UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF LOUISIANA

ROBERT S. COOPER and
SUE ANN COOPER

VERSUS CIVIL ACTION NO. 09-929-JJB

WYETH, INC., ET AL.

RULING ON MOTION TO DISMISS

Before the Court is a motion to dismiss (Doc. 117) filed by three defendants, PLIVA, Inc., Teva Pharmaceuticals USA, Inc., and Watson Laboratories, Inc., in response to a complaint by plaintiffs, Sue Ann Cooper and Robert S. Cooper,[1] seeking dismissal of plaintiffs' state law claims based on federal preemption. The plaintiffs filed an opposition (Doc. 119), and the defendants filed a reply (Doc. 125). Oral argument is unnecessary. Jurisdiction exists under 28 U.S.C. § 1332.

I. Factual and Procedural Background

The following facts are taken as true based on plaintiffs' second amended complaint. (Doc. 113). On or about May 21, 1998, plaintiff Robert Cooper's physician prescribed for him a drug, with the brand name of Reglan[2] and the generic name of metoclopramide,[3] to treat his acid reflux condition. He ingested the drug as prescribed by his physician until sometime in or

[1] Because Robert Cooper is the only plaintiff alleged to have taken the medicine and his wife's claims for loss of consortium are therefore derivative of his own alleged injuries, all subsequent references to Cooper will refer to Robert, unless otherwise noted.

[2] Reglan was first approved by the U.S. Food and Drug Administration ("FDA") in 1983 under the new drug application ("NDA") procedure. Wyeth, Inc., a defendant not party to this motion, is allegedly the successor-in-interest to Reglan.

[3] Because the defendants who filed this motion to dismiss all claim to be makers of the generic version of the drug, the Court will refer to the drug by its generic name in this motion. Defendants involved in this motion all submitted abbreviated new drug applications ("ANDA") to the FDA to sell metoclopramide based on the information provided in the Reglan NDA application.

around July 2009. Metoclopramide is a drug that is used for treatment of gastroesophageal reflux disease, irritable bowel syndrome, and/or other gastrointestinal disorders. The metoclopramide ingested by plaintiff Robert Cooper was allegedly manufactured by defendants.

Cooper's prescribing doctors relied upon information published in the package inserts and/or the Physician's Desk Reference ("PDR")[4] or otherwise disseminated by the manufacturers of metoclopramide. Neither plaintiff nor his physicians were aware of any information different from or contrary to the information disseminated in the PDR and product inserts authored and distributed by defendants. In mid-2009, Cooper began exhibiting injuries to his central nervous and extrapyramidal motor systems, including tardive dyskinesia, a severe and often permanent disfiguring neurological movement disorder, allegedly as a result of his use of metoclopramide.

Defendants allegedly failed to timely include warnings approved by the FDA in 2003 regarding use of metoclopramide in geriatric patients, as well as the warning prohibiting long-term use of the drug which was added to the labeling for the Reference Listed Drug ("RLD") in 2004. Despite their duty and ability to do so, defendants failed to alert the medical community and consumers to the addition of warnings to the labeling of metoclopramide regarding geriatric and long-term use, and as a result, plaintiff Robert Cooper and his physicians were unaware of the fact that therapy with the drug should not exceed 12 weeks.

On September 26, 2011, plaintiffs filed their Second Amended Complaint, which asserts the defendants' liability under the Louisiana Products Liability Act ("LPLA") (Doc. 113). Plaintiffs assert theories of liability against defendants under the LPLA for failure to warn, construction or composition defect, design defect, and breach of express warranty.

[4] PDR is a commercially published compilation of manufacturers' product inserts on prescription drugs.

Defendants contend that all the LPLA theories, no matter how they are worded by plaintiffs, are based on defendants' alleged failure to warn adequately of the purported risk of developing tardive dyskinesia, and other injuries, from long-term use of metoclopramide. As such, they move to dismiss all the claims raised against them in plaintiffs' complaint.

II. Standard of Review

Pursuant to Fed. Rule Civ. P. 12(b)(6), on a motion to dismiss for failure to state a claim, the Court accepts all well-pleaded, non-conclusory facts in the complaint as true. *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949 (2009). "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.'" *Id.* (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "[A] formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555.

