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SUPERIOR COURT OF NEW JERSEY
COUNTIES OF
ATLANTIC AND CAPE MAY

CAROL E. HIGBEE, P.J.Cv.

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MEMORANDUM OF DECISION ON MOTION
Pursuant to Rule 1:6-2(f)

CASE:	**In re Reglan Litigation**
DOCKET #:	**Case No. 289**
DATE:	**May 4, 2012**
MOTION:	**Motion of All Generic Defendants to Dismiss Plaintiffs' Second Amended Master Long Form Complaint**
ATTORNEYS:	**Frederick H. Fern, Esq., Harris Beach PLLC, Newark, New Jersey for Defendants**
	Theodore Oshman, Esq., Oshman & Mirisola, L.L.P., New York, New York for Plaintiffs

Having carefully reviewed the papers submitted and any response received, I have ruled on the above Motion as follows:

THIS MATTER comes before the court on generic defendants' collective Motion to dismiss. Plaintiffs filed a timely opposition to the motion, and generic defendants filed a reply. Generic defendants' Motion seeking dismissal of all claims is based on federal preemption and

the Supremacy Clause of the United States Constitution pursuant to the United States Supreme Court's recent decision in Pliva v. Mensing, 131 S. Ct. 2567, 180 L. Ed. 2d 580 (2011).

BACKGROUND

This pharmaceutical products liability action arises out of injuries allegedly caused by an anti-emetic prescription drug, metoclopramide, which is commonly used to treat digestive tract problems and is sold under the brand name Reglan. Plaintiffs filed suit against a variety of pharmaceutical entities—brand-name and generic manufacturers—alleged to have designed, manufactured, marketed, or sold metoclopramide. Plaintiffs allege they suffer from, among other things, tardive dyskinesia, a neurological disorder that causes involuntary repetitive movements.

- *FDA Regulatory Scheme*

All prescription drugs must be approved by the Food and Drug Administration ("FDA") before a company may market or sell them. Brand-name manufacturers must submit a New Drug Application ("NDA") to the FDA that contains extensive information regarding the safety of the drug based on clinical trials that the manufacturer has conducted. 21 U.S.C. §§ 355(a)-(b), (d); see also 21 C.F.R. § 201.56. Upon approval of the application, the brand-name manufacturer 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. To gain approval and entry in the market, generic manufacturers may submit an Abbreviated New Drug Application ("ANDA") to the FDA. The ANDA process removes the need for generic manufacturers to independently conduct clinical trials already completed by brand-name manufacturers as long as the generic drug is essentially the same as the brand-name drug and the generic drug's label is identical in relevant part to the brand-name drug's label. 21 C.F.R. § 314.94(a)(8). The ANDA process was

created through the passage of the Drug Price Competition and Patent Term Restoration Act in 1984, a statute that sought to allow the entry of affordable generic drugs into the market. This Act amended the Food, Drug, and Cosmetic Act ("FDCA"), and is known as the "Hatch-Waxman Amendments" to the FDCA. Under Hatch-Waxman, a generic drug manufacturer may produce a drug by showing bioequivalence to a reference-listed drug ("RLD") that is approved by the FDA. 21 U.S.C. §§ 355(j)(2)(A)(i)-(v). The FDA relies upon the brand-name manufacturer's studies to validate the generic product's safety and efficacy. Mova Pharm. Corp. v. Shalala, 140 F. 3d 1060, 1063 (D.C. Cir. 1998).

In terms of altering the label of a drug, there are two main ways that a label may be revised. "Major Changes" may be implemented through a prior approval supplement, where the FDA must approve the change that a manufacturer recommends before the change can be implemented. 21 C.F.R. § 314.70(b). "Moderate Changes" may be made through a Changes Being Effected ("CBE") process, which does not require pre-approval by the FDA. 21 C.F.R. §§ 314.70(c)(6)(iii)(A)-(D). The CBE process allows brand-name drug manufacturers to unilaterally "add or strengthen a contraindication, warning, [or] precaution," or "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product." 21 C.F.R. §§ 314.70(c)(6)(iii)(A)-(C)(2006); see also Wyeth v. Levine, 555 U.S. 555, 568, 129 S. Ct. 1187, 1196, 173 L. Ed. 2d 51, 62 (2009). According to the FDA and as held in Mensing, a generic manufacturer may only use the CBE process to "match an updated brand-name label or to follow the FDA's instructions." Mensing, supra, 131 S. Ct. at 2575.

