IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

JOYCE FULLINGTON PLAINTIFF

v. No. 4:10CV00236 JLH

PLIVA, INC., formerly known as
Pliva USA, Inc.; and MUTUAL
PHARMACEUTICAL COMPANY, INC. DEFENDANTS

OPINION AND ORDER

After taking the prescription drug metoclopramide for some time, Joyce Fullington developed tardive dyskinesia. She brought this action against the manufacturers of the brand-name form of metoclopramide, as well as the manufacturers of the generic form. The Court previously granted summary judgment in favor of the brand-name metoclopramide manufacturers because it is undisputed that Fullington did not use their product. Thereafter, the Supreme Court held that state-law causes of action alleging that the generic manufacturers of metoclopramide failed to give adequate warnings are preempted by federal law. *PLIVA, Inc. v. Mensing*, --- U.S. ---, 131 S. Ct. 2567, 2572-73, 180 L. Ed. 2d (2011). Fullington has now moved for reconsideration of the order dismissing the brand-name manufacturers, and the generic manufacturers have moved to dismiss the action pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. For the following reasons, the generic manufacturers' motion to dismiss is granted, while Fullington's motion for reconsideration as to the brand-name manufacturers is denied.

I.

Before marketing and distributing a brand-name prescription drug, the Food, Drug, and Cosmetic Act requires the pharmaceutical manufacturer, or "innovator," who produced the drug to obtain regulatory approval from the U.S. Food and Drug Administration by submitting a New Drug

Application. 21 U.S.C. § 355(a)-(i) (2010). This application must contain, *inter alia*, safety information, efficiency information, and a proposed label reflecting appropriate use, warnings, precautions, and adverse reactions. *Id.* at §§ 355(b), (d); *see also* 21 C.F.R. § 201.56. After the application is approved, the innovator has the exclusive right to market the drug for a certain period of time, after which other manufacturers may market generic versions of the drug if approval has been obtained. Since the adoption of the Hatch-Waxman Amendments to the Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), a generic manufacturer may choose to submit only an Abbreviated New Drug Application, which does not require independent evidence of safety or efficacy. 21 U.S.C. § 355(j). Instead, the generic manufacturer must establish, *inter alia*, that the generic drug has enough of the same active ingredients to be "bioequivalent" to the brand-name drug, and that the generic drug has essentially the same proposed label as the brand-name drug. *Id*. at § 355(j)(2)(A).

Metoclopramide was approved by the FDA in 1980 to treat ailments such as acid reflux disease and diabetic gastroparesis. The drug has been available in both brand-name and generic form since 1985. At different times, Wyeth LLC, Schwarz Pharma, Inc., and Alaven Pharmaceutical LLC manufactured and distributed "Reglan," the brand-name form of the drug.[1] PLIVA, Inc. and Mutual Pharmaceutical Company have manufactured generic metoclopramide since the mid-1980s. Pfizer Inc. never manufactured or distributed Reglan and was joined solely in its capacity as the parent company of Wyeth.

[1] Wyeth manufactured and distributed Reglan from 1989 through December 2001. Schwarz acquired from Wyeth the rights to Reglan in December 2001 and manufactured and distributed it until 2008. In 2008, Alaven acquired the rights to Reglan from Schwarz, and it currently manufactures the drug.

As the Supreme Court explained in *Mensing*:

> Evidence has accumulated that long-term metoclopramide use can cause tardive dyskinesia, a severe neurological disorder. . . . Accordingly, warning labels for the drug have been strengthened and clarified several times. In 1985, the label was modified to warn that "tardive dyskinesia . . . may develop in patients treated with metoclopramide," and the drug's package insert added that "[t]herapy longer than 12 weeks has not been evaluated and cannot be recommended." In 2004, the brand-name Reglan manufacturer requested, and the FDA approved, a label change to add that "[t]herapy should not exceed 12 weeks in duration." And in 2009, the FDA ordered a black box warning—its strongest—which states: "Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. . . . Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases."

Mensing, 131 S. Ct. at 2572-73 (internal citations omitted).

