IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION

SHIRLEY GROSS, Plaintiff, v. PFIZER, INC., *et. al*, Defendants.	Civil Action No. 10-cv-00110-AW

MEMORANDUM OPINION

Pending before the Court is Defendant Pliva USA, Inc. ("PLIVA")'s motion for judgment on the pleadings pursuant to Rule 12 of the Federal Rules of Civil Procedure. *See* Doc. No. 83. The Court has reviewed the motions and all supporting documents and finds no hearing is necessary. *See* Md. Loc. R. 105.6 (D. Md. 2010). For the reasons articulated below, the Court grants Defendant's motion.

I. FACTUAL & PROCEDURAL BACKGROUND

Plaintiff filed this action as a result of injuries she suffered from ingesting the prescription drug metoclopramide. Plaintiff stipulates that the drugs she consumed are a generic form of metoclopramide manufactured by Defendant PLIVA, and that she did not ingest any metoclopramide product manufactured by Pfizer, Wyeth or Schwarz. *See* Doc. No. 54. Plaintiff nonetheless filed suit against Defendants Pfizer, Wyeth, and Schwarz, who manufactured the brand-name form of metoclopramide, on theories of negligence, breach of warranty, strict

product liability, and misrepresentation. The Court dismissed Plaintiff's claims against the brand-name manufacturers because Maryland law only allows drug defect claims to proceed against the manufacturer whose drug allegedly caused the injury; in this case, the generic manufacturer PLIVA. *See* Doc. No. 63.

On April 7, 2011, the Court stayed proceedings against PLIVA pending the Supreme Court's decision in a collection of lawsuits addressing claims against generic manufacturers based on similar facts. On June 23, 2011, the Supreme Court decided *Pliva, Inc. v. Mensing*, 564 U.S. - - -, 131 S.Ct. 2567, 180 L.Ed.2d 580 (2011) (*reh'g denied*). In *Mensing*, the Supreme Court considered a state law tort claim based on the alleged failure of a manufacturer to provide adequate warning labels for generic metoclopramide. 131 S.Ct. at 2572. Under the Food and Drug Administration ("FDA") regulations, generic drug manufactures are required to make their warning labels identical to those provided by the brand-name manufacturers. *Id.* at 2577. Because FDA regulations do not allow generic manufacturers to independently change or strengthen their product labeling, the Court found that it would be impossible for a generic manufacturer to comply with both federal law and state tort law. *Id.* at 2578. As a result, the Court held that the federal regulations preempt state law failure to warn claims, reversing decisions by the Fifth and Eighth Circuit Courts of Appeals which had found otherwise. *Id.*

After the *Mensing* decision, Plaintiff filed a motion in the instant action to alter or amend the Court's entry of final judgment in favor of brand-name manufacturer Defendants as well as a motion to lift stay. *See* Doc. Nos. 74, 76. The Court denied Plaintiff's motion to reconsider its judgment in favor of the brand-name manufacturers but granted her motion to lift stay for the limited purpose of allowing the parties to brief the Court on the impact of the *Mensing* decision. *See* Doc. No. 80. Accordingly, PLIVA filed the present motion for judgment on the pleadings.

See Doc. No. 83. PLIVA argues that, after *Mensing*, Plaintiff's state-law claims against PLIVA are preempted. For the reasons discussed below, the Court agrees.

II. STANDARD OF REVIEW

A Rule 12 motion should be granted when, viewing the allegations in the complaint as true, including all inferences which may reasonably be drawn from the facts alleged, the complaint fails to state a claim upon which relief may be granted. *See Brockington v. Boykins*, 637 F.3d 503, 505-06 (4th Cir. 2011). Although the court should accept as true all well-pleaded allegations and should view the complaint in a light most favorable to the plaintiff, the Court should not accept unsupported legal allegations, *Revene v. Charles Cnty. Comm'rs*, 882 F.2d 870, 873 (4th Cir. 1989), "legal conclusion[s] couched as . . . factual allegation[s]," *Papasan v. Allain*, 478 U.S. 265, 286 (1986), or conclusory factual allegations devoid of any reference to actual events, *United Black Firefighters of Norfolk v. Hirst*, 604 F.2d 844, 847 (4th Cir. 1979).

In resolving a motion to dismiss, the court should proceed in two steps. First, the court should determine which allegations in the complaint are factual allegations entitled to deference, and which are mere legal conclusions that receive no deference. *See Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949-50 (2009). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* at 1949. Second, "[w]hen there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Id.* at 1950.