A complaint that pleads facts merely consistent with a defendant's liability "stops short of the line between possibility and plausibility." *Id.* at 557. When well-pleaded factual allegations populate the complaint, "a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Iqbal*, 129 S.Ct. at 1950. Courts may consider not only the complaint itself, but also documents attached to the complaint or documents incorporated into the complaint by reference. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322-23 (2007). The facts in the complaint are viewed collectively, not scrutinized in strict isolation. *Id.*

The burden of establishing the affirmative defense of preemption rests upon the party asserting the defense, and this burden is "demanding" when impossibility preemption has been asserted. *Wyeth v. Levine*, 555 U.S. 555, 573 (2009).

III. Law and Discussion

The Louisiana Products Liability Act ("LPLA"), La. R.S. 9:2800.51 *et seq.*, creates the exclusive remedy for injuries arising from product defects. La. R.S. 9:2800.52. To establish liability under the LPLA under any of the theories, a plaintiff must prove four elements: (1) defendant is a "manufacturer" of the product; (2) plaintiff's damages were proximately caused by a characteristic of the product; (3) the characteristic causing the damage made the product "unreasonably dangerous"; and (4) plaintiff's damages arose from a reasonably anticipated use of the product. *Stahl v. Novartis Pharmaceuticals Corp.*, 283 F.3d 254, 260-61 (5th Cir. 2002). Products become unreasonably dangerous from: (1) construction or composition defects; (2) design defects; (3) inadequate warnings; or (4) breach of an express warranty. *Id.*; La. R.S. 9:2800.54(B). In failure to warn cases, the law not only requires manufacturers to provide an adequate warning at the time the product left its control, if such warning is necessary to apprise ordinary consumers of the danger, La. R.S. 9:2800.57(A)-(B), it also demands they use reasonable care to provide adequate warnings after the product leaves its control, La. R.S. 9:2800.57(C). In prescription drug cases, the learned intermediary doctrine applies. *Stahl*, 283 F.3d at 265. In failure to warn claims against prescription drug manufacturers, therefore, the warning must adequately inform the prescribing physician of the risks involved in using the drug that was not otherwise known to the physician. *Id.* at 265-66.

In *PLIVA, Inc., v. Mensing*, --- U.S. ----, 131 S.Ct. 2567 (2011), the Supreme Court of the United States held that federal law preempted state tort and product liability laws imposing upon generic manufacturers a unilateral duty to change a drug's label. State tort law requires that a manufacturer that is, or should be, aware of its drug's danger to label it in a way that renders it reasonably safe. *Id.* at 2570. However, federal regulations, as interpreted by the FDA, prevent generic manufacturers from unilaterally changing their labels. *Id.* State duties impossibly

conflict with those federal regulations for preemption purposes "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…." *Id.* at 2571.

Under *Mensing*, any claims sounding in failure to warn under the LPLA are preempted if the LPLA obligations would conflict with federal law requiring generic drugs to retain the same label as the initially-approved, brand name drug. As will be demonstrated below, all of plaintiffs' claims in this case, save one, are preempted and must therefore be dismissed.

A. Failure to update the label to match the Reglan label required by the FDA.

The plaintiffs assert each of the defendants failed to comply with their labeling duties under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and regulations implemented by the Food and Drug Administration ("FDA") to update their labels to include warnings prohibiting the long term use of the drugs during the plaintiffs' exposure, which were approved by the FDA in 2003 and 2004, subsequent to defendants' ANDA approvals. (Doc. 113, p. 14, ¶¶ 3.64-3.65). Defendants argue these claims are preempted under *Mensing.*

The Supreme Court concluded that the relevant question for "impossibility" preemption analysis is whether the private party could independently do under federal law what state law requires of it. *Mensing*, 131 S.Ct. at 2579. When the "ordinary meaning" of federal law blocks a private party from independently accomplishing what state law requires without obtaining special approval from the federal government, that party has established preemption. *Id.* at 2580.

In this case, the Court finds that the failure to include an FDA-approved label in subsequent years after the FDA mandated a stronger label states a claim for relief under state law that is plausible on its face. Plaintiff Robert Cooper alleged that he was prescribed

metoclopramide beginning in 1998. The warning labels for the drug were strengthened and clarified several times between 1998 and 2009, when Cooper quit taking it:

> 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 (citation omitted).