- *History of Reglan*

The FDA first approved metoclopramide in 1980 to treat conditions such as acid reflux disease and diabetic gastroparesis. In 1985, generic drug manufacturers began producing

metoclopramide. At different times, Wyeth LLC, Schwarz Pharma, Inc., and Alaven Pharmaceutical LLC manufactured and distributed "Reglan," the brand-name form of the drug. From 1989 to 2001, Wyeth manufactured and distributed Reglan in three different forms: tablet, syrup (oral solution), and injectable. Starting in the early 2000s, Wyeth began selling its rights to Reglan to different pharmaceutical companies. Each form of the drug, except the syrup, was sold separately to a different company. In December 2001, Schwarz acquired from Wyeth the rights to Reglan's brand-name tablets. Since then, Wyeth has neither sold nor distributed any Reglan tablets. Schwarz manufactured and distributed the drug tablets until 2008. Subsequently, in 2008, Alaven acquired the rights to the Reglan tablets, and began manufacturing the drug until 2011. With regards to the injectable form of the drug, Wyeth sold its rights to Reglan injectable to Baxter, Inc., making it the subsequent NDA holder for Reglan injectable. The injectable form of Reglan is excluded from this motion. With regards to the syrup, Wyeth never sold its rights for Reglan syrup after it left the market in 2001-02. Following Wyeth's request, the FDA withdrew approval of the company's NDA for Reglan syrup in October 2002. FDA Notice, Withdrawal of Approval of 16 New Drug Applications and 30 Abbreviated New Drug Applications, 67 Fed. Reg. 63107, 63107 (Oct. 10, 2002). As a result, the metoclopramide syrup was manufactured and distributed by generic companies that received approval under the ANDA process, without a syrup NDA holder present in the market. FDA Notice, Determination That DECADRON Tablets and Nine Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 74 Fed. Reg. 22751, 22752 (May 14, 2009).

- *Reglan's Label*

The warning label for the drug has been amended several times over the years. In 1985, the label accompanying the drug warned 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 July 2004, the NDA holder of Reglan tablets, Schwarz Pharma, added an FDA-approved label which stated that "[t]herapy should not exceed 12 weeks in duration." Mensing, supra, 131 S. Ct. at 2572. This 2004 revision was a change that some generic manufacturers of the tablet did not incorporate into their post-2004 metoclopramide package-inserts. Brand-name Reglan injectables and syrup did not adopt this change, and as a result, neither did the generic manufacturers of metoclopramide injectables and syrup. Later, in 2009, the FDA added a "black box warning" to all forms of the Reglan/metoclopramide drug, which stated that "[t]reatment 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, supra, 131 S. Ct. at 2573 (citing PHYSICIAN'S DESK REFERENCE 2902 (65th ed. 2011)).

DISCUSSION

I. Legal Standard for a Motion to Dismiss

Pursuant to Rule 4:6-2(e), a defendant may move to strike all or part of a complaint for "failure to state a claim upon which relief can be granted." Such a motion entails scrutiny of the complaint to determine whether any viable cause of actions exists. "[T]he test for determining the adequacy of a pleading [is] whether a cause of action is 'suggested' by the fact . . . . At this preliminary stage of the litigation the Court is not concerned with the ability of plaintiffs to prove the allegation contained in the complaint." Printing Mart-Morristown v. Sharp Electronics Corp., 116 N.J. 739, 746 (1989) (quoting Velantzas v. Colgate-Palmolive Co., 109 N.J. 189, 192 (1988)).

II. Preemption

Arguments in this case turn on preemption. The Supremacy clause of the United States Constitution provides that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2. In Mensing, the plaintiffs alleged that their long-term use of generic metoclopramide resulted in tardive dyskinesia and sought remedies under state tort law against the generic manufacturers. It was undisputed that if the plaintiffs' allegations were true, then state tort law "required the manufacturers [of the generic drug] to use a different, safer label." Mensing, supra, 131 S. Ct. at 2574. Nevertheless, the Supreme Court pointed out that federal laws as promulgated by the FDA, impose more complex drug labeling requirements than do state tort laws. Ibid. This conflict between federal and state requirements led the Court to find that impossibility preemption exists because it is impossible for generic manufacturers to simultaneously comply with both federal and state laws. Id. at 2579.