III. ANALYSIS

The question before the Court is to what extent, if any, do Plaintiff's claims survive the Supreme Court's preemption ruling in *Mensing*. *Mensing* precludes consumer suits against generic manufacturers based on failure to warn claims. The Court in *Mensing* reasoned that generic manufacturers are unable to strengthen or change their warning labels under federal law, which requires that generic manufacturers make their warning labels identical to those provided by the brand manufacturer of the drug. 131 S.Ct. at 2578. The Court therefore found that federal law preempts state law tort claims attacking the sufficiency of the warning label on a generic drug. *Id.*

Defendant PLIVA argues that *Mensing* disposes of Plaintiff's state law tort claims, all of which are based on inadequate warnings. Plaintiff's claims attack the sufficiency of the warnings provided by PLIVA under state law. According to PLIVA, these are precisely the types of claims that *Mensing* held were preempted by federal law. However, Plaintiff contends that *Mensing* only preempted failure to warn claims involving the inadequacy of the warning PLIVA provided on its metoclopramide label, whereas Plaintiff has additionally alleged that: (1) PLIVA was negligent in selling its drug with a label that contained false information and lacked adequate instructions for use; (2) for failing to test and inspect its products; (3) for selling a product that was not fit for the purpose for which it was sold; (4) for concealing important safety information regarding its drugs; and (5) for placing an unreasonably dangerous product into the stream of commerce. While acknowledging "the unfortunate hand that federal drug regulation has dealt" Plaintiff as a consumer of a generic drug, *id.* at 2581, the Court finds that *Mensing* disposes of all these claims. The Court will proceed to address each of these allegations below.

A. Negligence for Continuing to Sell Metoclopramide

While Plaintiff acknowledges that her claims relating to PLIVA's inadequate labeling of metoclopramide are preempted after *Mensing*, she contends that her claims attacking PLIVA's continued sale of metoclopramide remain. Specifically, Plaintiff argues she has surviving claims that PLIVA was negligent for continuing to sell metoclopramide with an inadequate label, for continuing to sell a product that was not fit for the purpose for which it was sold, and for continuing to place an unreasonably dangerous product into the stream of commerce.

As an initial matter, under Maryland law Plaintiff's product liability claims must be based on a design defect, a manufacturing defect, or a failure to warn. *See Simpson v. Standard Container*, 527 A.2d 1337, 1339 (1987). Plaintiff has not stated a claim for a manufacturing defect, and this Court has found that "[d]esign defect claims are generally incompatible with actions concerning prescription medications because these medications are thought to be 'unavoidably unsafe.'" *King v. Pfizer Pharm. Co., Inc.*, No. RWT 11cv00127, 2011 WL 3157305, at *2 (D. Md. Jul. 25, 2011) (citation omitted). Thus, by process of elimination Plaintiff's claims attacking PLIVA's continued sales of metoclopramide must relate to PLIVA's alleged failure to warn consumers and physicians about the dangers of the drug.

The very arguments Plaintiff contends survive *Mensing* were adopted by the Eighth Circuit in *Mensing v. Wyeth, Inc.*, and later rejected by the Supreme Court in *Mensing*. Finding in favor of the Plaintiff-consumer in *Wyeth*, the Eighth Circuit reasoned that the "generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product. Instead, they are alleged to have placed a drug with inadequate labeling on the market and profited from its sales." *Wyeth*, 588 F.3d 603, 611 (8th Cir. 2009).

The Supreme Court rejected this reasoning on appeal and denied a rehearing despite the contentions of Respondents that the Supreme Court had "overlook[ed] the fact that the Petitioners could have 'independently' complied with both state and federal law simply by suspending sales of generic metoclopramide with warnings that they knew or should have known where inadequate." Respondents' Petition for Rehearing at 1, *Pliva, Inc. v. Mensing*, 131 S.Ct. 2567 (2011), Nos. 09-993, 09-1039, 09-1501, 2011 WL 2874547, at *1. Moreover, the Sixth Circuit considered the same argument in the plaintiff's supplemental brief to the court after the *Mensing* decision, and though it did not address it specifically, the court ruled that *Mensing* barred Plaintiff's state-law claims. *See Smith v. Wyeth, Inc.*, 657 F.3d 420, 423 (6th Cir. 2011).

Accordingly, the Court finds unavailing Plaintiff's argument that PLIVA could have simply stopped manufacturing metoclopramide and thus avoided violating either federal or state law. The Court is aware of no state law duty that would compel generic manufacturers to stop production of a drug that under federal law they have the authority to produce. Nor could such a state law duty exist, as it would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be marketed in interstate commerce. *See* 21 U.S.C. § 301 *et seq*. For all these reasons, the Court finds that Plaintiff's negligence claims based on PLIVA's continued sale of metoclopramide fail under *Mensing*.

B. Negligence for Concealing Important Safety Information

Plaintiff contends that its negligence claim based on PLIVA's alleged concealment of important safety information about metoclopramide survives *Mensing*. The Court disagrees. To the extent Plaintiff claims that PLIVA could have revealed safety information by adding to or

changing the metoclopramide label, her claims are clearly preempted by *Mensing*. To the extent Plaintiff claims that PLIVA should have revealed information to the FDA regarding the dangers of metoclopramide, her claims are also preempted. The Court in *Mensing* addressed arguments that generic pharmaceutical companies had a duty to ask the FDA to add to or strengthen the labeling for metoclopramide. The Court found that "[t]he federal duty to ask the FDA for help in strengthening the corresponding brand-name label, assuming such a duty exists, does not change this [preemption] analysis." 131 S.Ct. at 2578 (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001)). The Court additionally found that "federal law did not permit [generic drug] Manufacturers to issue additional warnings through Dear Doctor letters." *Id.* at 2576 (citations and internal quotation marks omitted). Accordingly, Plaintiff's claims based on PLIVA's alleged concealment of safety information are preempted under *Mensing*.

