

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

MILDRED JACOBSEN

CIVIL ACTION

VERSUS

NO. 10-0823

WYETH, LLC, et al.

SECTION: "G"(4)

ORDER AND REASONS

Before the Court is Defendants Actavis, Inc.; Actavis Elizabeth LLC; PLIVA, Inc.; and Northstar Rx LLC's (collectively, "Defendants") Motion to Dismiss,¹ wherein Defendants seek to dismiss the pending action for failure to state a claim on the basis that Plaintiff's claims brought under the Louisiana Product Liability Act² ("LPLA") are preempted by federal law and that Plaintiff fails to adequately plead a design defect claim.³ Having considered the motion, the response, the supplemental responses, the reply, the notices of supplemental authority, the record, and the applicable law, for the following reasons, the Court will grant the Motion to Dismiss and will dismiss Plaintiff's complaint with prejudice,⁴ finding Plaintiff's claims to be preempted and, further, that Plaintiff has not adequately pled a design defect claim.

¹ Rec. Doc. 103.

² La. R.S. § 9:2800.51, *et seq.*

³ The motion seeks to dismiss Plaintiff's claims only on the basis of preemption or the alleged failure of Plaintiff to adequately plead a design defect claim, but the Court notes that Defendants' reply in further support of the Motion to Dismiss argues that Plaintiff raises additional theories of liability not originally raised in her complaints. As such, Defendants' reply argues that, to the extent that the Court considers these claims, the claims should be dismissed for failure to state a claim upon which relief may be granted. However, as explained later, to the extent that Plaintiff has not stated such claims in her complaints, the Court will not consider them on their merits here.

⁴ Again, the Court notes that it here considers only the merits of those claims that were alleged by Plaintiff in her complaints, rather than those claims which Plaintiff attempts to assert by argument in her opposition to the Motion to Dismiss.

I. Background

A. Procedural and Factual Background

On March 9, 2010, Plaintiff Mildred Jacobsen filed her complaint in this matter,⁵ bringing causes of action under the LPLA against various drug manufacturers,⁶ including Defendants. On March 26, 2010, Plaintiff filed her First Amended and Restated Complaint,⁷ and on May 12, 2010, Plaintiff filed her Second Amended and Restated Complaint.⁸ The case arises from injuries allegedly sustained by Plaintiff as the result of taking the pharmaceutical drug metoclopramide.⁹ Specifically, Plaintiff alleges that she suffers from tardive dyskinesia and/or involuntary movement disorder as a result of ingesting metoclopramide.¹⁰ Metoclopramide is a generic form of a brand-name drug, Reglan, which was originally designed and manufactured by a third party. Defendants are manufacturers of the generic drug, and Plaintiff alleges that she was prescribed and later ingested the generic versions of the drug manufactured by these manufacturers over various periods of time.¹¹ Plaintiff alleges that Defendants are liable (1) for their alleged failure to safely monitor the drug; (2) because the drug was unreasonably dangerous in design; (3) because the drug was unreasonably

⁵ Rec. Doc. 1.

⁶ A number of these manufacturers have since been terminated from this suit. The pending motion has been brought by all remaining defendants.

⁷ Rec. Doc. 19.

⁸ Rec. Doc. 36.

⁹ *Id.* at ¶ 17 (“Plaintiff’s use of Reglan/metoclopramide, as prescribed, resulted in exposure to the drugs which caused Plaintiff to suffer serious, permanent and disabling injuries, including but not limited to, injuries of or associated with the central nervous and extrapyramidal motor systems.”).

¹⁰ *Id.* at ¶ 63.

¹¹ *Id.* at ¶¶ 2-4.

dangerous for failure to conform to an express warranty; and (4) because Defendants failed to provide an adequate warning for the drug.¹²

This case was originally assigned to Judge Lance M. Africk, Section “I” of the Eastern District of Louisiana. However, after the filing of this case, the United States Supreme Court granted certiorari in two cases involving the question of whether failure-to-warn claims against generic drug manufacturers are preempted by federal law.¹³ Accordingly, on December 17, 2010, Judge Africk granted an unopposed motion to stay these proceedings and administratively terminated this action.¹⁴ Following the Supreme Court’s decision in the consolidated case of *PLIVA, Inc. v. Mensing*,¹⁵ the above-captioned matter was re-opened on July 25, 2011.¹⁶ The parties then filed a joint motion to reinstate a limited stay for the purposes of briefing dismissal based on *Mensing*.¹⁷ However, Judge Africk denied the motion¹⁸ and, at the parties’ request, conducted a status conference to discuss the implications of *Mensing*.¹⁹ According to the Minute Entry for that status conference, “Plaintiff’s counsel advised the Court that plaintiff’s allegations include failure to warn claims as well as

¹² See, e.g., *id.* at ¶¶ 45-49, 52(A)-(E).

¹³ See *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010), *cert. granted* No. 09-1501, and *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009), *cert. granted* Nos. 09-993 and 09-1039.

¹⁴ Rec. Doc. 87.

¹⁵ 564 U.S. ___, 131 S.Ct. 2567 (2011) (expressly barring recovery from generic manufacturers on failure to warn claims brought under state law as preempted by federal law that sets forth a generic manufacturer’s duty as one of sameness).

¹⁶ Rec. Doc. 89.

¹⁷ Rec. Doc. 92.

¹⁸ Rec. Doc. 93.

¹⁹ The status conference was held on September 16, 2011. See Rec. Doc. 97.

defective design claims against a generic drug manufacturer. Counsel for defendants advised the Court that it would file a motion to dismiss with respect to the failure to warn claims”²⁰

On September 23, 2011, Defendants filed their motion, pending here, seeking to dismiss the case in its entirety “because the Supreme Court’s decision is outcome determinative with respect to Generic Defendants’ liability under both theories [i.e, failure to warn and defective design].”²¹ Alternatively, Defendants moved for judgment on the pleadings.²² While the motion to dismiss was pending, the case was transferred to this Section, Section “G” of the Eastern District of Louisiana.²³

B. Parties’ Arguments

1. The Pending Motion

On September 23, 2011, Defendants filed the pending Motion to Dismiss,²⁴ seeking to dismiss Plaintiff’s action under Federal Rule of Civil Procedure 12(b)(6) or, alternatively, under Federal Rule of Civil Procedure 12(c), on the grounds that Plaintiff’s claims are preempted by federal law under Supreme Court precedent in *Mensing*. Specifically, Defendants argue that *Mensing* held that a failure to warn claim against a generic drug manufacturer was preempted by federal law and that Plaintiff’s claims are precisely the type of claims that were held preempted in

²⁰ Rec. Doc. 102.