Fullington's claims are based upon the assertion that the defendants failed to give adequate and accurate warnings to her or the medical community of the known or apparent risks associated with metoclopramide's long-term use. Fullington ingested only generic metoclopramide; she did not ingest any metoclopramide manufactured or distributed by brand-name defendants Wyeth, Pfizer, Schwarz, or Alaven. Because Fullington did not use their product, the Court granted summary judgment in favor of these brand-name defendants. At the parties' request, the Court stayed the remaining claims in anticipation of the Supreme Court's consolidation and consideration of several cases, including an Eighth Circuit opinion, that could control relevant preemption issues.

On June 23, 2011, the Supreme Court released its decision in *Mensing*. Soon after, this Court lifted the stay and the generic manufacturers moved to dismiss. Fullington opposed the motion to dismiss and, as noted, moved for reconsideration of the summary judgment in favor of the brand-name manufacturers.

II. THE GENERIC MANUFACTURERS' MOTION TO DISMISS

The pleading standards, and the correlative standards for ruling on a motion to dismiss under Rule 12(b)(6), are well known. A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). While Rule 8(a)(2) does not require a complaint to contain detailed factual allegations, it does require a plaintiff to state the grounds of his entitlement to relief, which requires more than labels and conclusions. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 1964-65, 167 L. Ed. 2d 929 (2007). In ruling on a motion to dismiss, the Court must accept as true all factual allegations in the complaint and review the complaint to determine whether its allegations show that the pleader is entitled to relief. *Schaaf v. Residential Funding Corp.*, 517 F.3d 544, 549 (8th Cir. 2008). All reasonable inferences from the complaint must be drawn in favor of the nonmoving party. *Crumpley-Patterson v. Trinity Lutheran Hosp.*, 388 F.3d 588, 590 (8th Cir. 2004). The Court need not, however, accept as true legal conclusions, even those stated as though they are factual allegations. *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1949-50, 173 L. Ed. 2d 868 (2009).

State law that conflicts with federal law is preempted under the Constitution's Supremacy Clause. *See* U.S. Const., art. VI, cl. 2; *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372, 120 S. Ct. 2288, 2294, 147 L. Ed. 2d 352 (2000). Congressional intent to preempt state law is the "ultimate touchstone" of preemption analysis and may be expressed in statutory language or implied in the structure and purpose of federal law. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516, 112 S. Ct. 2608, 2617, 120 L. Ed. 2d 407 (1992). One form of implied preemption is conflict preemption, which means "state law is preempted if that law actually conflicts with federal law . . . ." *Id.* (citation omitted). Conflict preemption can be further broken down into categories, one

of which is impossibility preemption, which occurs when compliance with both state and federal law is impossible. *Crosby*, 530 U.S. at 372-73, 120 S. Ct. at 2294. The burden of proving impossibility preemption is demanding, falling entirely on the defendant. *Wyeth v. Levine*, 555 U.S. 555, 573, 129 S. Ct. 1187, 1199, 173 L. Ed. 2d 51 (2009).

In *Mensing*, the Supreme Court decided two cases in which consumers had sued generic metoclopramide manufacturers for violating state tort law by failing to provide adequate warnings of the drug's risks. Much like Fullington, the *Mensing* plaintiffs alleged that the generic manufacturers, *inter alia*, failed to report sufficient safety information on the label or 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). In response, the *Mensing* defendants argued that they could not simultaneously comply with both federal and state law because, assuming the allegations of inadequate warnings were true, state tort law required them to use a different label, while federal law required them to use the same label as the brand-name product. The Supreme Court agreed and held that the claims under state tort law were preempted because it was impossible for the defendants to comply with both state and federal law. *Mensing*, 131 S. Ct. at 2581. The Court explicitly grounded its conclusion on the fact that generic manufacturers would break federal law if they unilaterally changed warning labels or sent additional warnings to the medical community by way of "Dear Doctor" letters. *Id.* at 2575-76. The Court emphasized that the claims under state tort law were preempted regardless of whether manufacturers had a duty to propose stronger warning labels to the FDA. *Id.* at 2577. Even if such a duty existed, the Court opined, generic manufacturers would still be reliant on a third party, and the "question for 'impossibility'

is whether the private party could independently do under federal law what state law requires of it." *Id.* at 2579.