C. Negligence for Failing to Test and Inspect PLIVA's Products

Plaintiff contends that her allegation that PLIVA failed to test and inspect its products survives *Mensing*. The Court fails to see how these allegations are but a piece of Plaintiff's larger failure to warn claims. Accordingly, *Mensing* preempts these allegations as they relate to Plaintiff's failure to warn claims.

D. Plaintiff's Request to Amend Complaint to Allege Additional Facts

Finally, Plaintiff requests the opportunity to amend her complaint to allege additional facts relating to PLIVA's failure to include important warnings added to the labeling for metoclopramide in 2004. Specifically, Plaintiff contends that PLIVA's metoclopramide label differed from the brand-name label, which in July 2004 added to the already-existing language:

"Therapy longer than 12 weeks has not been evaluated and cannot be recommended," the statement: "Therapy should not exceed 12 weeks in duration."

However, Plaintiff does not claim that the alleged failure of PLIVA to update its label gives rise to any cause of action under Maryland law; nor is the Court aware of any such cause of action. Additionally, Plaintiff has consistently claimed that all warnings issued before 2009 relating to metoclopramide, including the brand-name warnings stating that "Therapy should not exceed 12 weeks in duration", were inadequate. *See* Compl.

Moreover, the weight of authority suggests that such claims are unavailing after *Mensing*. Identical arguments were made by plaintiffs in supplemental briefings to the Sixth and Eighth Circuits, and both courts nevertheless dismissed the plaintiffs' claims based on preemption under *Mensing*. *See* Doc. No. 85 Ex. 1 at 5; Ex. 2 at 4. The issue was also brought to the Supreme Court's attention by PLIVA's counsel before oral arguments were held in *Mensing*. *See* Doc. No. 85 Ex. 5 (letter from PLIVA's counsel informing the Supreme Court that "at least some of PLIVA's post-2004 labels do not include th[e] change."). Accordingly, the Court declines to allow Plaintiff to amend her complaint to allege additional facts relating to PLIVA's failure to implement the label change.

In dismissing Plaintiff's state-law tort claims against PLIVA, the Court joins a growing number of courts which, in the wake of *Mensing*, have dismissed similar lawsuits against generic drug manufacturers. *See*, *e.g.*, *Stevens v. Pliva, Inc.*, Civ. No. 6:10-0886 (W.D. La. Nov. 15, 2011) (Doc. No. 85 Ex. G at 3-6) (dismissing failure to warn and design defect claims under *Mensing*); *In re: Accutane Prod. Liab.*, MDL 1626 (M.D Fla. Nov. 9, 2011) (Doc. No. 85 Ex. I) (dismissing claims that, *inter alia*, defendant-pharmacy sold a product that was not fit for the purposes intended and did not conduct a proper investigation, based on *Mensing*); *Richardson v.*

Wyeth Inc., No. 10-0883, 2011 WL 5402184, at *2 (W.D. La. Oct. 20, 2011) (dismissing plaintiff's failure to warn claims under *Mensing*); *Guarino v. Wyeth LLC*, No. 8:10-cv-2885 (M.D. Fla. Nov. 7, 2011) (Doc. No. 85 Ex. K at 5) (dismissing claims that generic manufacturer's label was "inaccurate, misleading, materially incomplete, false and otherwise inadequate" and that manufacturer failed to send Dear Doctor letters to prescribing physicians, under *Mensing*); *Morris v. Wyeth, Inc.*, No. 3:09-CV-854, 2011 WL 5024448, at *1 (M.D. Fla. Oct. 20, 2011) (dismissing plaintiff's claims against generic drug manufacturer for negligence, strict liability, breach of warranties, misrepresentation, fraud, and negligence *per se*, under *Mensing*).

Like the Court in *Mensing*, this Court "acknowledge[s] the unfortunate hand that federal drug regulation has dealt" Plaintiff as a consumer of generic metoclopramide. As Justice Sotomayor noted in her dissent,

> [A] drug consumer's right to compensation for inadequate warnings now turns on the happenstance of whether her pharmacist filled her prescription with a brand-name drug or a generic. If a consumer takes a brand-name drug, she can sue the manufacturer for inadequate warnings under our opinion in *Wyeth* [*v. Levine*, 555 U.S. 555 (2009)]. If, however, she takes a generic drug, as occurs 75 percent of the time, she now has no right to sue.

131 S.Ct. at 2592. Accordingly, federal drug regulations have foreclosed Plaintiff's means of seeking a judicial remedy in the instant action, and legislative action remains as the most appropriate means of redress at this juncture.

IV. CONCLUSION

For the foregoing reasons, the Court grants Defendant's motion for judgment on the

pleadings. An Order will follow.

November 22, 2011
Date

/s/
Alexander Williams, Jr.
United States District Judge