UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

COLLEEN AND STEVE LYMAN Plaintiffs, v. PFIZER, INC., WYETH, INC., SCHWARZ PHARMA, INC., TEVA PHARMACEUTICALS USA, INC., PLIVA USA, INC., ACTAVIS-ELIZABETH, L.L.C. Individually and as a subsidiary of ACTAVIS, INC. and as successor TO PUREPAC PHARMACEUTICAL, INC, Defendants.	:	Case No. 2:09-cv-262

Opinion and Order

Plaintiffs Colleen and Steve Lyman have brought suit against the brand name and generic manufacturers of metoclopramide for injuries arising from Colleen Lyman's ingestion of the drug. They allege that the medication caused her to develop tardive dyskinesia, a severe neurological disorder causing involuntary repetitive tic-like movements. Following the United States Supreme Court's decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), Defendants Actavis Elizabeth LLC and PLIVA, Inc. (collectively "Generic Defendants") have moved for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c), contending that all claims against them are preempted by federal law. For the reasons that follow, the motion, ECF No. 182, is **granted in part and denied in part**.

I. Background

The Food and Drug Administration ("FDA") approved metoclopramide in tablet form for the treatment of gastrointestinal disorders under the brand name Reglan in 1980.[1] Generic manufacturers received approval to produce metoclopramide in 1985. According to the Lymans' Complaint, the Generic Defendants knew or should have known that the labeling for metoclopramide substantially understated the risk of developing tardive dyskinesia, particularly as a result of long-term use of the drug.

Warnings included in labeling for metoclopramide have been modified and strengthened over the years, in 1985, in 2004, and in 2009. *Mensing*, 131 S. Ct. at 2572-73. In 2004, the FDA approved a change to the label to add that "[t]herapy should not exceed 12 weeks in duration." *Id.* at 2573; *see also Kellogg v. Wyeth*, 612 F. Supp. 2d 421, 427 (D. Vt. 2008). In 2009, the FDA required the addition of a "black box warning," stating that "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 2573.

Colleen Lyman was prescribed and took metoclopramide from

[1] The FDA regulates the manufacture, sale, and labeling of prescription drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended. 21 U.S.C. §§ 301-399d.

2003 until at least 2006. The Lymans filed suit against the name brand and generic manufacturers of metoclopramide on November 25, 2009. Their Complaint alleges claims against the Generic Defendants for negligence; strict liability; breach of an implied warranty of merchantability; breach of an implied warranty of fitness for a particular purpose; misrepresentation, suppression of evidence and fraud; and gross negligence. In their Statement of Facts, they assert that Colleen Lyman's injuries

> came about as a foreseeable and proximate result of Defendants' dissemination of inaccurate, misleading, materially incomplete, false and otherwise inadequate information concerning the potential effects of exposure to and long-term ingestion of Reglan/metoclopramide to the medical community, Colleen Lyman, and other foreseeable users of the drug.

Compl. ¶ 3.19, ECF No. 1. In essence, the Lymans' claims arise from the Defendants' "failure to warn doctors and patients of information within their knowledge or possession which indicated that the subject Reglan/metoclopramide, when taken for long periods of time, caused serious, permanent and debilitating side effects, including tardive dyskinesia." *Id.* ¶ 3.22.

Specifically, the Lymans' Complaint alleges that the Generic Defendants disseminated false and misleading information about the risks of metoclopramide through their package inserts. *Id.* ¶¶ 3.67-69. They also allege that the Generic Defendants failed to review and report on adverse drug event information, relevant scientific literature and material safety information; and failed

to conduct and report post-market safety surveillance on metoclopramide. *Id.* ¶¶ 3.72-77. They allege that the Generic Defendants knowingly concealed from physicians material facts pertaining to the risk of serious side effects resulting from use of the drug for longer than twelve weeks. *Id.* ¶¶ 3.78-81.