In their motion to dismiss, generic defendants PLIVA and Mutual argue that *Mensing* is directly on point because it involved the same medication, injuries, basic claims, and even some of the same parties as the present action. *Mensing*, they assert, holds that all claims under state tort law against generic drug manufacturers based on an alleged failure to warn are preempted because the manufacturers cannot comply with federal law barring generic manufacturers from additional warnings and with state law requiring additional warnings. In response, Fullington argues that *Mensing* is narrow because the Supreme Court only ruled concerning the specific content of drug labels, and at least some of her claims survive because they do not concern drug labeling.

In *Mensing*, the Supreme Court held that federal law preempts "state tort-law claims based on certain drug manufacturers' alleged failure to provide adequate warning labels for generic metoclopramide." *Id.* at 2572. The Supreme Court also said in *Mensing* that federal law did not permit generic manufacturers "to issue additional warnings through Dear Doctor letters" because the FDA viewed such warnings as "labeling." *Id.* at 2576. Thus, *Mensing*'s preemption coverage, even if restricted to "labeling," extends beyond the actual paper attached to the bottle.[2] That the holding of *Mensing* encompasses all failure-to-warn claims against generic manufacturers has been

[2] The relevant statutes and regulations also contain a remarkably broad definition of labeling. *See* 21 C.F.R. 202.1(l)(2) ("Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published . . . for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling as defined in section 201(m) of the act.").

recognized in a plethora of subsequent lower court cases that have considered the decision. *See, e.g.*, *Smith v. Wyeth, Inc.*, 657 F.3d 420, 423 (6th Cir. 2011) (affirming, based on *Mensing*, a district court's conclusion that "state-law failure-to-warn claims against the generic defendants were preempted by federal law"); *Guarino v. Wyeth LLC*, --- F. Supp. 2d ---, 2011 WL 5358709, at *3 (M.D. Fla. Nov. 7, 2011) ("In short, any state-law claim involving a generic drug label or warning is preempted and must be dismissed with prejudice under *Mensing*."); *Metz v. Wyeth*, No. 8:10-CV-2658, 2011 WL 5024448, at *4 (M.D. Fla. Oct. 20, 2011) (dismissing metoclopramide claims based on a "purported failure to adequately warn consumers and the medical community" because of *Mensing*); *Morris v. Wyeth, Inc.*, No. 3:09-CV-854, 2011 WL 4973839, at *2 (W.D. La. Oct. 19, 2011) ("In *Mensing*, the Supreme Court held that federal law governing labeling of pharmaceuticals preempts state law failure to warn claims."); *Guilbeau v. Wyeth Inc.*, No. 09-1652, 2011 WL 4948996, at *1 (W.D. La. Oct. 14, 2011) (noting that *Mensing* held that "state-law tort claims based on an alleged failure to warn of the risks of generic medications are preempted by federal law"); *Fisher v. Pelstring*, --- F. Supp. 2d ---, 2011 WL 4552464, *1 (D.S.C. Sept. 30, 2011) (noting that *Mensing* "considered the issue of federal preemption of state-law failure to warn claims involving generic drug manufacturers"); *Schork v. Baxter Healthcare Corp.*, No. 4:10-cv-00005, 2011 WL 4402602, at *3 (S.D. Ind. Sept. 22, 2011) (noting that the Supreme Court in *Mensing* "found that state law claims against manufacturers of generic drugs for failure to warn are preempted by federal law"); *Couick v. Wyeth, Inc.*, No. 3:09CV210, 2011 WL 5826020, *2 (W.D.N.C. Aug. 12, 2011) (noting that the Supreme Court in *Mensing* "held that state law failure to warn claims are preempted . . . ."). The interpretation of *Mensing* by these lower courts coincides with that of the four dissenting Supreme Court justices. *See Mensing*, 131 S. Ct. at 2582 (Sotomayor, J., dissenting,

joined by Ginsburg, Breyer, and Kagan, JJ.) (noting that the majority held "that federal law immunizes generic-drug manufacturers from all state law failure-to-warn claims . . . .").[3]

