

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

JOYCE FULLINGTON

PLAINTIFF

v.

No. 4:10CV00236 JLH

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

DEFENDANTS

OPINION AND ORDER

Joyce Fullington developed tardive dyskinesia after taking the prescription drug metoclopramide from April 2008 until April 2009. She then brought this action against the manufacturers of the brand-name and generic forms of metoclopramide. In a previous order, the Court granted summary judgment in favor of the brand-name manufacturers because it is undisputed that Fullington did not use their product. In light of the Supreme Court holding in *PLIVA, Inc. v. Mensing*, --- U.S. ---, 131 S. Ct. 2567, 180 L. Ed. 2d 580 (2011), that all state-law causes of action against generic manufacturers for failure to warn are preempted, the Court thereafter granted a motion to dismiss filed by generic metoclopramide manufacturers PLIVA, Inc. and Mutual Pharmaceutical Company, Inc. Fullington has now filed an amended complaint, and the generic manufacturers have again moved to dismiss the action pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. For the following reasons, the motion to dismiss is granted, except as to Fullington's failure-to-warn claim against PLIVA for the period of time after February 2009. On that claim, PLIVA's motion will be converted to a motion for summary judgment, and Fullington will be given an opportunity to present evidence in opposition to the motion.

I.

The pleading standards and the correlative standards for ruling on a motion to dismiss under Rule 12(b)(6) are well known. A complaint must contain “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2). While Rule 8(a)(2) does not require a complaint to contain detailed factual allegations, it does require a plaintiff to state the grounds of his entitlement to relief, which requires more than labels and conclusions. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 1964-65, 167 L. Ed. 2d 929 (2007). In ruling on a motion to dismiss, the Court must accept as true all factual allegations in the complaint and review the complaint to determine whether its allegations show that the pleader is entitled to relief. *Schaaf v. Residential Funding Corp.*, 517 F.3d 544, 549 (8th Cir. 2008). All reasonable inferences from the complaint must be drawn in favor of the nonmoving party. *Crumpley-Patterson v. Trinity Lutheran Hosp.*, 388 F.3d 588, 590 (8th Cir. 2004). The Court need not, however, accept as true legal conclusions, even those stated as though they are factual allegations. *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 1949-50, 173 L. Ed. 2d 868 (2009).

II.

The Court need not recount the facts, as it has already done so in its previous opinion. *See* Document #72, at 1-3. In that opinion, the Court held that: (1) all of Fullington’s claims against generic manufacturers depended on failure-to-warn allegations; and (2) these failure-to-warn claims were all preempted, per *Mensing*, because it is impossible for generic manufacturers simultaneously to comply with federal law, which bars them from unilaterally changing warning labels, and state law, which allegedly requires them to change the labels. *Id.* at 6-8. The Court also stated that, to the extent that Fullington alleged other claims such as a design defect, in addition to a failure to warn,

the allegations were insufficient. *Id.* at 8-9. Thus, the Court dismissed all of Fullington's claims against the generic manufacturer without prejudice but permitted Fullington to file an amended complaint. *Id.* at 12; Document #76.¹

In her amended complaint, Fullington asserts claims for relief under Arkansas law for strict liability, negligence, gross negligence, fraudulent misrepresentation, negligent misrepresentation, fraudulent concealment, and breach of the implied warranties of merchantability and fitness for a particular purpose. Document #77. Fullington's amended complaint adds the following eleven paragraphs to her original complaint:

5.13 In 2003, the FDA approved the addition of additional information to the labeling for Reglan/metoclopramide regarding the manner in which the drug should be used in order to safely treat geriatric patients.

5.14 In July, 2004, the FDA approved the addition of bolded warnings to the labeling for Reglan/metoclopramide stating that therapy with the drug **“should not exceed 12 weeks in duration.”**

* * *

6.46 All Defendants failed to communicate the true and accurate risks accompanying the ingestion of drugs containing Reglan/metoclopramide, and the fact that the drug should not be used for longer than 12 weeks. Defendants PLIVA and Mutual failed to communicate the addition of warnings to the labeling for metoclopramide in 2003 and 2004 that were directed at discouraging use of metoclopramide for longer than 12 weeks, or in geriatric patients. As a result, physicians and consumers remained unaware that use of metoclopramide for longer than 12 weeks was not likely to be reasonably safe.