Within their negligence claim, the Lymans assert failure to exercise reasonable care in the design, manufacture, marketing and testing of metoclopramide, as well as failure to provide adequate warnings. *Id.* ¶¶ 4.02-03. In their strict product liability claim, the Lymans assert that metoclopramide was defective in design and marketing and unreasonably dangerous, and failure to provide adequate warnings rendered the drug "unreasonably dangerously defective as designed and marketed." *Id.* ¶ 4.08. The Lymans' breach of an implied warranty of merchantability claim asserts that metoclopramide was not merchantable as fit for safe use because, as designed, it was capable of causing serious injury as suffered by Colleen Lyman. *Id.* ¶ 4.11. Their breach of an implied warranty of fitness for a particular purpose asserts that they relied on the Generic Defendants' skill and judgment when purchasing metoclopramide, which was not fit for its particular purpose. *Id.* ¶ 4.14. Within their fraud and misrepresentation claim, the Lymans assert that the Generic Defendants made false material representations and omitted material information concerning the risk of serious

permanent side effects, the inadequacy of testing, and the inadvisability of use for longer than twelve weeks. *Id.* ¶ 4.17-23. The Lymans also assert that the Generic Defendants' negligent acts or omissions amount to gross negligence, warranting exemplary damages. *Id.* ¶ 4.26-27.

On February 15, 2011, this Court granted a partial stay of proceedings in anticipation of a decision by the United States Supreme Court in the consolidated cases of *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009), and *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010), *rev'd sub nom. PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). The Supreme Court issued its decision on June 23, 2011. *See Mensing*, 131 S. Ct. at 2567.

In *PLIVA, Inc. v. Mensing*, the United States Supreme Court held that federal law preempted state laws imposing a duty on generic drug manufacturers to provide adequate warning labels for their products. 131 S. Ct. at 2572, 2581. Like Colleen Lyman, the plaintiffs in the cases before the Court were prescribed and took generic metoclopramide. After taking the drug for several years, these women developed tardive dyskinesia. *Id.* at 2573. Their lawsuits alleged "that long-term metoclopramide use caused [their] tardive dyskinesia and that the [generic manufacturers] were liable under state tort law . . . for failing to provide adequate warning labels." *Id.*

The *Mensing* Court first identified a state tort duty to

warn, that allegedly would require the generic manufacturers to use a stronger, safer label than the one approved by the FDA. The Court then summarized the different labeling requirements for brand-name and generic drug manufacturers, observing that under the Drug Price Competition and Patent Term Restoration Act of 1984,[2] a generic drug manufacturer "is responsible for ensuring that its warning label is the same as the brand name's." *Id.* at 2574.

The Supreme Court rejected the suggestions that generic drug manufacturers have opportunities to strengthen their warnings, either (1) through the FDA's "changes-being-effected" process, or (2) through the delivery of "Dear Doctor" letters to healthcare professionals. *Id.* at 2575-76. It assumed, without deciding, that generic drug manufacturers have a duty to propose that the FDA require stronger warning labels, but concluded that complying with such a duty would not satisfy a state-law duty to provide adequate labeling. *Id.* at 2576-78. Consequently, the Court concluded that it is impossible for generic manufacturers to comply both with state requirements to supply an adequate warning label and federal requirements that their labels be the same as the brand name's label. *Id.* at 2577-78. Given that the Supremacy Clause establishes that federal law prevails in cases

[2] Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly referred to as the "Hatch-Waxman Amendments."

of direct conflict with a state law, the Court held that the plaintiffs' failure to warn claims against the generic manufacturers were preempted. *Id.* at 2577, 2581.

In their motion, the Generic Defendants argue that *Mensing* requires dismissal of all of the Lymans' claims against them. The Lymans concede that they cannot pursue claims against the Generic Defendants for failure to add new or strengthened warnings to their labeling for metoclopramide that did not appear in the labeling for Reglan. Nevertheless, they argue that their complaint also alleges viable claims that the Generic Defendants failed to correct the label for metoclopramide to reflect that therapy with the drug should not exceed twelve weeks, actively concealed information that metoclopramide was not safe for long-term use, and failed to perform their duties to monitor and report information on the safety of metoclopramide to the FDA. These allegations, they contend, are not preempted.