Specifically, the Court held, "[t]o decide these cases, it is enough to hold that when 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 duties for preemption purposes." Id. at 2580-81. The practical effect of Mensing's holding is that generic manufacturers who comply with the FDA requirement that they mimic the brand-name manufacturers' warning labels cannot be held liable under state tort law for failure to warn. As a result, the Mensing plaintiffs' state claims were found preempted "because it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same." Id. at 2578.

In their motion to dismiss, generic defendants argue that Mensing is directly on point because it involved the same medication, same injuries, same parties, and same causes of action as the

present action. According to defendants, Mensing holds that *all* claims under state tort law against them based on an alleged failure to warn theory are preempted because the manufacturers cannot comply with both federal and state law. By contrast, plaintiffs have adopted a rather narrower interpretation of the Mensing decision, claiming that the Supreme Court's ruling only applies to the specific content of the package inserts.

The question before the court is to what extent, if any, do plaintiffs' claims survive the preemption ruling in Mensing. The facts of the instant case are largely identical to those in Mensing. Here, plaintiffs attempt to espouse a narrow interpretation of Mensing by contending that Mensing only preempted failure to warn claims involving the adequacy of the warning as provided on the label, and as a result, some of their claims should survive because they do not concern drug labeling.

a. Effect of 2007 FDAAA Amendments on Preemption Analysis

While it is true that the Supreme Court in Mensing considered federal statutes and regulations that were in place before the 2007 amendments to FDAAA[1] took effect, it is clear that the amendments do not change or eliminate any of those laws or regulations which control this decision. The "sameness" requirement remains in full effect. The generic manufacturers' inability to use the CBE process to unilaterally change their warnings also continues. A generic manufacturer still cannot "independently do under federal law what state law" may require. Mensing, supra, 131 S. Ct. at 2579. The new changes in FDAAA do not eliminate or alter the conflict the Supreme Court described in Mensing. As a result, claims based on any such duty are preempted post-FDAAA to the same extent as they were pre-FDAAA.

[1] The Food and Drug Administration Amendments Act of 2007 was enacted on September 27, 2007. Pub. L. No. 110-85, 121 Stat. 823 (2007).

b. Plaintiffs' Theories of Liability

Plaintiffs second master long form complaint pleads several causes of action, including but not limited to, defective design, failure to warn, negligence, negligence per se, fraud, misrepresentation and suppression, constructive fraud, breach of express and implied warranties, unfair and deceptive trade practices, and unjust enrichment. Further, plaintiffs allege that in light of published studies the generic defendants knew or should have known that the product created "a high risk of unreasonable harm." Second Am. Compl. ¶367.

Stripped down to the very basics, plaintiffs' claims are "traditional product liability claims for injuries caused by [the Generic Defendants'] . . . failure to provide adequate warning for their products." Kellogg v. Wyeth, No. 2:07–cv–82, 2012 WL 368658, at *2 (D. Vt. Feb. 3, 2012). Although plaintiffs attempt to distinguish their various theories of liability, the claims are all based on generic manufacturers' alleged failure to provide adequate information or warnings, and thus are preempted under Mensing. Like Mensing, "at the core of all of Plaintiffs' claims is the basic assertion that [defendants] failed to adequately warn about the association between long-term ingestion of [metoclopramide] and movement disorders." Mensing v. Wyeth, Inc., 562 F. Supp. 2d. 1056, 1058 (D. Minn. 2008); see also Moretti v. Mut. Pharm. Co., No. 10-896, 2012 WL 465867, at *4 (D. Minn. Feb. 13, 2012) ("Despite the different 'labels' given these claims, the essence of these claims is that important safety information as to metoclopramide was not disseminated, or made clear, to the public or the medical community. In other words, Defendants failed to warn of material safety information concerning metoclopramide."). Like Mensing, plaintiffs here have also asserted claims of design defect, breach of express and implied warranties, negligence, misrepresentation, and fraud. There are no claims in the plaintiffs' complaint that were not also asserted in Mensing, and the court cannot find any meaningful distinction between these two cases. See generally Demahy v. Actavis, 650 F. 3d