6.47 All Defendants failed to exercise reasonable care in the design of the packaging for their metoclopramide products in that they chose to use bulk packaging which invited long-term use of the drug, rather than other packaging design options, such as unit-of-use packaging, which deters extended use.

¹In giving its permission to file an amended complaint, the Court made it clear that its previous summary judgment order in favor of the brand-name defendants still stands. Document #76. Thus, the numerous allegations in Fullington's amended complaint against the brand-name defendants will be disregarded.

* * *

6.59 Defendant Pliva failed to include information necessary for the safe and effective use of Reglan/metoclopramide in geriatric patients in its label for metoclopramide, despite FDA approval of these additions to the label for the [Reference Listed Drug] in April, 2003.

6.60 Defendant PLIVA failed to include warnings prohibiting the use of Reglan/metoclopramide for periods in excess of 12 weeks in its label for metoclopramide, despite FDA approval of these additions to the label for the RLD in July, 2004.

6.61 Defendant PLIVA failed to exercise reasonable care in the design or manufacture of its metoclopramide products in that the metoclopramide it distributed differed from the manufacturer's specification that the labeling for their product be the same as that of the Reference Listed Drug.

6.62 All Defendants violated provisions of federal law enacted to protect the health and safety of consumers in the manufacturing and marketing of their metoclopramide products. These provisions include the following: . . .²

* * *

7.03 Defendant Pliva's negligence includes the failure to include FDA-approved warnings directed at discouraging geriatric and long-term use of metoclopramide in its label for the drug, its failure to alert the medical community and consumers to the addition of these strengthened warnings, and its failure to accompany its metoclopramide with adequate instructions for safe use, including the instruction that therapy with metoclopramide should not exceed 12 weeks in duration, that geriatric patients should receive the lowest dose of metoclopramide possible, and that metoclopramide should be discontinued if parkinsonian symptoms appear.

* * *

7.07 The metoclopramide manufactured by Defendant Pliva was unreasonably dangerous in that its label failed to include language indicating that use of the drug should not exceed 12 weeks in duration and was not likely to be safe in geriatric patients when prescribed at the recommended dosage, and instead misleadingly implied that metoclopramide use for longer than 12 weeks and in geriatric patients was safe and effective.

* * *

²This omitted portion of Paragraph 6.62 in the amended complaint actually contains nine new paragraphs. All of these paragraphs, however, concern claims that have already been found preempted by this Court in its earlier decision (i.e. inadequate warning claims unrelated to the generic manufacturers' failure to update their labels in 2004).

7.18 Defendant Pliva concealed the facts that important safety-related changes had been made to the labeling for Reglan/metoclopramide in 2003 and 2004, that use of the drug in geriatric patients was not likely to be safe, and that metoclopramide therapy should not exceed 12 weeks in duration.

Document #77 (bold in the original).

The generic defendants have now moved to dismiss Fullington’s amended complaint, arguing that, much like her original complaint, Fullington’s new allegations are either preempted because they are based on a failure to warn or they fail to state a claim for which relief could be granted under Rule 12(b)(6). Fullington responds by arguing that she has alleged claims that survive *Mensing*. She primarily contends that her claims based on the alleged failure to update labels in 2003 and 2004 are not preempted. She also argues that other claims, including her design defect, manufacturing defect, and fraud claims, are not preempted and are sufficiently pled to survive a motion to dismiss.

III.

Fullington added no allegations to her misrepresentation or implied warranty claims. These claims are therefore dismissed based on the Court’s earlier opinion. Document #72. Fullington did, however, add allegations arguably relating to negligence, fraudulent concealment, manufacturing defect, design defect, and failure to warn.