²¹ Rec. Doc. 103.

²² *Id.* at p. 1.

²³ Rec. Doc. 108.

²⁴ Rec. Doc. 103.

Mensing.²⁵ Additionally, Defendants argue that Plaintiff has not adequately pled a design defect claim²⁶ or, alternatively, that the same principles that applied to preempt a failure to warn claim also preempt any design defect claim.²⁷

2. Plaintiff's Response

Plaintiff filed her response in opposition on October 4, 2011.²⁸ Therein, Plaintiff readily admits that “*Mensing* does affect the theories of liability asserted against Defendants in the present case.”²⁹ However, Plaintiff argues that *Mensing* “is by no means dispositive of all of the claims asserted by Plaintiff.”³⁰ Plaintiff argues that “[a]s Plaintiff has alleged theories of liability which would not impose a requirement on generic manufacturers to provide warnings different or in addition to the branded manufacturer, *Mensing* is distinguishable with regard to its finding of

²⁵ See, e.g., Rec. Doc. 103-1 at p. 1 (“Plaintiff’s claims are indistinguishable from those the Supreme Court found preempted in *Mensing* and those that have been dismissed by federal courts post-*Mensing*.”).

²⁶ *Id.* at p. 10 (“But Plaintiff’s design defect claim is not well pled; she does no more than improperly provide a ‘formulaic recitation of the elements of [the] cause of action,’ and alleges no facts to support her claim.”)

²⁷ *Id.* (“... the same principles of conflict preemption applied in *Mensing* bar design defect claims against generic drug manufacturers as well. Simply, the 21 U.S.C. § 355(j) ‘sameness’ requirement applies with equal force to both the labeling and design of a generic drug.”).

²⁸ Rec. Doc. 105.

²⁹ *Id.* at p. 3.

³⁰ *Id.* In support of the proposition that preemption does not automatically apply to all causes of action, Plaintiff relies on three United States Supreme Court cases: *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992); *Altria Group, Inc. v. Good*, 555 U.S. 70 (2008); and *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005). Plaintiff also relies on Louisiana state and federal cases for this proposition. See Rec. Doc. 105 at pp. 18-20 (citations omitted). However, as Defendants point out, these cases involved express preemption, rather than conflict preemption. See, e.g., Rec. Doc. 114 at p. 9 (citation omitted). Nonetheless, despite Plaintiff’s citation to cases that are not entirely on point, this Court will consider whether each asserted claim is preempted under conflict or impossibility preemption because the Supreme Court specifically identified this type as the applicable type of preemption in *Mensing*. See *Mensing*, 131 S.Ct. at 2577-78.

preemption.”³¹ Specifically, Plaintiff argues that Defendants remain liable (1) for their failure to monitor the drug’s safety, (2) because the drug was unreasonably dangerous in design; (3) because the drug failed to conform to an express warranty; and (4) because Defendants failed to provide an adequate warning.

a. Failure to Monitor Drug Safety

First, Plaintiff contends that Defendants failed to safely monitor the drug once it entered the marketplace, that Defendants were required to take action under federal law if they had concerns about the safety of their products, and that Defendants took no such action.³² Specifically, Plaintiff argues that “generic manufacturers have a duty to keep abreast of information regarding their drug’s effect on consumers in the marketplace, and that they must take action (notifying the [Food and Drug Administration (“FDA”)] and/or brand-name manufacturer) when there is evidence that [their] drug may be harming people.”³³ Plaintiff contends that “*Mensing* says absolutely nothing about a manufacturer’s duty to *provide* a warning (i.e. communicate information appearing in FDA-approved labeling to physicians or consumers)” or about a manufacturer’s duty “to *discover and report* the risks associated with its product.”³⁴

³¹ Rec. Doc. 105 at pp. 1-2.

³² *Id.* at p. 2.

³³ *Id.* at p. 5.

³⁴ *Id.* at p. 7.

b. Design Defect

Additionally, in Plaintiff's response, Plaintiff alleges that metoclopramide was unreasonably dangerous in design and that there existed available alternative designs that would have reduced the risk of harm associated with the use of metoclopramide, such as "unit of use" packaging, which limits the amount of a drug to be dispensed to a particular patient and which provides warning information directly to the consumer.³⁵ According to Plaintiff, "[s]uch an alternative design could undoubtedly have reduced the risks posed by metoclopramide to Plaintiff."³⁶

c. Failure to Conform to Express Warranty

Plaintiff next argues that the package insert provided by Defendants contained false statements regarding the risk of side effects posed by metoclopramide and that this induced Plaintiff's physician to prescribe the drug, thus failing to conform to an express warranty.³⁷

d. Failure to Provide Adequate Warning

Finally, Plaintiff argues that *Mensing* only preempted claims regarding the inadequacy of drug labeling as it applies to the label's content³⁸ and that Defendants failed to provide any additional warning information to Plaintiff or her physicians.³⁹ According to Plaintiff, "if the generic [drug

³⁵ *Id.* at pp. 21-22.

³⁶ *Id.* at p. 22.

³⁷ *Id.* at p. 24.

³⁸ *Id.* p. 2.

³⁹ *Id.*

manufacturers] could have complied with any of [their] duties under state law by taking actions other than changing the content of [the drug's] label (such as refraining from putting its metoclopramide on the market, which neither federal nor state law required it to do), a claim based on such law would not be preempted.”⁴⁰

Specifically, Plaintiff argues that the defendant manufacturers could have minimized risk by such methods as sending “Dear Doctor” letters to healthcare practitioners, using specialized packaging to enhance safe use of the drug products, or providing other training and notification programs.⁴¹ According to Plaintiff, such tools “are available for use by *all* manufacturers, branded and generic alike.”⁴² Further, Plaintiff contends that *Mensing* did not preempt “any claim where the manufacturer could have satisfied its duty under state law by approaching the FDA with information supporting a label change for metoclopramide. Instead, it addresses only those claims involving a generic manufacturer’s duty to change the *content* of the drug’s labeling.”⁴³

Additionally, by Plaintiff’s response in opposition, Plaintiff contends that defendant PLIVA, Inc. (“PLIVA”) never updated its warning labels to include prohibitions on long-term use of metoclopramide even after changes were made to the label for metoclopramide in 2004.⁴⁴ In support of this contention, Plaintiff attaches a letter from counsel for PLIVA, which appears to acknowledge that PLIVA failed to update its warning label for metoclopramide after a 2004 change.⁴⁵ Therefore,

⁴⁰ *Id.* at p. 9.

