesting the drug. Qualitest and other manufactures advertised metoclopramide as a safe and effective treatment of

diabetic gastroparesis, gastrophageal reflux disease, and other gastrointestinal disorders.

In March 2000, plaintiff Susan Schrock's ("Susan") physician prescribed Susan metoclopramide to treat her reflux. According to plaintiffs, Susan's physician relied upon information published in the metoclopramide's package insert and/or the Physicians' Desk Reference or information otherwise disseminated by the Reference Listed Drug company and/or New Drug Application Holder. Plaintiffs allege that Susan ingested the metoclopramide as prescribed and that Susan's long-term ingestion of the drug caused her to suffer from tardive dystonia.[1]

On April 30, 2008, plaintiffs filed their Complaint. On February 8, 2011, the Court stayed the case at bar pending review by the United Stated Supreme Court in the matters of *Demahy v. Actavis*, *Inc*., 593 F.3d 428 (5th Cir. 2010) certiorari granted no. 09-1501, and *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009), certiorari granted Nos. 09-993 and 09-1039. After granting certiorari, the Supreme Court consolidated the matters and issued its opinion styled as *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (hereafter, "*Mensing*"). Accordingly, on August 22, 2011, the Court lifted the stay in this matter.

In the Court's July 20, 2010 Order, the Court found that the statute of limitations barred plaintiffs' recovery for negligence, strict liability, gross negligence, misrepresentation, fraud, and punitive damages. Plaintiffs' sole remaining claim against Qualitest is for breach of warranties.

II. Standard

Regarding the standard for determining whether to dismiss a claim pursuant to Rule 12(b)(6), the United States Supreme Court has held:

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[1]Tardive dystonia is a debilitating neurological disorder characterized by involuntary and uncontrollable movements of the head, neck, face, arms, legs and trunk. There is no cure for tardive dystonia.

> 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. 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. Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief.

Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009) (internal quotations and citations omitted). Further, "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged - but it has not shown - that the pleader is entitled to relief." *Id.* (internal quotations and citations omitted). Additionally, "[a] pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do. Nor does a complaint suffice if it tenders naked assertion[s] devoid of further factual enhancement." *Id*. at 1949 (internal quotations and citations omitted).

III. Discussion

In *Mensing*, the Supreme Court concluded that federal drug regulations prevented generic manufacturers from independently changing their safety and efficacy labels. *Mensing*, at 2577. Further, the Supreme Court specifically held that federal drug regulations preempted a state law imposed duty to provide an adequate and safe warning label. *Id.* at 2581. The Supreme Court further opined:

> [W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes.
>
> Here, state law imposed a duty on the Manufacturers to take a certain

> action, and federal law barred them from taking that action. The only action the Manufacturers could independently take—asking for the FDA's help—is not a matter of state-law concern.

Id. In light of the Supreme Court's decision in *Mensing*, plaintiffs' breach of warranties claim is preempted by federal drug regulations. The gravamen of plaintiffs' breach of warranties claim alleges that "[d]efendants marketed and promoted their [metoclopramide] as safe and efficacious for its intended uses . . . . Defendants expressly and impliedly warranted that the [metoclopramide] were not unreasonably dangerous and instead were merchantable and fit for its intended use . . . ." Plaintiff's First Amended Complaint [docket 228], at ¶ 4.08. Based upon the *Mensing* decision, plaintiffs' breach of warranties claim is preempted because federal regulations bar Qualitest from independently changing its safety and efficacy labels; Qualitest's only independent action was asking for the FDA's help. Therefore, Qualitest could not satisfy its state law imposed duty for preemption purposes.

Accordingly, the Court should dismiss this matter as plaintiffs' breach of warranties claim is preempted.

IV. Conclusion

For the reasons set forth above, the Court GRANTS Qualitest's Motion to Dismiss, or in the Alternative, Motion for Continuance [docket no. 315] and DISMISSES plaintiffs' claim against Qualitest.

IT IS SO ORDERED this 8th day of December, 2011.

VICKI MILES-LaGRANGE
CHIEF UNITED STATES DISTRICT JUDGE