A. **Negligence/Gross Negligence**

Fullington now alleges that PLIVA’s “negligence includes the failure to include FDA-approved warnings . . . ,” among other related things. Document #77, at ¶ 7.03. These negligence claims are transparently failure-to-warn claims. *See* Document #72, at 8 (“[A]ll of Fullington’s claims against the generic manufacturers depend on her failure-to-warn allegations.”). Whether Fullington’s new failure-to-warn claims are viable will be addressed later in this opinion.

B. Fraudulent Concealment

Fullington now alleges that PLIVA “concealed the facts that important safety-related changes had been made to the labeling for Reglan/metoclopramide in 2003 and 2004, that use of the drug in geriatric patients was not likely to be safe, and that metoclopramide therapy should not exceed 12 weeks in duration.” Document #77, at ¶ 7.18. In this context, claiming that PLIVA concealed information concerning drug labels is simply another way of saying that PLIVA provided an inadequate warning. Again, the Court will analyze inadequate warning claims in a later subsection.

C. Manufacturing Defect

As the Court noted in its earlier opinion, Arkansas products liability law encompasses three types of claims—manufacturing defects, design defects, and inadequate warnings. Document #72, at 8-9 (citing *West v. Searle & Co.*, 305 Ark. 33, 37, 806 S.W.2d 608, 610 (1991)). In that opinion, the Court held that Fullington failed to state a separate manufacturing defect claim because she only mentioned “once, in passing, that unspecified defendants failed to use due care in manufacturing metoclopramide.” Document #72, at 9 (footnote omitted). In her amended complaint, Fullington adds the following allegation: “PLIVA failed to exercise reasonable care in the design or manufacture of its metoclopramide products in that the metoclopramide it distributed differed from the manufacturer’s specification that the labeling for their product be the same as that of the Reference Listed Drug.” Document #77, at ¶ 6.61. While this allegation is more specific, it is not a manufacturing defect claim because it does not concern the product itself but rather the labeling of the product. *See Linden v. CNH Am., LLC*, 673 F.3d 829, 834 (8th Cir. 2012) (“[A] manufacturing defect is a departure from a product unit’s design specifications Common examples of manufacturing defects are products that are physically flawed, damaged, or incorrectly assembled.”

(quoting Restatement (Third) of Torts: Product Liability § 2 cmt. C (1998))). *Cf. Nat'l Bank of Commerce of El Dorado, Ark. v. Dow Chem. Co.*, 165 F.3d 602, 608 n.8 (8th Cir. 1999) (finding preempted claims that “are clearly premised on a failure to warn or to properly label”). Fullington’s manufacturing defect allegation restates her inadequate warning claim concerning the alleged failure to match the generic label with that of the brand-name label in 2004. Again, the Court will address such inadequate warning claims in a later subsection.

D. Design Defect

In the previous opinion, this Court held that Fullington’s allegations of design defect were conclusory and therefore insufficient, in part because she made “no factual allegations that PLIVA or Mutual, as opposed to the brand-name manufacturers, actually designed metoclopramide,”³ she made “scarcely any allegations describing the nature of any alleged design defect,” and she made “no allegations as to how any design defect caused [her] injuries.” Document #72, at 9.

In her amended complaint, Fullington adds two new allegations concerning design defect. First, she brings the same allegation as her manufacturing defect claim; namely, that PLIVA failed to exercise reasonable care in its design because its label differed from the brand-name manufacturer. For substantially the same reasons as explained above, this claim is actually an inadequate warning claim. Second, Fullington alleges that “All Defendants failed to exercise reasonable care in the design of the packaging for their metoclopramide products in that they chose to use bulk packaging which

³Fullington correctly notes that the Court erred by suggesting that the seller of a defectively designed product cannot be liable for a design defect unless the seller designed the product. *See Ark. Code Ann. § 4-86-102; Hill v. Searle Labs.*, 884 F.2d 1064, 1066-67 (8th Cir. 1989) (“In Arkansas, a supplier of a product is liable under a strict liability theory if [] the product is in a defective condition which rendered it unreasonably dangerous Defective design . . . may provide the defective condition required for proof of strict liability.”). That error does not change the outcome, however, as the original complaint still failed to allege a claim for design defect.