II. Discussion

A. Rule 12(c) Motion

"'To survive a Rule 12(c) motion, [plaintiffs'] complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" *Hayden v. Paterson*, 594 F.3d 150, 160 (2d Cir. 2010) (quoting *Johnson v. Rowley*, 569 F.3d 40, 44 (2d Cir. 2009) (per curiam)). The Court accepts as true all well-pleaded factual allegations, and draws

all reasonable inferences in plaintiffs' favor. *L-7 Designs, Inc. v. Old Navy, LLC*, 647 F.3d 419, 429 (2d Cir. 2011).

In considering a motion for judgment on the pleadings, a court may first identify pleadings that, being no more than conclusions, are not entitled to the presumption of truth. *Id.* at 430; *see Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009). Assuming the truth of well-pleaded factual allegations, a court may then determine whether they plausibly entitle the pleader to relief. *L-7 Designs*, 647 F.3d at 430; *see Iqbal*, 129 S. Ct. at 1950. The Court therefore first examines the factual allegations of the Lymans' Complaint, independent of their characterization as claims of negligence, strict product liability, breach of warranty or fraud.[3]

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[3] The Generic Defendants have argued that the Lymans' claims for negligence, strict liability, breach of implied warranties and gross negligence are considered as merged into one strict product liability action under Vermont law. This is incorrect. When the Vermont Supreme Court adopted the doctrine of strict product liability as set forth in section 402A of the Restatement (Second) of Torts in *Zaleskie v. Joyce*, 333 A.2d 110, 113-14 (1975), it "expanded [Vermont] common law to include strict product liability," *Hay v. Med. Ctr. Hosp. of Vt.*, 496 A.2d 939, 945 (Vt. 1985); it did not eliminate traditional negligence and warranty claims for injuries to consumers. *See Webb v. Navistar Int'l Transp. Corp.*, 692 A.2d 343, 350 (Vt. 1996); *see also Huey v. Bates*, 375 A.2d 987, 990 (Vt. 1977) (noting that causes of action for negligence, breach of implied warranties and strict product liability are recognized in Vermont); *Kellogg*, 762 F. Supp. 2d at 704 (observing that "[n]either the Vermont Courts nor the Vermont legislature have collapsed negligence actions into strict liability actions where products are involved," citing *Webb*).

B. The Allegations of Failure to Strengthen or Add to the Labeling

As the Lymans concede, their claims that the Generic Defendants failed to strengthen or add to the federally-approved warnings that they provided in package inserts and other labeling are preempted. *See Mensing*, 131 S. Ct. at 2581. It is irrelevant whether such claims sound in negligence, strict product liability or breach of implied warranties. *See id.* at 2572 (holding that state tort-law claims against generic drug manufacturers based on failure to provide adequate warning labels were preempted).

C. The Design and/or Manufacturing Defect Allegations

The Lymans' claims that the Generic Defendants' metoclopramide should have been designed or manufactured differently, *see* Compl. ¶¶ 4.02-03, 4.05, 4.07-09, 4.11, are preempted as well by *Mensing*'s logic. Generic metoclopramide is required by federal law to be bioequivalent to the reference listed drug Reglan. *See Mensing*, 131 S. Ct. at 2574 & n.2; *see also* 21 U.S.C. § 355(j)(2)(A)(iv). The Generic Defendants' "federal duty of sameness," *see Mensing*, 131 S. Ct. at 2575, therefore applies to the design or composition of the drug as well as to its labeling. Applying the *Mensing* holding requires dismissal of the Lymans' design claims as well.[4]

[4] The Lymans have not adequately pled claims for manufacturing or design defects, in any event. In their