In her complaint, Fullington asserts claims for relief under Arkansas law for strict liability, negligence, gross negligence, fraudulent misrepresentation, negligent misrepresentation, fraudulent concealment, and breach of the implied warranties of merchantability and fitness for a particular purpose. The factual allegations as to wrongdoing by the generic manufacturers are contained in paragraphs 6.41 through 6.56 of the complaint. All of those allegations are allegations that the generic manufacturers provided inadequate or inaccurate information regarding the harm that metoclopramide may cause. Thus, all of Fullington's claims against the generic manufacturers depend on her failure-to-warn allegations. *See Morris*, 2011 WL 4973839 at *3 (recognizing that defective design, breach of express warranty, and defective construction/composition claims were failure-to-warn claims because the factual allegations only covered a failure to warn); *Metz*, 2011 WL 5024448 at *1 n.4 (recognizing negligence, strict liability, warranty, misrepresentation, fraud, and negligence *per se* claims as essentially failure-to-warn claims); *Guarino*, 2011 WL 5358709 at *2 (dismissing negligence, strict liability, warranty, misrepresentation, and fraud claims as "on their face, premised on an allegedly inadequate warning").

While products liability law in Arkansas encompasses claims for relief other than failure to warn, Fullington has not adequately pled any such claims. Arkansas recognizes three types of product defects – manufacturing defects, design defects, and inadequate warnings. *West v. Searle*

[3] Notably, while the *Mensing* majority interacts with various arguments put forth by the dissent, it does not rebut this or similar statements. On the contrary, the majority states that it "acknowledge[s] the unfortunate hand that federal drug regulation has dealt Mensing, Demahy, and others similarly situated." *Id.* at 2581.

& Co., 305 Ark. 33, 37, 806 S.W.2d 608, 610 (1991). In her complaint, Fullington mentions once, in passing, that unspecified defendants[4] failed to use due care in manufacturing metoclopramide. *See* Original Comp., ¶ 7.01. This conclusory allegation, unsupported by any factual allegations, is not enough to state a manufacturing defect claim. *See Ashcroft*, 129 S. Ct. at 1949-50 (noting that "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice"). Fullington's allegations of design defect are also conclusory. *See, e.g.*, Pl.'s Original Comp., ¶ 7.01 ("These Defendants failed to exercise reasonable care in the design of Reglan/metoclopramide because as designed, it was capable of causing serious personal injuries such as those suffered by Ms. Fullington during foreseeable use . . . ."); *id.* at ¶ 7.06 ("Reglan/metoclopramide was unreasonably defective in design and marketing, considering the utility of the product and the risk involved in its use, because as designed and marketed, Reglan/metoclopramide could cause injuries such as those suffered by Ms. Fullington during foreseeable use."). The complaint makes no factual allegations that PLIVA or Mutual, as opposed to the brand-name manufacturers, actually designed metoclopramide; it makes scarcely any allegations describing the nature of any alleged design defect; and it makes no allegations as to how any design defect caused Fullington's injuries. To the extent that these allegations allege a design defect in addition to a failure to warn, they fail under *Ashcroft*.

Fullington argues that the defendants are liable for failing to notify Fullington or her physicians about the existence of the 2004 label change to metoclopramide approved by the FDA, as is required. She cites a letter from PLIVA's counsel to the Supreme Court in the *Mensing* case

[4] The complaint makes separate factual allegations against the brand-name manufacturers and the generic manufacturers, the "claims for relief" sections of the complaint refer to "the Defendants" without specifying which defendants are alleged to have committed which tort.

as evidence that PLIVA has admitted this failure. *See* Document #64-3. The Court need not decide whether such a claim is preempted because Fullington did not allege such a claim in her complaint, nor did she allege that she ingested metoclopramide during the relevant period when PLIVA and brand-name labels were different.