⁴¹ *Id.* at pp. 16-17.

⁴² *Id.* at p. 17.

⁴³ *Id.*

⁴⁴ Rec. Doc. 105 at p. 2.

⁴⁵ *Id.*, Exhibit A.

Plaintiff alleges that PLIVA did not update its warning label during the majority of the time in which Plaintiff was taking the drug.⁴⁶ Plaintiff also filed a supplemental memorandum in opposition on October 13, 2011,⁴⁷ wherein Plaintiff further addressed this issue. There, Plaintiff cites *Fisher v. Pelstring*,⁴⁸ a District of South Carolina case in which *Mensing* was held not to be dispositive regarding a failure to warn claim based on the failure of the defendant, PLIVA, to alter a warning label following the FDA's approval of an additional warning.⁴⁹ In that case, the court relied on a letter from PLIVA's national counsel to the United States Supreme Court,⁵⁰ the same letter cited by Plaintiff here, in which PLIVA's counsel informed the Supreme Court that 2004 revisions to the drug's label "were not included in certain post-2004 PLIVA metoclopramide package inserts."⁵¹ Plaintiff argues that *Mensing* does not bar Plaintiff's claims as they relate to inadequate notice of information already appearing in FDA-approved labeling and that PLIVA failed to update its label during the time Plaintiff was taking metoclopramide, thus violating its duties under the LPLA.

3. Defendants' Reply

On October 27, 2012, Defendants filed a reply memorandum in support of their Motion to Dismiss.⁵² Therein, Defendants argue that Plaintiff's response advances new theories of liability not

⁴⁶ Rec. Doc. 105 at p. 18.

⁴⁷ Rec. Doc. 110.

⁴⁸ 817 F.Supp.2d 791 (D.S.C. 2011).

⁴⁹ *See id.* at 805.

⁵⁰ *Id.* at 805 n.4.

⁵¹ *See* Rec. Doc. 105-1.

⁵² Rec. Doc. 114.

included within her original complaint and/or not recognized under the LPLA.⁵³ Defendants argue that these claims must fail because they were not properly pled and, furthermore, that because the LPLA provides the exclusive remedy under state law for product liability claims, Plaintiff's "novel" theories not recognized under the LPLA must fail as a matter of law.⁵⁴ Additionally, Defendants assert that many of Plaintiff's claims are simply re-styled inadequate warning claims, such that they are nonetheless preempted under *Mensing*.⁵⁵

Specifically, Defendants first argue that Plaintiff's failure to monitor drug safety claims must fail because, even assuming such a duty exists, the duty would exist only under federal law and "only the federal government may bring an action to enforce the provisions of the Food, Drug, and Cosmetic Act ("FDCA")."⁵⁶ Additionally, Defendants argue that *Mensing* specifically held as preempted claims based on the generic drug manufacturer's failure to "take steps" and that *Mensing*'s analysis would also govern alleged failures to conduct post-marketing activities.⁵⁷

Concerning Plaintiff's arguments that Defendants are liable for a design defect, Defendants contend that "[g]eneric drug manufacturers are no more at liberty to use a different design than they are to use a different warning."⁵⁸ Thus, Defendants conclude that "[d]esign defect claims are,

⁵³ *Id.* at p. 1.

⁵⁴ *Id.* at p. 2.

⁵⁵ *Id.* (citation omitted).

⁵⁶ *Id.* at p. 3 (citing 21 U.S.C. § 337(a); *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 349 n.4 (2001)).

⁵⁷ *Id.* at p. 3-4.

⁵⁸ *Id.* at p. 8.

therefore, preempted to the same extent as failure-to-warn claims.”⁵⁹ Additionally, Defendants contend that Plaintiff has not adequately pled a design defect claim because the necessary element of an alternative design was only raised in Plaintiff’s opposition to the motion, rather than pled in Plaintiff’s complaint, and further that the alleged alternative design was not an alternative design but instead alternative packaging.⁶⁰

Next, Defendants contend that Plaintiff’s argument that Defendants are liable for failure to conform to an express warranty fails for two reasons. First, Defendants note that Plaintiff “fails to identify any express representations made to her regarding metoclopramide other than those contained in the product’s labeling,” which makes Plaintiff’s express warranty claim nothing more than a failure to warn claim that is preempted under *Mensing*.⁶¹ Additionally, Defendants argue that this claim fails factually because “Plaintiff argued in her response that Generic Defendants ‘never provided Plaintiff or her physicians with ANY warning or other information with regard to metoclopramide.’”⁶² Thus, argue Defendants, Defendants could not have made any express warranties if they provided no information.⁶³

Finally, Defendants argue that Plaintiff’s failure to warn claims are preempted. Specifically, Defendants assert that Defendants’ failure to use other communication methods to warn potential patients, such as Dear Doctor letters, cannot result in liability because *Mensing* has found such

⁵⁹ *Id.*

⁶⁰ *Id.* at p. 8 and n.4.

⁶¹ *Id.* at p. 7.

⁶² *Id.* at p. 7 (citing Rec. Doc. 105 at p. 2).

⁶³ *Id.*

claims preempted.⁶⁴ Regarding Plaintiff’s claims that Defendants are liable for a failure to warn during the time period in which the brand-name drug company had made a label change but the generic companies had failed to match the change, Defendants first note that this argument is absent from Plaintiff’s complaint.⁶⁵ Further, Defendants allege that this is a “basic failure-to-warn claim” and that it is another impermissible attempt to enforce provisions of the FDCA.⁶⁶

II. Standard of Review

The Federal Rules of Civil Procedure provide under Rule 12(b)(6) that an action may be dismissed “for failure to state a claim upon which relief can be granted.” Likewise, under Federal Rule of Civil Procedure 12(c), “[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings.” Both a motion to dismiss and a motion for judgment on the pleadings are governed by the same standard.⁶⁷ Accordingly, to survive such a motion, “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim for relief that is plausible on its face.’”⁶⁸ “Factual allegations must be enough to raise a right to relief above the speculative level,”⁶⁹ and a claim is facially plausible when the plaintiff has pled facts that allow the court to “draw a reasonable inference that the defendant is liable for the misconduct

⁶⁴ *Id.* at pp. 5-6.