If the defendants did not label their products with the FDA labels that were required of Reglan (and/or the RLD) at the time, then it would not be in compliance with federal law. *See Mensing*, 131 S.Ct. at 2574 ("A generic drug application must also 'show that the [safety and efficacy] labeling proposed ... is the same as the labeling approved for the [brand-name] drug.'"). In considering such allegations, the conflict preemption analysis from *Mensing* does not readily apply, as the defendants' inclusion of the approved labeling would satisfy any federal law. Since, as *Mensing* makes clear, the FDA's labeling regulations set the ceiling for labeling strength, any state law purporting to impose more stringent requirements would be preempted. However, a generic drug manufacturer's failure to adhere to the brand-name label the generic drug is tied to would plainly violate federal law and likely violate state law under the LPLA. In the latter scenario, the requirements of state law would coextend with, but would not exceed, the requirements of federal law, rendering impossibility preemption inapplicable.

Nothing in *Mensing* forbids this result. *See, e.g.*, *Couick v. Wyeth, Inc.*, No. 3:09-CV-210-RJC-DSC, 2012 WL 79670, at **3-5 (W.D.N.C. Jan. 11, 2012); *Fisher v. Pelstring*, ---

F.Supp.2d ----, No. 4:09-CV-00252-TLW, 2011 WL 4552464, at **3 (D.S.C. Sept. 30, 2011) (both finding *Mensing*'s impossibility analysis for preemption inapplicable to claims that generic metaclopramide manufacturers failed to update their labels to match the Reglan label mandated by the FDA). Thus, this claim is not preempted, and the Court therefore denies dismissal of this claim.

Likewise, the defendants' alleged failure to communicate the strengthened labels following FDA approval (apart from the actual paper label on the bottle) survives dismissal, since the failure to warn in that scenario would similarly be entirely consistent with the FDA's mandated labeling. Thus, a "Dear Doctor" letter notifying a prescribing physician of the newly-updated and strengthened FDA label the generic drug was tied to would not run afoul of any federal law, which therefore leaves state law free to impose such a burden on the generic manufacturer so long as the state law's requirements would not purport to require the letter to breach the parameters for such correspondence set by the FDA.

Defendants further argue that plaintiffs have already admitted the un-updated labels would have been inadequate even if they included the then-newly-mandated FDA labels. Defendants think this point shows plaintiffs' position is inconsistent with basic tort concepts of duty and causation. This is a misplaced and premature argument. As La. R.S. 9:2800.53(9) and 9:2800.57(C) make clear, defendants' legal duties to warn do not change based on what these two plaintiffs subjectively think adequate because their potential breach of the duty to warn is an objective inquiry into the mind of the ordinary, reasonable user. Moreover, defendants may be mistaking causation with damages in this scenario. In the abstract, a stronger warning, even if still "inadequate" in plaintiffs' mind for purposes of their case against the brand-name manufacturer, could nonetheless be inadequate to a lesser degree, thereby potentially permitting

a lower recovery without necessarily obviating causation. Regardless, plaintiffs are permitted to inconsistently plead separate causes of action under Fed. Rule Civ. P. 8(d)(3) without electing their remedy at the pleading stage.

Finally, defendants argue these claims are barred because the FDCA bars private enforcement of the FDCA. While true, it is irrelevant. Plaintiffs are enforcing the LPLA, not federal law. This state law may independently coextend with the reach of federal law, but federal law does not subsume the LPLA for this reason alone.

B. Failure to comply with federal duties to monitor the safety of drug products and report findings to the FDA.

Plaintiffs contend that the *Mensing* decision and the government's *amicus curiae* brief submitted to the Supreme Court in that case indicate that generic manufacturers are required to monitor the safety of their drug products once they enter the marketplace, and that federal law requires them to take certain action if and when they have concerns regarding the safety of their drugs. As plaintiffs have alleged that defendants did not comply with these duties, opting instead to remain willfully ignorant of the risks metoclopramide posed to consumers, they believe such a theory is not preempted.

Defendants assert that a breach of duty to monitor the safety of its products and report its findings to the FDA are not viable claims under state law as the FDA is the sole governmental body that can bring an action to enforce the provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"). Defendant also asserts that even if such a state-law duty exists, it is merely a step in changing the product's warnings which *Mensing* found, if not preempted, "would render conflict pre-emption largely meaningless because it would make most conflicts between state and federal law illusory." 131 S. Ct. at 2579.