D. The Allegation of Selling an Unreasonably Dangerous Product

The Lymans also argue that they may still seek to hold the Generic Defendants liable for selling an unreasonably dangerous product without adequate instructions for use, by having concealed important safety information and provided a label containing false information. *See* Compl. ¶ 3.23. They contend that, as a panel of the Eighth Circuit Court of Appeals commented, "[i]f [the generic defendants] realized their label was insufficient . . ., they could have simply stopped selling the product." *Mensing*, 588 F.3d at 611.[5] These claims, however, remain based upon a state law duty to provide stronger or safer warnings, and are preempted under *Mensing*, to the extent that the Lymans claim that the instructions, information or labeling should have provided more or different information than that

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Complaint, they mention only that "Defendants" (presumably including both generic and name brand manufacturers) failed to use due care in developing, designing and manufacturing Reglan/metoclopramide, and that Reglan/metoclopramide was unreasonably defective in design. *See* Compl. ¶¶ 4.03a, 4.08-09. These conclusory statements do not satisfy Rule 8's requirement that a complaint contain factual matter "that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 129 S. Ct. at 1949. The Lymans do not allege facts from which the Court could conclude that the Generic Defendants developed or designed metoclopramide, that they failed to exercise due care in these activities, or that a manufacturing defect caused Colleen Lyman's injuries.

[5] Upon remand from the United States Supreme Court, the Eighth Circuit Court of Appeals vacated the portion of its opinion that included this statement. *Mensing v. Wyeth, Inc.*, 658 F.3d 867, 867 (8th Cir. 2011).

approved by the FDA for Reglan. *See Mensing*, 131 S. Ct. at 2577; *see also Gross v. Pfizer, Inc.*, ___ F. Supp. 2d ___, ___, No. 10-cv-00110-AW, 2011 WL 5865267, at *3 (D. Md. Nov. 22, 2011) (rejecting a state law duty to stop production of a federally-approved drug).

E. The Allegations That the Generic Defendants Failed to Monitor and Report Safety Information, to Review Adverse Drug Event Information or to Conduct Safety Surveillance

The Lymans also state that the Generic Defendants violated "numerous other provisions of federal law," including "failure to perform post-marketing surveillance for their drugs, to ensure the accuracy of statements appearing in their package insert, to review all adverse drug event information, and to report important information relating to the safety of their drug products." Pls.' Mem. in Opp'n 20, ECF No. 183. To the extent that these contentions support a claim of breach of a state tort duty to provide different or additional information or warnings than those approved by the FDA for Reglan, the claim is precluded under *Mensing*. *Mensing*, 131 S. Ct. at 2572. If these contentions are intended to support a different theory of relief, they are inadequately pled, as the Complaint merely asserts generally that these violations support the contention that all drug manufacturer defendants were negligent in the design and marketing of Reglan/metoclopramide, and failed to warn that it was capable of causing injuries such as those suffered by Colleen

Lyman. Compl. ¶¶ 4.02-03. *See Iqbal*, 129 S. Ct. at 1949 ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.").

F. The Allegation that the Generic Defendants Failed to Provide Warnings That Were Consistent with FDA-Approved Labeling

The Lymans also argue that by 2004 when the FDA approved a label change for Reglan to add that "[t]herapy should not exceed 12 weeks in duration," the Generic Defendants could and should have disseminated information through labeling and otherwise that was consistent with the updated and strengthened warning. They contend that no manufacturer of metoclopramide communicated this information to healthcare providers or to consumers, and that long-term therapy remained a common practice as a result. Pls.' Mem. in Opp'n 19. If the Lymans' Complaint can be read to assert that the Generic Defendants are liable for failure to update their labeling in 2004, or to otherwise inform physicians or consumers from that point on that metoclopramide should not be prescribed for more than twelve weeks, *Mensing* does not require dismissal of these claims.