invited long-term use of the drug, rather than other packaging design options, such as unit-of-use packaging, which deters extended use.” Document #77, at ¶ 6.47. While it is true that a “design defect [] may have its inception in poor packaging,” *Slater v. Republic-Vanguard Ins. Co.*, 650 F.3d 1132, 1138 (8th Cir. 2011) (quoting *LaBatt Co. v. Hartford Lloyd’s Ins. Co.*, 776 S.W.2d 795, 800 (Tex. App. 1989)) (discussing Texas law), it is also true that packaging issues can instead relate to inadequate warning claims. *See Walker v. Blitz USA, Inc.*, 663 F. Supp. 2d 1344, 1363 n.18 (N.D. Ga. 2009) (“Claims brought under Georgia’s product liability statute . . . fall into one of three categories: (1) design defects, (2) manufacturing defects and (3) packaging/labeling defects.”). Fullington alleges that the packaging was defective because it encouraged long-term use—a communication issue that ties directly into her claim that the warnings as to long-term use were inadequate. That her allegation of a design defect, in substance, is a claim of inadequate warning dovetails with the rest of Fullington’s claims throughout her complaint, all of which revolve around accusations that the metoclopramide manufacturers failed to warn consumers of the dangers of the drug. Thus, this allegation is also an inadequate warning claim and not a true design defect claim. Fullington has failed to allege a design defect claim. *See Cooper v. Wyeth, Inc.*, Civ. Act. No. 09-929, 2012 WL 733846, *9 (M.D. La. March 6, 2012) (“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.’ . . . The Court finds it is merely a failure-to-warn claim that has been worded to appear otherwise . . .”).

Fullington points to a recent decision by the First Circuit in which that court upheld a trial verdict against a generic drug manufacturer, on the basis of a defective design, after dismissing inadequate warning claims. *See Bartlett v. Mutual Pharm. Co., Inc.*, --- F.3d ----, 2012 WL 1522004

(1st Cir. 2012). *Bartlett* is not on point. In *Bartlett*, the core theory was that the risks of the generic drug sulindac outweighed its benefits, which made it unreasonably dangerous to consumers. *Id.* at *1. Fullington, on the other hand, alleges that metoclopramide is unreasonably dangerous only when taken for more than twelve weeks. *See, e.g.*, Document #77, at ¶ 6.57 (“[Generic] Defendants also concealed the fact that the treatment of . . . gastric disorders with Reglan/metoclopramide for longer than 12 weeks is unlikely to be reasonably safe.”); *id.* at ¶ 7.07 (“The metoclopramide manufactured by Defendant Pliva was unreasonably dangerous in that its label failed to include language indicating that use of the drug should not exceed 12 weeks in duration . . . and instead misleadingly implied that metoclopramide use for longer than 12 weeks . . . was safe and effective.”).⁴ In other words, Fullington concedes that metoclopramide is not unreasonably dangerous if used properly; it is dangerous only if taken for more than twelve weeks. Thus, her claim, in reality, is that the generic manufacturers should have adequately warned that the drug should not be taken past the proper period of time—twelve weeks. Fullington says as much in her amended complaint. *See id.* at ¶ 7.06 (“Nonetheless, Defendants failed to warn that Reglan/metoclopramide as designed and marketed was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use. Such a failure to warn rendered the Reglan/metoclopramide unreasonably dangerously defective as designed and marketed.”). *Bartlett* does not necessitate revisiting the Court’s earlier holding that Fullington had stated an inadequate warning claim rather than a design defect claim.⁵

⁴Fullington makes the same concession in her response to the motion to dismiss. Document #84, at 4 (“The basic premise for Plaintiff’s design defect claims is that the metoclopramide manufactured by PLIVA and Mutual was unreasonably dangerous because it . . . causes movement disorders . . . *when used long-term.*” (emphasis added)).