According to the FDA, generic manufacturers are required to propose stronger warning labels to the agency if they believed such warnings were needed. *Mensing,* 131 S. Ct. at 2577 ("Generic drug manufacturers that become aware of safety problems must ask the agency to work toward strengthening the label that applies to both the generic and brand-name equivalent drug.") However, the Supreme Court ruled that presuming such a duty exists, the matter is still preempted:

> We find impossibility here. It was not lawful under federal law for the Manufacturers to do what state law required of them. And even if they had fulfilled their federal duty to ask for FDA assistance, they would not have satisfied the requirements of state law.… The federal duty to ask the FDA for help in strengthening the corresponding brand-name label, assuming such a duty exists, does not change this analysis. Although requesting FDA assistance would have satisfied the Manufacturers' federal duty, it would not have satisfied their state tort-law duty to provide adequate labeling. State law demanded a safer label; it did not instruct the Manufacturers to communicate with the FDA about the possibility of a safer label. Indeed, Mensing and Demahy deny that their state tort claims are based on the Manufacturers' alleged failure to ask the FDA for assistance in changing the labels.

Mensing, 131 S. Ct. 2577-78.

Presuming that the defendants had a duty to conduct post-marketing surveillance for their products in order to monitor the safety of its products, those post-marketing activities would be merely steps in requesting the FDA for help in strengthening the corresponding brand-name label. Thus, even if federal law required defendants to begin dialogue with the FDA if and when the safety of metoclopramide came into question, the best result for plaintiffs that could have ensued from those discussions would have been a stronger label, precisely the type of failure to warn claim that *Mensing* found preempted. As *Mensing* unambiguously stated, "[t]he only action [generic drug manufacturers] could independently take—asking for the FDA's help—is

not a matter of state-law concern." 131 S.Ct. at 2581. These claims are undoubtedly preempted and must be dismissed.

C. Failure to withdraw from the market.

Defendants argue that the Eighth Circuit's judgment considered the "failure to withdraw from the market" argument and thus the Supreme Court's reversal in *Mensing* is dispositive on that issue, even though the Supreme Court did not address it. Additionally, defendants argue that the Supreme Court denied the petition for rehearing that was filed by the *Mensing* plaintiffs based on that issue, thus leading the conclusion that the Supreme Court has implicitly decided that the failure to withdraw from the market claim is preempted. Plaintiffs cite *Fernandez v. Chardon*, 681 F.2d 42, 51 n. 7 (1st Cir. 1982), *aff'd*, 103 S.Ct. 2611 (1983), arguing that "the denial of a petition for rehearing can have no greater precedential effect than the denial of a petition for certiorari, which is to say none."

Because the Supreme Court did not address this argument in *Mensing*, dismissal based on preemption might arguably appear inappropriate. But even ignoring the arguments over the precedential value of rehearing denials and judgment reversals, dismissal is nevertheless appropriate here. Charging a generic drug manufacturer with a duty to withdraw its product from the market fits uneasily into any of the four recognized claims under the LPLA. It is plainly not a manufacturing or design defect claim, nor is it a warranty claim. If anything, it is a failure to warn claim. The logic would go something like this: a manufacturer has a duty to warn consumers of dangers; the drug labeling indicates some of its dangers, but the labeling itself is not enough; federal law disallows stronger labeling, so the only way to responsibly account for the danger is to take the drug off the market altogether. *See Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (8th Cir. 2009), *rev'd*, 131 S.Ct. 2567 (2011). But if it is this logic which

permits a withdrawal from the market claim to stand, that claim did not survive the Supreme Court's reversal of the Eighth Circuit in *Mensing*. Such contentions cleverly dress up failure to warn claims in a tempting but ultimately illegitimate guise. If state law could *require* a generic drug manufacturer to wholly withdraw from the market based on the unreasonable danger of the product (which is all a successful failure to withdraw from the market claim could be), it *necessarily* must repudiate the label approved by the FDA. But that is precisely what *Mensing* teaches state law cannot do. The motion to dismiss must therefore be granted on this claim.