⁶⁵ *Id.* at p. 4.

⁶⁶ *Id.*

⁶⁷ *Jebaco, Inc. v. Harrah’s Operating Co.*, 587 F.3d 314, 318 (5th Cir. 2009).

⁶⁸ *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2008)).

⁶⁹ *Twombly*, 550 U.S. at 556.

alleged.”⁷⁰

On a motion to dismiss or a motion for judgment on the pleadings, asserted claims are liberally construed in favor of the claimant, and all facts pleaded are taken as true.⁷¹ However, although required to accept all “well-pleaded facts” as true, the court is not required to accept legal conclusions as true.⁷² “While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations.”⁷³ Similarly, “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements” will not suffice.⁷⁴ The complaint need not contain detailed factual allegations, but it must offer more than mere labels, legal conclusions, or formulaic recitations of the elements of a cause of action.⁷⁵ That is, the complaint must offer more than an “unadorned, the defendant-unlawfully-harmed-me accusation.”⁷⁶

From the face of the complaint, there must be enough factual matter to raise a reasonable expectation that discovery will reveal evidence as to each element of the asserted claims.⁷⁷ If factual allegations are insufficient to raise a right to relief above the speculative level, or if it is apparent

⁷⁰ *Id.* at 570.

⁷¹ *Leatherman v. Tarrant Cnty. Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 164 (1993); *see also Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322-23 (2007).

⁷² *Iqbal*, 556 U.S. 662, 677-78.

⁷³ *Id.* at 679.

⁷⁴ *Id.* at 678.

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Lormand v. U.S. Unwired, Inc.*, 565 F.3d 228, 257 (5th Cir. 2009).

from the face of the complaint that there is an “insuperable” bar to relief, the claim must be dismissed or judgment on the pleadings granted.⁷⁸

III. Law and Analysis

A. Overview of the Louisiana Products Liability Act

Under Louisiana law, the LPLA establishes the exclusive remedy for injuries arising from product defects⁷⁹ and sets forth the only four theories of recovery under which a plaintiff may recover.⁸⁰ To establish liability under any of these theories, a plaintiff must prove: (1) that the defendant is a “manufacturer” of the product, as that term is defined under the statute; (2) that the plaintiff’s damages were proximately caused by a characteristic of the product; (3) that the damage-causing characteristic made the product “unreasonably dangerous”; and (4) that the plaintiff’s damages arose from a reasonably anticipated use of the product.⁸¹ A plaintiff can establish that a product is unreasonably dangerous under any of four theories: (1) a defect in construction or composition; (2) a design defect; (3) a failure to provide an adequate warning; or (4) a failure to comply with an express warranty.⁸²

⁷⁸ *Moore v. Metro. Human Serv. Dep’t*, No. 09-6470, 2010 WL 1462224, at * 2 (E.D. La. Apr. 8, 2010) (Vance, C.J.) (citing *Jones v. Bock*, 549 U.S. 199, 215 (2007); *Carbe v. Lappin*, 492 F.3d 325, 328 & n. 9 (5th Cir. 2007)).

⁷⁹ La. R.S. § 9:2800.52.

⁸⁰ La. R.S. § 9:2800.54.

⁸¹ *Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254, 260-61 (5th Cir. 2002).

⁸² La. R.S. § 9:2800.54; *see also Stahl*, 283 F.3d at 260-61.

1. Construction or Composition Defect

To establish a construction or composition defect claim, a plaintiff must establish that, at the time the product left the manufacturer's control, the product "deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer."⁸³ This LPLA provision provides a cause of action for a product that is defective because of a mistake in the manufacturing process.⁸⁴

2. Design Defect Claim

To establish a design defect claim, a plaintiff must establish that, at the time the product left the manufacturer's control, "[t]here existed an alternative design for the product that was capable of preventing the claimant's damage" and that the danger of the damage outweighed the burden on the manufacturer of adopting the alternative design.⁸⁵ An adequate warning about a product is considered in evaluating the likelihood of damage when the manufacturer has used reasonable care to provide an adequate warning to users of the product.

3. Failure to Provide Adequate Warning

Failure to provide adequate warning labels may result in liability under the LPLA where a plaintiff can establish (1) that "the product possessed a characteristic that may cause damage" and (2) that "the manufacturer failed to use reasonable care to provide an adequate warning of such

⁸³ La. R.S. § 9:2800.55. *See also Stahl*, 283 F.3d at 263.

⁸⁴ *Stahl*, 283 F.3d at 263 (citing La. R.S. § 9:2800.55).

⁸⁵ La. R.S. § 9:2800.56.

characteristic and its danger to users and handlers of the product.”⁸⁶ To meet the first prong of this test, the Fifth Circuit has provided that a plaintiff must establish evidence about the “cause, frequency, severity, or consequences” of the dangerous characteristic in question.⁸⁷ To satisfy the second prong of this test, a plaintiff must prove the language of the warning was inadequate to reasonably inform the recipient about the nature of the danger involved.⁸⁸ A plaintiff is not required to prove a design defect in order to establish a failure to warn claim; even if a product is not defective in design or construction, the manufacturer “may still have a duty to warn consumers about any characteristic of the product that unreasonably may cause damage.”⁸⁹ Further, a manufacturer’s duty does not necessarily end when the product leaves the manufacturer’s control.⁹⁰

4. *Failure to Conform to Express Warranty*

An express warranty exists where the manufacturer of a good voluntarily undertakes and extends a guarantee to customers.⁹¹ Under the LPLA, an express warranty is defined as:

a representation of alleged fact or promise about a product or its nature, material or workmanship that represents, affirms or promises that the product or its nature, material or workmanship possesses specified characteristics or qualities or will meet a specified

⁸⁶ La. R.S. § 9:2800.57(A).

⁸⁷ See *Krummel v. Bombardier Corp.*, 206 F.3d 548, 552 (5th Cir. 2010).

⁸⁸ *Stahl*, 283 F.3d at 267.

⁸⁹ *Grenier v. Med Eng’g Corp.*, 243 F.3d 200, 205 (5th Cir. 2001).