⁵It should be noted that, even if Fullington alleged a design defect claim, a strong argument can be made that design defect claims are also preempted under *Mensing*’s rationale. *See Lyman v.*

E. Failure to Warn

In *Mensing*, the Supreme Court detailed the history of metoclopramide labeling requirements:

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

Mensing, 131 S. Ct. at 2572-73 (internal citations omitted). In her previous briefs before the Court, leading up to the prior opinion, Fullington asserted that PLIVA had admitted to failing to implement the aforementioned 2004 FDA-approved warning, thus nullifying its preemption argument and opening itself up to liability. Document #64, at 20-21. In response, the Court stated that it “need not decide whether such a claim is preempted because Fullington did not allege such a claim in her complaint, nor did she allege that she ingested metoclopramide during the relevant period when PLIVA and brand-name labels were different.” Document #72, at 10. Fullington has now alleged such a claim in her amended complaint. The question remains, however, whether her claim is preempted, and if not, whether it can still survive.

As a preliminary matter, Fullington’s new inadequate warning claim does not survive against Mutual because Fullington has not alleged that Mutual failed to update its labeling in 2004. As noted, Fullington previously argued that PLIVA failed to update its labels, and her amended complaint,

Pfizer, Inc., No. 2:09-cv-262, 2012 WL 368675, *4 (D. Vt. Feb. 3, 2012) (design defect claims “are preempted as well by *Mensing*’s logic,” since the “‘federal duty of sameness’ . . . applies to the design or composition of the drug as well as to its labeling”); *Bartlett*, 2012 WL 1522004 at *5 (noting that there is a “developing split in the lower courts” on the issue). The Court need not decide this issue.

likewise, only implicates PLIVA in this failure. *See* Document #77, at ¶¶ 6.59, 6.60, 7.03, 7.18. The same goes for her response. *See* Document #84, at 12 (“PLIVA never included the warnings added in 2003 and 2004 to its label for metoclopramide.”). The only part of the amended complaint or response that could conceivably be argued otherwise states that “PLIVA and Mutual failed to communicate the addition of warnings to the labeling for metoclopramide in 2003 and 2004” Document #77, at ¶ 6.46. A close look, however, reveals that this sentence does not, in fact, state that Mutual failed to update its labels. Rather, it states that Mutual failed to communicate to others that the labels were updated, which is a different claim—one that is preempted as a general failure-to-warn claim.⁶ Thus, the claim against Mutual will be dismissed due to impossibility preemption because Fullington has not alleged that Mutual failed to update its labels in 2004.

As to Fullington’s claim against PLIVA for failing to update its label to comply with the warning approved by the FDA in 2004, reasonable arguments can be presented for and against the proposition that the claim is preempted. On one hand, the Eighth Circuit and Supreme Court have been made aware of the issue of PLIVA’s failure, and they have found PLIVA to be nevertheless protected by preemption. *See Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 660, 663 (D. Md. 2011). On the other hand, neither court discussed the issue, and numerous district courts have held, even post-*Mensing*, that a failure to warn claim against a generic drug manufacturer is not preempted when the label does not conform to the label approved by the FDA. *See, e.g., Fisher v. Pelstring*, 817 F. Supp. 2d 791, 805 (D.S.C. 2011) (“Mr. Fisher was prescribed metoclopramide during the time period that PLIVA’s labeling for generic metoclopramide may not have included the warnings added to the

⁶The plaintiff’s response confirms that these are different claims. *See* Document #84, at 13 (“As a result of PLIVA’s failure to include this information on its label, and both Generic Defendants’ failure to communicate the information”).

Reglan labeling in 2003 and 2004. The Court finds that this possible deviation in PLIVA's label for generic metoclopramide . . . is sufficient to conclude the plaintiffs' claims are not entirely preempted."); *Morris v. Wyeth, Inc.*, Civ. Act. No. 09-0854, 2012 WL 601455, *3 (W.D. La. Feb. 23, 2012) (similar); *Lyman*, 2012 WL 368675 at *5 (similar); *Couick v. Wyeth*, No. 3:09-CV-210, 2012 WL 79670, *5 (W.D.N.C. Jan. 11, 2012) (similar). *But see Gross*, 825 F. Supp. 2d at 663 (“[T]here are strong arguments that such a claim is preempted . . .”). The Court need not decide the issue, however, as Fullington's new failure-to-warn claims still fail, even assuming they are not preempted.