D. Failure to use additional methods of communication to provide warnings to physicians.

The "changes-being-effected" ("CBE") process permits drug manufacturers to "add or strengthen a contraindication, warning, [or] precaution," 21 CFR § 314.709(c)(6)(iii)(A), or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," § 314.70(c)(6)(iii)(C). When making labeling changes using the CBE process, drug manufacturers need not wait for preapproval by the FDA, which ordinarily is necessary to change a label – they need only simultaneously file a supplemental application with the FDA. 21 CFR § 314.70(c)(6). "Dear Doctor" letters explain the risks associated with drugs to medical professionals. *Demahy v. Actavis, Inc.*, 593 F. 3d 428, 444 (5th Cir. 2010).

In *Mensing*, the Supreme Court deferred to both the FDA's interpretation of its CBE process and "Dear Doctor" letters: the FDA interpreted both options as unavailable to generic manufacturers independently since both options are considered "labeling" in the arena of drug regulation. *Mensing*, 131 S. Ct. at 2576-77. But this only applied to communications "to strengthen their warning labels." *Id.* at 2576. Nothing in *Mensing* forbids using these communication methods to relate a label warning already approved by the FDA. *See id.*

In this case, the plaintiffs allege that the defendants failed to use additional methods of communication that are neither CBEs nor "Dear Doctor" letters to provide warnings to physicians. Presuming that the defendants could have used additional means, the Court concludes that the additional means, which the FDA does not consider "labeling," are nevertheless communications that warn. In other words, the failure to utilize additional methods of communication is in reality a failure to warn claim. All alleged avenues of communication, other than the "Dear Doctor" letters mentioned *infra* in Part III.A regarding the failure to update the labeling claims, therefore appear calculated to have provided informal warnings stronger than the FDA-approved labeling. Therefore the Court dismisses these claims as preempted.

E. Defendant Teva's liability based on RLD status.

Plaintiffs assert that because defendant Teva at some point became one of the reference listed drugs ("RLD") for metoclopramide, it bears the burden of a brand-name manufacturer and is not entitled to preemption. *See Mensing*, 131 S.Ct. at 2581-82 (distinguishing *Wyeth*, 555 U.S. 555, as governing brand-name drugs and acknowledging the "little sense" the statutory scheme makes). Plaintiffs base their argument on the fact that *Mensing* defined "generic drug" as "a drug designed to be a copy of a reference listed drug (typically a brand-name drug), and thus identical in active ingredients, safety, and efficacy." 131 S. Ct. at 2574, n. 2 (citations omitted). Additionally, Plaintiffs cite 21 U.S.C. § 355(j)(4)(G), 21 CFR § 314.94(a)(8)(iii) and 21 CFR § 314.150(b)(1) (emphasizing the phrase "listed drug" and "reference listed drug") as authority for their conclusion that generic manufacturers that hold RLD status bear the same burden that brand name manufacturers face as holders of a new drug application ("NDA") (Doc. 119 at 30).

Teva asserts that 1) its metoclopramide tablets are not and have never been the RLD, which is the product allegedly ingested by plaintiff Robert Cooper, and 2) plaintiffs misinterpret

federal regulations applicable to prescription drug products. Teva contends that generic manufacturers, as holders of an abbreviated new drug application ("ANDA"), do not acquire the rights and responsibilities of the holder of a NDA by virtue of its product becoming the RLD.

The Court agrees with Teva. While not alleged in the complaint, plaintiffs now argue that becoming an RLD at some point for metoclopramide oral solution imbues Teva with NDA duties and liability for metoclopramide tablets. But plaintiffs only alleged he ingested the tablets, (Doc. 113, ¶ 3.20), and the regulations do not appear to treat the oral solution and the tablets as therapeutically equivalent. (*See* Prescription Drug Product List, Doc. 119-11). Plaintiffs point to nothing showing why RLD status for the oral solution should be treated as RLD status for the tablets, making their belated, un-alleged arguments insufficient here.

Additionally, plaintiffs' interpretation of federal law appears at odds with the FDA's. While the relevant statutes and regulations are not models of terminological clarity in making clear differentiations between listed drugs, reference listed drugs, and how those terms relate to NDA applicants (*i.e.*, brand-name drugs) and ANDA applicants (*i.e.*, generic drugs), the process basically works as follows:

> First, a pioneering drug company must obtain FDA approval for its drug by submitting a New Drug Application ("NDA"). … As part of the NDA process, the drug company must inform the FDA of all patents covering its drug or the methods of using the drug, 'with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.' … Drugs approved by the FDA are known as 'listed drugs.' …
>
> Second, to facilitate the development of generic versions of listed drugs, the Hatch-Waxman Act provides an Abbreviated New Drug Application ("ANDA") process for generic drug manufacturers.… The ANDA process streamlines FDA approval of generic drugs by allowing applicants to rely on the results of the safety and efficacy studies that supported the FDA's approval of a listed drug. Under the ANDA process, a generic drug company must submit

> information to show, inter alia, that its generic drug and the relevant listed drug share the same active ingredients and are bioequivalent.

Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc., 527 F. 3d 1278, 1282 (Fed. Cir. 2008) (citations omitted).

The FDA has provided a summary of its interpretations of its own regulations in 72 Fed. Reg. 39629-01, *available at* 2007 WL 2047956. In that case, Brethine (terbutaline sulfate) injection was withdrawn from sale for reasons unrelated to safety or effectiveness. *Id.* at 39629. The FDA noted that "ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as *the 'listed drug,' which is a version of the drug that was previously approved under a new drug application (NDA).*" *Id.* at 39629 (emphasis added). It is thus clear that the FDA considers "listed drugs" to be synonymous with NDA applicants. NDA-approved drugs, in turn, are synonymous with "brand-name drugs." *Mensing*, 131 S.Ct. at 2574, n. 2. If a brand-name drug which holds the original NDA is removed from the market, the FDA may replace it with a generic version and designate the generic as the new RLD for purposes of evaluating subsequent ANDA applications for that same drug. 72 Fed. Reg. at 39630. The FDA's views earn great weight and are deemed conclusive unless plainly erroneous, plainly inconsistent with the regulations, or when there is reason to doubt they reflect the FDA's fair and considered judgment. *Mensing*, 131 S.Ct. at 2575 (citation omitted).

Plaintiffs point to no authority authorizing the FDA to elevate the duties of a generic ANDA drug to the level of a brand name NDA drug simply because the FDA chooses that generic as the comparison model for bioequivalency measurements arising from the processing of subsequent ANDAs. Presuming the factual allegations made by the plaintiffs are true, Teva

does not hold NDA status by virtue of becoming an RLD and thus does not bear the burden of its brand name counterpart. It is the FDA that is responsible for mandating changes in labeling, and as *Mensing* recognized, NDA-approved drug makers alone retain duties above and beyond those of generic drug makers. Therefore, the Court grants the motion on this claim.

F. Breach of express warranty.

Plaintiffs assert that the complaint alleges facts sufficient to support a claim for breach of express warranty under the Louisiana Products Liability Act ("LPLA") (Doc. 113, ¶ 4.05). Defendants assert that the plaintiffs failed to allege that the defendants made any representations other than those contained in the labeling.

The Court finds that the plaintiffs do not allege that the defendants advertised its products, detailed its products to doctors, or made any other forms of communications regarding its products beyond the package insert. The warning labeling materials, if containing a warranty, are preempted. They thus fail to assert a complaint which contains sufficient factual matter to state a claim to relief based on state law that is plausible on its face. Dismissal is therefore proper on grounds of both preemption and factually insufficient allegations.

G. Design defect claim.

Plaintiffs assert that defendants' products were unreasonably dangerous in design for failing to incorporate design changes "such as packaging designs intended to mitigate the risk posed by long-term use." (Doc. 113, ¶ 4.03). Defendants assert that the claim is preempted and in the alternative, it is inadequately pled. The Court finds it is merely a failure-to-warn claim that has been worded to appear otherwise, and under *Mensing* it is preempted. No factual allegations show the generic, ANDA-approved versions of metoclopramide deviated from the

model, NDA-approved Reglan version. Therefore, the Court grants the motion on this claim on grounds of both preemption and factually insufficient allegations.

H. Manufacturing defect claim.

As defendants' memorandum points out, the threadbare allegations of a manufacturing or composition defect in the complaint (Doc. 113, ¶ 4.02) simply recite the elements of the cause of action and fail to amount to anything more than a conclusory statement. Thus, dismissal based on Rule 12(b)(6) is appropriate.

IV. Conclusion; Order

Accordingly, the defendants' motion to dismiss (Doc. 117) is GRANTED in part and DENIED in part.

Signed in Baton Rouge, Louisiana, on March 6, 2012.

JAMES J. BRADY, DISTRICT JUDGE
MIDDLE DISTRICT OF LOUISIANA