⁹⁰ La. R.S. § 9:2800.57(C) (“A manufacturer of a product who, after the product has left his control, acquires knowledge of a characteristic of the product that may cause damage and the danger of such characteristic, or who would have acquired such knowledge had he acted as a reasonably prudent manufacturer, is liable for damage caused by his subsequent failure to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.”).

⁹¹ *Fields v. Walpole Tire Serv., L.L.C.*, 37 So.3d 549, 557 (La. App. 2 Cir. 2010).

level or performance. “Express warranty” does not mean a general opinion about or general praise of a product⁹²

A warranty is not a warning, nor is it a mandatory packaging or labeling condition that constitutes a state-imposed requirement.⁹³ Under the LPLA, a manufacturer may be liable if a product contains an express warranty that has “induced the claimant or another person or entity to use the product and the claimant’s damage was proximately caused because the express warranty was untrue.”⁹⁴

B. Preemption

Article VI of the United States Constitution provides, “This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land.”⁹⁵ Therefore, where federal and state law directly conflict, the state law must “give way.”⁹⁶ When it is “impossible for a private party to comply with both state and federal requirements,” such a conflict exists and the state law is preempted by the federal.⁹⁷ Therefore, “[w]hen the ‘ordinary meaning’ of federal law blocks a private party from independently accomplishing what state law requires, that party has established pre-emption.”⁹⁸ However, the burden to establish the affirmative

⁹² La. R.S. § 9:2800.53(6).

⁹³ *Fields*, 37 So.3d at 557 (citation omitted).

⁹⁴ La. R.S. § 9:2800.58.

⁹⁵ U.S. Const., Art. VI, cl. 2.

⁹⁶ *Mensing*, 131 S.Ct. at 2577 (citing *Wyeth v. Levine*, 555 U.S. 555, 583 (2009) (Thomas, J., concurring in judgment); *Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 372 (2000) (“state law is naturally preempted to the extent of any conflict with a federal statute”)).

⁹⁷ *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995).

⁹⁸ *Mensing*, 131 S.Ct. at 2580.

defense of impossibility preemption rests on the party seeking to establish it.⁹⁹ All causes of action are not preempted by federal law simply because particular claims are preempted, and a court must instead scrutinize each claim individually.¹⁰⁰

In *Mensing*,¹⁰¹ the United States Supreme Court was confronted with the question of whether a generic drug manufacturer's alleged failure to provide an adequate warning label in accordance with state law directly conflicted with federal drug regulations applicable to generic drug manufacturers, such that federal law would preempt claims brought against generic drug manufacturers for violations of applicable state laws.¹⁰² A majority of the Court held that federal law did preempt such claims.¹⁰³ The case involved two separate actions that were consolidated before the Supreme Court, each of which brought claims under state tort law against a generic drug manufacturer for failure to provide adequate warning labels¹⁰⁴; one of the plaintiffs, Julie Demahy, brought her claims under the LPLA.¹⁰⁵ In the consolidated action, the defendant manufacturers argued that federal statutes and FDA regulations preempted the state tort claims because the statutes and regulations required their labels to provide the same safety and efficacy labeling as the brand-name counterpart drugs.¹⁰⁶ Therefore, argued the defendant manufacturers, it was impossible for

⁹⁹ See *Wyeth v. Levine*, 555 U.S. 555, 573 (2009).

¹⁰⁰ See, e.g., *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992).

¹⁰¹ 131 S.Ct. 2567.

¹⁰² *Id.* at 2572.

¹⁰³ *Id.*

¹⁰⁴ *Id.* at 2573.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

them simultaneously to comply with federal law and also to satisfy their state tort duties, which would require the generic manufacturers to use a different label than that currently used by their brand-name counterparts.¹⁰⁷

The Court began by outlining the parameters of federal drug law, noting that a generic drug gains FDA approval by demonstrating that it is the same as an already-approved brand name version¹⁰⁸ and concluding that “brand-name and generic drug manufacturers have different federal drug labeling duties.”¹⁰⁹ Specifically, the Court concluded that “generic drug manufacturers have an ongoing federal duty of ‘sameness.’”¹¹⁰ In response, the plaintiffs each presented several arguments that their state law claims were not preempted because, despite this duty of sameness, there existed actions that the generic drug manufacturers could have taken but did not.¹¹¹ Accordingly, argued the plaintiffs, there existed no impossibility such that their claims were preempted.

First, the plaintiffs each argued that there existed an FDA process – the “changes-being-effected” (“CBE”) process – that allowed generic drug manufacturers to change their labels when necessary.¹¹² However, the Court noted that the FDA denied that generic drug manufacturers could unilaterally effect label change because a generic drug manufacturer would only be permitted to

¹⁰⁷ *Id.*

¹⁰⁸ *Id.* at 2574-75 (stating that generic drugs “gain FDA approval simply by showing equivalence to a reference listed drug that has already been approved by the FDA”).

¹⁰⁹ *Id.* at 2574.

¹¹⁰ *Id.* at 2574-75 (citing 57 Fed. Reg. 17961 (1992) (“[T]he [generic drug’s] labeling must be the same as the listed drug product’s labeling because the listed drug product is the basis for [generic drug] approval.”)).

¹¹¹ *Id.* at 2575-77.

¹¹² *Id.* at 2575.

change a label to match an updated brand-name drug label or per FDA instructions¹¹³; accordingly, the Court deferred to the FDA and found that unilateral change, as would be required by the state laws in question, would violate the generic manufacturers' duty of sameness.¹¹⁴ The plaintiffs further argued that there existed other avenues by which manufacturers could provide additional warnings to patients, such as "Dear Doctor" letters in which additional warnings were sent to physicians and healthcare professionals.¹¹⁵ Again, the Court deferred to the FDA and determined that such an avenue was unavailable to generic manufacturers because such letters would constitute labeling and, therefore, would be in violation of the duty of sameness.¹¹⁶

Having denied that generic manufacturers could use the CBE process or "Dear Doctor" letters to effect change, the FDA noted in its amicus brief that an additional avenue existed for generic manufacturers to strengthen a label: proposing a stronger warning label to the FDA.¹¹⁷ However, the Court determined that even *if* there existed a duty for the generic manufacturers to work toward strengthening a drug's label, preemption nonetheless existed because the generic manufacturer still would not be in compliance with state law.¹¹⁸ The Court stated:

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 [assumed]

¹¹³ *Id.* at 2575.