1045 (5th Cir. 2011) (dismissing as preempted claims of failure-to-warn, design defect, negligence, misrepresentation, and fraud); Smith v. Wyeth, Inc., 657 F. 3d 420 (6th Cir. 2011) (finding claims of products liability, negligence, negligence per se, fraud, fraud by concealment, and breach of express and implied warranties preempted under Mensing); Gaeta v. Perrigo Pharm. Co., No. 09–1500, 2012 WL 605678 (9th Cir. Feb. 27, 2012) (affirming the district court's dismissal of plaintiff's design defect, marketing defect, breach of express and implied warranties, negligence, and deceit by concealment claim, based on the Mensing decision). In certain prescription drug cases, the design defect claims may differ from failure to warn claims, but not as asserted in these cases.

c. Exemption from Preemption

In Mensing, the Supreme Court pointed out that "[i]n 2004, the brand-name Reglan manufacturer requested, and the FDA approved, a label change to add that 'therapy should not exceed 12 weeks in duration.'" Mensing, supra, 131 S. Ct. at 2572. The passage formerly stated "therapy longer than 12 weeks has not been evaluated and cannot be recommended." Ibid. The brand-name manufacturer that requested this change was Schwarz Pharma, which manufactured and marketed Reglan tablets. It appears that some generic manufacturers failed to update their labeling to include this change. See Fisher v. Pelstring, 817 F. Supp. 2d 791, 805 n.4 (D.S.C. 2011). Mensing's entire premise is based on the notion that as long as generic manufacturers of a product obey the "sameness" requirement and mimic the brand-name product's labels, then preemption applies and state tort claims cannot be brought against those manufacturers. In analyzing Reglan's convoluted history, the court has reached the conclusion that each form of metoclopramide (tablet, syrup, injectable) is a distinct product, and generic manufacturers of each form must follow the brand-name manufacturer's label for that specific form to satisfy the "sameness" requirement.

Here, generic manufacturers of the Reglan tablet have not proven that any federal law prevented them from adding the additional warnings to their generic metoclopramide tablet products. In fact, they clearly had a duty to adopt the brand-name changes. The court agrees that private enforcement of FDA requirements is foreclosed by 21 U.S.C. § 337(a) ("proceedings for the enforcement, or to restrain violations, of [the Federal Food, Drug, and Cosmetic Act] shall be by and in the name of the United States."). But if labels belonging to generic manufacturers of tablets did not match the brand-name manufacturers of tablets, then there are least some changes to their labels that federal law would allow, or even require, these defendants to make, and state tort law in this situation does not conflict with federal law. Consequently, this absence of "sameness" runs afoul of the preemption ruling in Mensing, and the court finds that to the extent that generic manufacturers of metoclopramide tablets failed to update the labels to be the same as the brand-name label, they are excluded from preemption.

d. Failure-to-Communicate Theory

Plaintiffs argue that federal law allows generic manufacturers to disseminate truthful, non-misleading information to doctors about the risks associated with their product through means other than labeling, and that therefore it was not "impossible" for the generic defendants to comply with both state and federal requirements. In making these arguments, plaintiffs contend that defendants should have more effectively communicated and disseminated the FDA approved label to the medical community, engaged in risk minimization strategies, and/or suspended drug sales. For example, plaintiffs raise a failure to communicate theory, which questions defendants' conduct in failing to send out "Dear Doctor letters" or otherwise communicate warnings to the medical community. In support of this argument, plaintiffs primarily rely on Fisher v. Plestring, where the court held that generic manufacturers "had

avenues available to communicate with physicians about the . . . label changes without seeking FDA approval first." 817 F. Supp. 2d at 813.

In Mensing, the Court accepted the FDA's interpretation that generic drug manufacturers may not use "Dear Doctor" letters to send additional warnings to physicians because such letters are labeling and "must be 'consistent with and not contrary to [the drug's] approved . . . labeling.'" Mensing, supra, 131 S. Ct. at 2576 (quoting 21 C.F.R. § 201.100(d)(1)) (alteration and omission in original). By contrast, the court in Fisher reasoned that the generic drug manufacturers could have taken *other* avenues to communicate the changes in the warnings without impinging upon the preemption ruling of Mensing. As a result, Fisher accepted plaintiffs' alternative theory of recovery based on the argument that defendants should have done more when the 2003 and 2004 label changes occurred, such as issue a "Dear Doctor" letter that explained the changes that had occurred.