Fullington took metoclopramide for approximately twelve months—from April 2008 to April 2009. Document #77, at ¶ 5.02. Fullington therefore ingested metoclopramide manufactured by PLIVA during the period after PLIVA failed to update its labels to match the 2004 brand-name labeling. Importantly, however, Fullington also alleges in her complaint that all warnings, brand-name and generic, were inadequate until February 2009 when the FDA issued its most recent and severe warning. *See id.* at ¶ 5.15 (“Recognizing the inadequate nature of the Defendants' label and warnings, in February 2009 the United States Food and Drug Administration . . . issued an advisory requiring the addition of a Boxed Warning for Reglan/metoclopramide.”). Thus, even assuming that PLIVA failed to update labels relied on by Fullington, she has not stated a failure-to-warn claim from April 2008 to February 2009 because the only option for PLIVA during that period would have been to update to a warning that Fullington alleges was inadequate. *See, e.g., Bowman v. Wyeth, LLC*, Civ. No. 10-1946, 2012 WL 684116, *7 (D. Minn. March 2, 2012) (“[T]here is no duty for a manufacturer to provide an *inadequate* warning.”); *Morris*, 2012 WL 601455 at *4 (“[I]t is impossible to construe a facially plausible claim from [the complaint] because PLIVA's warning label

would have been inadequate even if it had complied with the 2004 revision.”); *Gross*, 825 F. Supp. 2d at 664 (“Given the irreconcilable inconsistency between what Plaintiff has pled and her present theory of relief . . . dismissal of Plaintiff’s claim relating to the 2004 label change is proper . . .”).

The final issue is whether Fullington’s failure-to-warn claim against PLIVA for the period between February 2009 and April 2009, after the FDA had issued the new warning and while Fullington was consuming metoclopramide, can survive. Based on the complaint, alone, it would appear that this claim could survive against PLIVA, assuming that it is not preempted. However, PLIVA has presented Fullington’s pharmaceutical records showing that Fullington did not receive metoclopramide produced by PLIVA in 2009. *See* Document #79-11.⁷

When a court relies on matters outside the pleadings in considering a motion to dismiss, it must convert the motion to dismiss into a motion for summary judgment under Rule 56 of the Federal Rules of Civil Procedure. Fed. R. Civ. P. 12(d); *Brooks v. Midwest Heart Grp.*, 655 F.3d 796, 799-800 (8th Cir. 2011). When a Rule 12(b)(6) motion is converted to a motion for summary judgment, the court must give reasonable notice that conversion is occurring so that the opposing party may “produce affirmative evidence to counter the movant’s allegations or file an affidavit under Rule 56(f) requesting more time to obtain such evidence in order to resist the motion.” *Brooks*, 655 F.3d at 800.

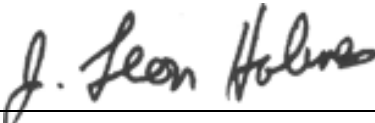
Fullington will have fourteen days from the entry of this order to present evidence that she ingested metoclopramide originating from PLIVA after February 2009. If she does not do so, summary judgment will be entered in favor of PLIVA on Fullington’s claim that PLIVA’s warnings were inadequate after February 2009.

⁷This documentation conforms with statements in court opinions that PLIVA discontinued its production of metoclopramide in December 2008. *Morris*, 2012 WL 601455 at *2 (citing a March 11, 2011 letter from PLIVA’s counsel).

CONCLUSION

For the reasons stated, defendants PLIVA, Inc. and Mutual Pharmaceutical Company, Inc.'s joint motion to dismiss is GRANTED, except as to Fullington's claim of inadequate warning against PLIVA for the period after February 2009. Document #78. As to that claim, the defendants' motion to dismiss is converted to a motion for summary judgment. Fullington's inadequate warning claim against PLIVA for the period of time after February 2009 will be dismissed with prejudice unless Fullington presents evidence that she consumed PLIVA's metoclopramide after February 2009.

IT IS SO ORDERED this 23rd day of May, 2012.



J. LEON HOLMES
UNITED STATES DISTRICT JUDGE