¹¹⁴ *Id.*

¹¹⁵ *Id.* at 2576.

¹¹⁶ *Id.*

¹¹⁷ *See id.*

¹¹⁸ *Id.* at 2577 ("Because we ultimately find pre-emption even assuming such a duty existed, we do not resolve the matter [of whether a duty existed].")

federal duty to ask for FDA assistance, they would not have satisfied the requirements of state law.¹¹⁹

The Court found that even such a 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.*”¹²⁰

However, the plaintiffs argued that because the defendant manufacturers had done nothing to attempt to change the labels, the plaintiffs’ claims should not be preempted because the manufacturers might have been able to accomplish what state law required of them and, therefore, there existed no impossibility sufficient to support preemption.¹²¹ Specifically, “Mensing and Demahy assert[ed] that when a private party’s ability to comply with state law depends on approval and assistance from the FDA, proving pre-emption requires that party to demonstrate that the FDA would not have allowed compliance with state law.”¹²² Although this argument persuaded four members of the Court,¹²³ it did not persuade the majority.¹²⁴ The majority concluded that “[t]he question for ‘impossibility’ is whether the private party could independently do under federal law what state law requires of it,” and the majority determined that conflict preemption would be

¹¹⁹ *Id.*

¹²⁰ *Id.* at 2578 (emphasis added).

¹²¹ *Id.* at 2578.

¹²² *Id.* at 2578-79.

¹²³ *See id.* at 2582-83 (Sotomayor, J., dissenting).

¹²⁴ *Mensing*, 131 S.Ct. at 2579 (“Here, [plaintiffs] argue, the Manufacturers cannot bear their burden of proving impossibility because they did not even *try* to start the process that might ultimately have allowed them to use a safer label. This is a fair argument, but we reject it.”) (internal citation omitted).

rendered largely meaningless if the Court were to accept plaintiffs' argument.¹²⁵ The Court concluded, "pre-emption analysis should not involve speculation about ways in which federal agency and third-party actions could potentially reconcile federal duties with conflicting state duties. When the 'ordinary meaning' of federal law blocks a private party from independently accomplishing what state law requires, that party has established pre-emption."¹²⁶ Therefore, the Court held that the plaintiffs' claims were preempted.¹²⁷

In *Mensing*, the Court did not specifically reverse, or even address, one of the arguments that had been raised before one of the appellate courts below.¹²⁸ There, *Mensing* had put forth an argument that the manufacturer could have removed the drug from the market and therefore could have accomplished its duties under state law.¹²⁹ However, on remand, the Eighth Circuit interpreted the Supreme Court's ruling in *Mensing* to encompass the failure-to-withdraw theory, and the Eighth Circuit vacated the portion of its opinion that had embraced that theory.¹³⁰ Moreover, federal courts within Louisiana have considered this argument and have found it without merit:

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 is not enough; federal law disallows stronger labeling, so the only way to responsibly

¹²⁵ *Id.* at 2579.

¹²⁶ *Id.* at 2580-81 ("[W]hen 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 state duties for pre-emption purposes.").

¹²⁷ *Id.* at 2581.

¹²⁸ *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009).

¹²⁹ *Id.* at 611.

¹³⁰ *See Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011).

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.¹³¹

Additionally, although the Supreme Court in *Mensing* was only confronted with the question of whether a plaintiff's failure to warn claim would be preempted by federal law, numerous lower courts have since confronted the question of whether a design defect claim is also preempted as a result of the generic manufacturer's duty of sameness. Overwhelmingly, these courts have found that such a claim is preempted,¹³² largely on the basis that federal law requires a generic drug to be of the same design as its brand name counterpart.¹³³ A generic drug must be the same as the reference listed drug in active ingredients, safety, and efficiency.¹³⁴ Therefore, these courts have found it would be impossible for a generic manufacturer to alter the design of its product without violating the generic manufacturer's federal duty of sameness, creating impossibility and thus preempting such claims.

¹³¹ *Cooper v. Wyeth, Inc.*, No. 09-0929, 2012 WL 733846 (M.D. La. Mar. 6, 2012); *see also Johnson v. Teva Pharms. USA, Inc.*, No. 10-0404, 2012 WL 1866839, at *5 (W.D. La. May 21, 2012). Federal courts sitting in Louisiana are not alone in their conclusion that a failure to withdraw from the market argument does not overcome impossibility preemption. *See, e.g., Eckhardt v. Qualitest Pharms., Inc.*, No. 11-0235, 2012 WL 1511817 (S.D. Tex. Apr. 30, 2012).

¹³² *See, e.g., Stevens v. PLIVA, Inc.*, No. 10-0886, 2011 WL 6224569, at *2 (W.D. La. Nov. 15, 2011); *Johnson*, 2012 WL 1866839, at *4; *Eckhardt*, 2012 WL 1511817, at *7 (“Therefore, Generics were required to produce a drug that was equivalent to the brand-name drug and were not free to unilaterally pursue a safer alternative design in order to comply with state law. The design defect claim is thus preempted and therefore dismissed.”).

¹³³ *See* 21 U.S.C. § 355(j) (setting forth that a generic drug must be bioequivalent to its brand name reference drug to receive FDA approval via an abbreviated process).

¹³⁴ *Id.*

C. Analysis

In this case, Plaintiff primarily presents arguments of precisely the type rejected by the Supreme Court in *Mensing*, and this Court finds that all of Plaintiff's claims asserted in her complaints¹³⁵ either are preempted in accordance with that decision or fail to state a claim upon which relief may be granted, or both.

1. Failure to Monitor Drug Safety

First, the Court notes that the LPLA provides the exclusive remedy for product liability claims under Louisiana law,¹³⁶ and failure to monitor drug safety does not fall under the available avenues of relief.¹³⁷ However, the Court also finds that Plaintiff's claim asserted as failure to monitor drug safety is more appropriately considered as a failure to warn claim. Plaintiff asserts that Defendants failed to monitor the safety of their products once they entered the market, but the LPLA provides that a manufacturer may be "liable for damage caused by his subsequent failure to use reasonable care to provide an adequate warning . . ."¹³⁸ and even post-market monitoring efforts must necessarily result in warnings to patients and physicians if they are to have any effect. The Court in

¹³⁵ Again, the Court notes that it need not consider the viability of Plaintiff's claim that PLIVA failed to provide an adequate warning because of its alleged failure to update its warning label following FDA approval of label changes, given that Plaintiff has not alleged such a claim in any version of her complaints.