Although the *Mensing* Court concluded that generic drug manufacturers were precluded from issuing substantial additional warnings that were inconsistent with or contrary to the drug's approved labeling, it did not rule that generic drug manufacturers were precluded from issuing "labeling," as that

term is defined in 21 U.S.C. § 321(m) and 21 C.F.R. § 202.1(l)(2), that is "consistent with and not contrary to . . . approved or permitted labeling." 21 C.F.R. § 201.100(d)(1). Had the *Mensing* Court been presented with this precise question, it could not have used the same rationale to find preemption, because the *Mensing* Court based its decision on "impossibility." *Mensing*, 131 S. Ct. at 2577. Because it was not only possible--but required by federal law--to provide updated labeling that contained the new caution against use for longer than twelve weeks, the Generic Defendants cannot argue that it was not possible for them to change their labeling without violating federal law. *See Wyeth v. Levine*, 555 U.S. 555, 573 (2009) (holding that a brand name drug manufacturer had failed to demonstrate that it was impossible for it to comply with a state law duty to provide a stronger warning and a federal duty to avoid misbranding, remarking that "[i]mpossibility pre-emption is a demanding defense"); *see also Fisher v. Pelstring*, ___ F. Supp. 2d ___,___, No. 4:09-cv-00252-TLW, 2011 Wl 4552464 at *3 (D.S.C. Sept. 30, 2011) (finding that a generic manufacturer's deviation from the approved Reglan labeling rules out impossibility preemption); *Brasley-Thrash v. Teva Pharm. USA, Inc.*, No. 10-00031-KD-N, 2011 WL 4025734 at *3-4 (S.D. Ala. Sept. 12, 2011) (allowing a plaintiff leave to amend her complaint to assert liability based on failure to communicate stronger warnings

contained in the FDA-approved label, finding no preemption).

Moreover, the *Mensing* holding does not prevent the Lymans from asserting liability against the Generic Defendants for distributing a drug that is misbranded. Federal law prohibits a manufacturer from introducing into commerce a misbranded drug. 21 U.S.C. § 331(a). A drug is misbranded "[i]f its labeling is false or misleading in any particular," *id.* § 352(a), or does not provide adequate directions for use and adequate warnings. *Id.* § 352(f). A drug's "labeling must be updated when new information becomes available that causes the labeling to become inaccurate, false, or misleading," 21 C.F.R. § 201.56(a)(2); moreover, its "labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug." 21 C.F.R. § 201.80(e).

Although *Mensing* precludes a state tort claim based on the contention that the federally approved labeling for metoclopramide was false or misleading, the Lymans may, without running afoul of *Mensing*, pursue state tort claims against the Generic Defendants for distributing metoclopramide without the labeling approved for Reglan in 2004. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (noting that the preemption provision of the Medical Device Amendments of 1976 did not "prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations," because "the state

duties in such a case 'parallel,' rather than add to, federal requirements"); *accord Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 769 (5th Cir. 2011) (holding in a medical device case that a state failure to warn claim based on an assertion that the defendant violated a relevant federal statute or regulation was not preempted).

Although such claims are not preempted by the holding in *Mensing*, the Lymans' Complaint does not plead sufficient facts under *Iqbal* to survive the motion for judgment on the pleadings. *See Iqbal*, 129 S. Ct. at 1949-50. The factual allegations supporting the Lymans' claims, filed before the Supreme Court's decision in *Mensing*, understandably do not distinguish between the Generic Defendants' conduct before and after the Reglan label change in 2004, and therefore do not supply sufficient information to conclude that the complaint states a plausible claim for relief. *See id.* at 1950. Accordingly, the Lymans have leave to move to amend their Complaint within ten days of the date of this order.

III. Conclusion and Order

For the reasons stated above, the Generic Defendants' Motion for Judgment on the Pleadings, ECF No. 182, is **granted in part and denied in part.** If the Lymans do not move to amend their Complaint within ten days, the Court will amend its order to grant the motion in its entirety.

On September 16, 2011, the Court stayed the filing of pretrial motions until resolution of any motion filed in connection with the *Mensing* decision. This motion having been resolved, the stay is lifted, and the deadline for pretrial motions, including *Daubert* motions and dispositive motions, is March 1, 2012.

Dated at Burlington, Vermont this 3rd day of February, 2012.

/s/ William K. Sessions III
William K. Sessions III
United States District Judge