Under 21 C.F.R. § 202.1(1)(2), labeling is defined to include virtually any type of audio, visual or printed matter descriptive of a drug and supplied by a manufacturer. Plaintiffs maintain that Mensing does not necessarily require preemption of state law causes of action where the duty to warn could have been satisfied through the submission of "Dear Doctor" letters, or other methods of communication, that are consistent with the labels. While this argument has some merit, this court does not find sufficient authority to impose such legal responsibility upon generic manufacturers who have otherwise provided the warnings that they were required to use in the package inserts to independently send out "Dear Doctor" letter emphasizing the changes. Therefore, to the extent that plaintiffs' claims can be read to assert liability against the generic manufacturers solely for failure to highlight changes in the required warnings through dissemination of "Dear Doctor" letter, or other non-promotional materials, these claims are also preempted.

e. **Suspension of Sales**

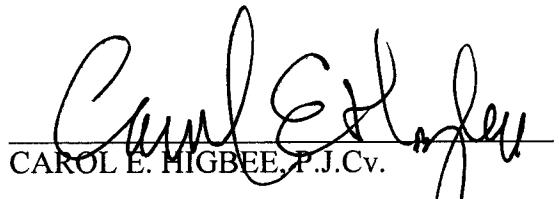
Plaintiffs have alleged that generic defendants "could simultaneously comply with [their] duties under both state and federal law if [they] stopped selling [their] drug." Pls.' Opp'n Br. 3. Plaintiffs have raised this argument before the Eighth and Sixth Circuits, and both courts have rejected it. See Appellant Gladys Mensing's Motion for Leave to File a Supplemental Brief, Mensing v. Wyeth, Inc., No. 08-3850, 2008 WL 5707474, at *4 (8th Cir. Sept. 8, 2011) ("[C]ompanies should have suspended sales of the drug until such time as an adequate warning was approved by the FDA."), dismissed by Mensing v. Wyeth, Inc., No. 08-3850, 2011 WL 4636653, at *1 (8th Cir. Sept. 29, 2011); Smith, Pls.' Br. 6 ("While the Generic Drug Company Appellees may not have been able to strengthen their warnings without prior FDA approval, no federal statute or regulation prohibited from 'independently' suspending sales of their product out of concern that their labeling lacked adequate warnings."), dismissed by Smith v. Wyeth, 657 F. 3d 420 (6th Cir. 2011).

Plaintiffs' "failure to suspend sales" argument is a solution that goes beyond the duties and remedies that have ever been applied in state courts. The duty has always been to prove that the product was defective, not that it should have been withdrawn from the market. Tort law remedies allow compensation but never an order to stop selling the product. The conflict between state and federal law would be much more pronounced if the state courts upheld a decision that an FDA-approved drug should not have been on the market. This "failure to suspend sales" argument was rejected by the Eight Circuit following Mensing's remand, and the Sixth Circuit in Smith. This court likewise rejects this argument at this time.

CONCLUSION

The Supreme Court in Mensing, in signaling that the case spells the end of lawsuits like plaintiffs, suggested that those seeking redress in such cases must look not to the courts, but to "Congress and the FDA . . . to change the laws and regulations if they so desire." Mensing, supra, 131 S. Ct. at 2582. The alleged failure to warn is clearly the central thrust of plaintiffs' lawsuits here and it underlies every count in the complaint. A generic drug manufacturer may not independently change its warnings, labels, or package-inserts. Id. at 2575-76. The court acknowledges that, at least with respect to plaintiffs' failure to warn claims, the disposition of this motion could have turned out differently had plaintiffs' prescriptions been filled with the brand-name drug instead of the generic product. This result is inevitable as voiced in Justice Sotomayor's dissent in Mensing. Id. at 2592 (Sotomayor, J., dissenting). At this point, precedent constrains this court's decision. Until FDA modifies its regulations, or Congress takes action to amend the statutes, there is no authority to allow claims for "failure to warn" to proceed against generic drug manufacturers that have mimicked the brand-name labeling.

In conclusion, the court will dismiss all counts of the plaintiffs' complaints against the generic manufacturers of the tablets, except for any claims that are made against a generic manufacturer of the tablet that did not change the label on their product to match the brand-name's label. As stated previously, the generic syrup products are distinct from the generic tablet product and the generic syrup manufacturers could not change their label when there was no brand-name manufacturer.[2] The claims against the generic manufacturers are dismissed.



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[2] See decision relating to the motion by Morton Grove and Wockhardt USA, which holds that only the FDA had the power to change the label when there was no NDA holder in the market.