Finally, Fullington contends that impossibility preemption does not apply because the generic manufacturers could have complied with both state and federal law by simply pulling the drug off the market entirely. While the Eighth Circuit in *Mensing* agreed with this argument, *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (8th Cir. 2009), the Supreme Court reversed the Eighth Circuit's judgment in *Mensing*. The Eighth Circuit then vacated the portions of its *Mensing* opinion that addressed preemption, including the section adopting the argument that impossibility preemption did not apply because the manufacturers could pull the drug from the market. *Mensing v. Wyeth*, 658 F.3d 867 (8th Cir. 2011). Thus, Fullington's argument has been overruled. The final result in *Mensing* was dismissal of the claims against the generic manufacturers of metoclopramide as preempted by federal law. The result will be the same here.

III. FULLINGTON'S MOTION FOR RECONSIDERATION

Fullington requests relief from the Court's order granting summary judgment to the brand-name defendants, citing Federal Rule of Civil Procedure 60(b)(5). Rule 60(b) states the grounds for relief from "a final judgment, order, or proceeding." The order that granted summary judgment in favor of the brand-name manufacturers was not a final judgment or order. *See Porter v. Williams*, 436 F.3d 917, 919 (8th Cir. 2006) ("Generally, partial summary judgments are not final . . . ."). That order did not adjudicate all of Fullington's claims against all of the defendants. Any decision "that adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties . . . may

be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities." Fed. R. Civ. P. 54(b). Therefore, the Court will consider Fullington's motion as a motion for reconsideration of the order granting summary judgment to the brand-name manufacturers without regard to the strictures of Rule 60(b).

The decision to grant summary judgment in favor of the brand-name manufacturers was based on Arkansas law. Arkansas law, like the law of most states, provides that a plaintiff in a products liability action must plead and prove that he used the defendant's product. *See Fullington v. Pfizer*, No. 4:10CV00236, 2010 WL 3632747 (E.D. Ark. Sept. 17, 2010). Nothing in *Mensing* purported to overrule this principle of state law, nor would the United States Supreme Court have the authority to overrule such a principle of state law in the absence of a conflict between state law and federal law. Nothing in federal law requires states to permit plaintiffs in products liability actions to recover from suppliers or manufacturers whose product the plaintiff did not use. In its original opinion in *Mensing*, the Eighth Circuit upheld the dismissal of the brand-name manufacturers because the plaintiff did not ingest their product. *Mensing*, 588 F.3d at 612-14. The court did so because "[t]raditional products liability requires a plaintiff to show that she actually consumed the defendant's product." *Id*. at 612 (citing *Bixler by Bixler v. Avondale Mills*, 405 N.W.2d 428 (Minn. App. 1987). Although the Eighth Circuit vacated the remainder of its opinion after the Supreme Court's decision in *Mensing*, it did not vacate this section. *See Mensing v. Wyeth*, 658 F.3d 867 (8th Cir. 2011). Because that portion of the Eighth Circuit's opinion in *Mensing* was based on Minnesota law, we may infer that the Eighth Circuit did not construe the Supreme Court's *Mensing* opinion to overrule the principle of state law providing that a manufacturer of a product

cannot be held liable to a consumer who did not use that manufacturer's product. The motion for reconsideration is denied.

CONCLUSION

For the reasons stated, defendants PLIVA, Inc., and Mutual Pharmaceutical Company, Inc.'s joint motion to dismiss is granted. Document #62. Fullington's claims against PLIVA, Inc., and Mutual Pharmaceutical Company, Inc., are dismissed without prejudice pursuant to Fed. R. Civ. P. 12(b)(6). Plaintiff's motion for relief from judgment is denied. Document #65.

Fullington may file a motion for leave to amend, with a proposed amended complaint attached as required by Local Rule 5.5(e), within twenty-one days from the entry of this order. If she fails to do so, the court will assume that she has decided to rest on her original complaint, so the Court then will enter a final and appealable judgment. If she moves for leave to amend, the defendants may file briefs opposing the motion pursuant to Local Rule 7.2(a).

IT IS SO ORDERED this 12th day of December, 2011.

J. LEON HOLMES
UNITED STATES DISTRICT JUDGE