¹³⁶ La. R.S. § 9:2800.52.

¹³⁷ La. R.S. § 9:2800.54. Thus, even assuming that there existed a duty to report, such a duty would exist only as a matter of federal law, and only the federal government may bring an action to enforce the provisions of the Food, Drug, and Cosmetic Act ("FDCA"). See 21 U.S.C. § 337(a) (providing that proceedings for enforcement, or to restrain violations, of the FDCA "shall be by and in the name of the United States"); see also *Buckman Co.*, 531 U.S. at 349 n.4 ("FDCA leaves no doubt that it is the federal government rather than private litigants who are authorized to file suit for noncompliance.").

¹³⁸ La. R.S. § 9:2800.57(C).

Mensing expressly found preempted such warnings in contravention of the generic manufacturer's federal duty of sameness, as further explained below. Thus, this claim fails and must be dismissed.

2. Design Defect

Next, Plaintiff asserts that metoclopramide was unreasonably dangerous in design. However, to establish a design defect claim, among other requirements, Plaintiff must demonstrate the “essential element”¹³⁹ that there existed an available alternative design.¹⁴⁰ Plaintiff's complaints are devoid of any such allegations of alternative design; it is only in Plaintiff's arguments in response to the pending motion that Plaintiff first alleges an available alternative design – “unit of use” packaging, which would limit the amount of drug dispensed to a particular patient and provide warning information directly to the patient. However, generally a court “must not go outside the pleadings” when ruling on a motion to dismiss.¹⁴¹ Federal Rule of Civil Procedure 7 defines “pleadings” to include only complaints, answers, and, if ordered by the Court, a reply to an answer.¹⁴² Thus, Plaintiff's design defect claim must fail for being inadequately pled.

¹³⁹ See, e.g., *Ivory v. Pfizer*, No. 09-0072, 2009 WL 323061, at *3 (W.D. La. Sept. 30, 2009) (citing *Guidry v. Events Pharms., Inc.*, 418 F. Supp. 835, 842 (M.D. La. 2006); *Green v. BDI Pharms.*, 803 So.2d 68, 78 (La. App. 2 Cir. 2001)).

¹⁴⁰ See La. R.S. § 9:2800.56.

¹⁴¹ See, e.g., *Scanlan v. Texas A&M Univ.*, 343 F.3d 533, 536 (5th Cir. 2003) (answering the question of whether, on a motion to dismiss, a district court erred in relying on documents outside the complaints and noting that a district court “may not go outside the complaint” except for the “limited exception” of when the court considers documents that are attached to the motion to dismiss and those documents “are referred to in the plaintiff's complaint and are central to the plaintiff's claim”).

¹⁴² Fed. R. Civ. P. 7(a) (“PLEADINGS. Only these pleadings are allowed: (1) a complaint; (2) an answer to a complaint; (3) an answer to a counterclaim designated as a counterclaim; (4) an answer to a crossclaim; (5) a third-party complaint; (6) an answer to a third-party complaint; and (7) if the court orders one, a reply to an answer.”). All other documents fall within Rule 7(b), “MOTIONS AND OTHER PAPERS.”

Furthermore, even if this Court were to go outside the pleadings to consider the late-alleged alternative design as pled, the alleged alternative design is a proposed alternative packaging, rather than an alternative design for the drug. As such, even if this Court were not inclined to agree with lower courts that have found design defect claims preempted under *Mensing*¹⁴³ and if this Court had not itself previously found design defect claims preempted under *Mensing*,¹⁴⁴ Plaintiff cites no authority that deems unit of use packaging an adequate alternative design. This Court finds that this particular claim sounds in failure to warn and is preempted under *Mensing*. Thus, this claim also must be dismissed.

3. Failure to Provide Adequate Warning

As in *Mensing*, the defendants here could not change, strengthen, or alter the label in any way without the prior approval of the FDA, and thus, Defendants “could [not] independently do under federal law what state law require[d] of [them]” without violating federal law, thus establishing preemption. Plaintiff appears to acknowledge this result.¹⁴⁵ However, Plaintiff argues that Defendants were not prevented from “taking actions other than changing the content of [the drug’s]

¹⁴³ In *Mensing*, the Supreme Court noted that a generic drug manufacturer has a duty of sameness, and federal law specifically requires a generic drug to be the bioequivalent of its name-brand counterpart. See 21 U.S.C. § 355(j). Therefore, a generic manufacturer cannot alter the design of a drug without violating federal law and this duty of sameness, making it impossible for a generic manufacturer independently to comply with both federal and state law. Numerous lower courts have considered this issue and have found the failure-to-warn reasoning of *Mensing* equally applicable to design defect claims. See, e.g., *Stevens*, 2011 WL 6224569, at *2; *Johnson*, 2012 WL 1866839, at *4; *Eckhardt*, 2012 WL 1511817, at *7.

¹⁴⁴ *Aucoin v. Amneal*, No. 11–1275, 2012 WL 2990697 (E.D. La. July 20, 2012) (Brown, J.).

¹⁴⁵ Rec. Doc. 105 at p. 3.

label”¹⁴⁶ and argues that there was much that Defendants could have and were required to do.¹⁴⁷ Plaintiff points out that the Court in *Mensing* assumed that there existed a duty for generic manufacturers to seek to change a drug’s label if it had reason to believe that a change was necessary and argues that claims based on such inaction are not preempted by *Mensing*.¹⁴⁸ Additionally, Plaintiff argues that Defendants could have removed the drug from the market¹⁴⁹ and that Defendants could have utilized tools and other communication methods such as “Dear Doctor” letters to minimize risk.¹⁵⁰

These arguments, however, have previously been considered and rejected by the Supreme Court.¹⁵¹ Plaintiff ignores the fact that the majority of the Supreme Court in *Mensing* explicitly rejected these same arguments regarding other actions that could have been taken¹⁵² and the fact that the Supreme Court explicitly held that even if a duty to work toward label changes existed, the plaintiffs’ claims were preempted nonetheless.¹⁵³ Additionally, this Court finds that Plaintiff’s arguments regarding Defendants’ failure to withdraw from the market fail. Although not specifically addressed by the Supreme Court, this Court agrees with the reasoning advanced by other courts that

¹⁴⁶ *Id.* at p. 9.

¹⁴⁷ *See id.* at p. 5-6.

¹⁴⁸ *Id.* at pp. 5-6 and 17 (“Nor does [*Mensing*] preempt any claim where the manufacturer could have satisfied its duty under state law by approaching the FDA with information supporting a label change for metoclopramide.”).

¹⁴⁹ *Id.* at p. 9 (“such as refraining from putting its metoclopramide on the market”).

¹⁵⁰ *Id.* at p. 16-17.

¹⁵¹ *Mensing*, 131 S.Ct. at 2579.

¹⁵² *Id.* at 2575-77

¹⁵³ *Id.* at 2577.

have considered this issue since the *Mensing* decision was rendered.¹⁵⁴ To require a generic manufacturer to remove a drug from the market would repudiate the label approved by the FDA.

However, Plaintiff also argues in her response in opposition that defendant PLIVA never updated its warning label to match brand-name labels and include prohibitions on long-term use of metoclopramide after changes to the label were approved by the FDA, such that Plaintiff's claims are not preempted.¹⁵⁵ A review of Plaintiff's complaints reveals that nowhere in the four corners of Plaintiff's Complaint, First Amended and Restated Complaint, or Second Amended and Restated Complaint does Plaintiff assert that PLIVA failed to update its warning label for its generic drug after changes had been approved by the FDA; this argument appears only in Plaintiff's opposition to the pending motion. As this Court has already noted, a court generally should not consider claims not alleged within a plaintiff's complaint.

Additionally, the Court notes that Plaintiff has not requested leave to amend her complaint to include this allegation concerning PLIVA's alleged failure to update its warning label, nor has Plaintiff made any statements that could be construed as such a request. Leave to amend is "entrusted to the sound discretion of the district court."¹⁵⁶ A great deal of time has passed since Defendants filed their reply to the pending motion, which opposition should have alerted Plaintiff that this particular claim was absent from her complaints. Although the deadline for amendments to pleadings had long since passed when Defendants' opposition was filed,¹⁵⁷ Plaintiff could have

¹⁵⁴ See, e.g., *Cooper*, 2012 WL 733846; *Johnson*, 2012 WL 1866839; *Eckhardt*, 2012 WL 1511817.

¹⁵⁵ Rec. Doc. 105 at p. 2.

¹⁵⁶ *Jones v. Robinson Prop. Grp., L.P.*, 427 F.3d 987, 994 (5th Cir. 2005) (quoting *Quintanilla v. Tex. Television, Inc.*, 139 F.3d 494, 499 (5th Cir. 1998)).

¹⁵⁷ See Rec. Doc. 61.

sought leave to amend.¹⁵⁸ Considering that Plaintiff has not requested leave to amend her complaint, that Plaintiff has twice amended her complaint previously, that a great deal of time has passed since Plaintiff was put on notice that this claim was omitted, and that PLIVA would be prejudiced were this Court to hold otherwise, this Court does not find it appropriate to construe Plaintiff's newly asserted argument as a request to amend her complaint.¹⁵⁹

Thus, this Court need not reach a conclusion regarding whether a claim against PLIVA for failure to update its warning labels after changes were approved by the FDA is preempted. Accordingly, Plaintiff has not properly pled a failure to warn claim based on PLIVA's failure to update its warning label, and Plaintiff's other failure to warn claims are preempted and must be dismissed in accordance with the United States Supreme Court's decision in *Mensing*.

4. *Failure to Conform to Express Warranty*

Finally, Plaintiff alleges that the package insert provided by Defendants contained false statements about the risk of side effects posed by the drug, resulting in a failure of the drug to conform to an express warranty by the manufacturers. However, Plaintiff's complaints fail to allege or identify any express warranties by Defendants beyond the allegedly false statements contained in the package insert. Specifically, Plaintiff has not alleged that Defendants advertised their products, detailed their products to doctors, or made any other forms of communication regarding the drug.

¹⁵⁸ Federal Rule of Civil Procedure 16(b) governs amendment of pleadings after the scheduling order's deadline for amendments has passed, as here; the rule provides that a scheduling order "may be modified only for good cause and with the judge's consent."

¹⁵⁹ Likewise, in a case where allegations were not pled in an amended complaint and were only asserted in later briefings on a motion to dismiss for failure to state a claim, the Fifth Circuit left undisturbed the district court's decision to decline to consider the allegations. *City of Dallas v. Hall*, 562 F.3d 712, 723 (5th Cir. 2009).

In fact, Plaintiff stated in her opposition to the pending motion that Defendants “never provided Plaintiff or her physicians with ANY warning *or other information* with regard to metoclopramide.”¹⁶⁰

Thus, the only express warranty allegedly violated by Defendants’ drug was the alleged warranty on the package insert. However, “[a] warranty is not a warning, nor is it a mandatory packaging or labeling condition. . . .”¹⁶¹ Thus, Plaintiff has failed to allege a violation of an express warranty and has merely restyled her failure to warn claim as such. As explained above, such failure to warn claims are expressly preempted under *Mensing*, and so this alleged failure to conform to an express warranty claim also must fail because Plaintiff has failed to allege a violation of an express warranty that is not actually a failure to warn claim preempted by *Mensing*.

IV. Conclusion

For the reasons set forth above, the Court will dismiss Plaintiff’s failure to monitor drug safety claim as a failure to warn claim preempted under *Mensing*; will dismiss Plaintiff’s design defect and failure to conform to an express warranty claims as failure to warn claims preempted under *Mensing*, or alternatively, for failure to satisfy the requisite pleading standard to state a claim; and will dismiss Plaintiff’s failure to provide an adequate warning claim as preempted under *Mensing*. Accordingly,

¹⁶⁰ Rec. Doc. 105 at p. 2 (emphasis added).

¹⁶¹ *Fields*, 37 So.3d at 557.

IT IS HEREBY ORDERED that Defendants' Motion to Dismiss¹⁶² is **GRANTED** and that the above-captioned case is **DISMISSED WITH PREJUDICE**.

NEW ORLEANS, LOUISIANA, this 20th day of August, 2012.

Nannette Jolivette Brown
NANNETTE JOLIVETTE BROWN
UNITED STATES DISTRICT JUDGE

¹⁶² Rec. Doc. 103.