UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF LOUISIANA

ROBERT S. COOPER AND
SUE ANN COOPER

CIVIL ACTION

VERSUS

NO. 09-929-SDD-SCR

WYETH, INC., ET AL.

ORDER AND RULING

Before the Court is Defendants', PLIVA, Inc. and Watson Laboratories, Inc., *Motion for Reconsideration*[1] seeking review of this Court's March 6, 2012 *Ruling and Order*[2] granting in part, and denying in part Defendants' *Motion to Dismiss*.[3] Plaintiffs, Robert S. Cooper and Sue Ann Cooper, have filed an *Opposition*[4] to which Defendants have filed a *Reply Brief*.[5] Oral argument is not necessary. The Court has jurisdiction under 28 U.S.C. § 1332. For the following reasons, the Court grants Defendants' *Motion for Reconsideration* and amends the Court's March 6, 2012, Ruling.

I. Brief Background

On or about May 21, 1998, Plaintiff Robert Cooper's (hereinafter "Cooper")[6] physician prescribed him a drug with the brand name of Reglan and the generic name of metoclopramide to treat his acid reflux condition. Cooper ingested the drug as prescribed until sometime around July 2009. The metoclopramide ingested by Cooper was allegedly manufactured by Defendants.

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[1] Rec. Doc. 149.
[2] Rec. Doc. 129.
[3] Rec. Doc. 117. The Motion to Dismiss was filed on behalf of three of the five named Defendants in this matter: PLIVA, Inc., Teva Pharmaceuticals USA, Inc., and Watson Laboratories. The Plaintiffs have dismissed their claims against Teva. Rec. Doc. 140.
[4] Rec. Doc. 152.
[5] Rec. Doc. 155.
[6] Robert Cooper is the only Plaintiff who allegedly ingested the medication. Sue Ann Cooper's claims are derivative of her husband's alleged injuries. Therefore, all subsequent references to Cooper will refer to Robert unless otherwise noted.

Cooper's prescribing physicians relied upon information published in package inserts and/or the Physician's Desk Reference ("PDR") or otherwise disseminated by the manufacturers of metoclopramide. Neither Plaintiff nor his physicians were aware of any information contrary to that disseminated in the PDR and product inserts authorized and distributed by Defendants. Importantly, the brand name manufacturers (Reglan) of metoclopramide changed their label in 2004 to include drug use warnings when used beyond a twelve (12) week period. In mid-2009, Cooper began exhibiting injuries to his central nervous system and extrapyramidal motor systems, including tardive dyskinesia, a severe and often permanent disfiguring neurological movement disorder, allegedly as a result of the metoclopramide. Subsequently, Plaintiffs filed the pending lawsuit.

On October 31, 2011, Defendants PLIVA, Inc., Teva Pharmaceuticals USA, Inc.,[7] and Watson Laboratories, Inc. (hereinafter "Defendants") filed a *Motion to Dismiss* Plaintiffs' claims based on the federal law of preemption. On March 6, 2012, this Court issued a *Ruling* dismissing all of Plaintiffs' claims under the theory of preemption except for one arising under the Louisiana Products Liability Act (LPLA), La. R.S. 9:2800.51 *et seq.*: Plaintiffs' claim that Defendants—generic drug manufacturers—failed to update their labels to include warnings approved by the FDA in 2003 and 2004 prohibiting the long term use of drugs during Plaintiff's exposure and to communicate revisions to their generic drug labels. In its *Ruling*, the Court explained that the warning labels for metoclopramdide had been strengthened and clarified several times between 1998 and 2009; therefore, if Defendants failed to label their products with the FDA labels required of their brand-name manufacturer counterparts, then they were not in compliance with

[7] On November 21, 2012, the parties entered a consent stipulation dismissing without prejudice Defendant Teva. Rec. Doc. 140.

federal law. The Court found that Plaintiffs' claim was not preempted by the Supreme Court decision, *PLIVA v. Mensing*, where the Supreme Court held that federal law demands "generic drug labels be the same at all times as the corresponding brand-name labels."[8] Here, the Court reasoned as follows:

> 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 the impossibility preemption inapplicable.[9]

Accordingly, the Court further found 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."[10] Therefore, Plaintiffs' only remaining claim against Defendants is for failure to warn under the Louisiana Products Liability Act (LPLA), based on the theories of failure to communicate and update to include an FDA-approved label on their generic drug products.

In this Court's view, this interpretation and application of *Pliva v. Mensing* was based on sound reason and logic. However, the Fifth Circuit has since interpreted and applied the Supreme Court guidance of *PLIVA v. Mensing* to a different end.[11] This Court is obliged to follow the law of this Circuit.

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[8] *Pliva v. Mensing*, 131 S.Ct. 2567, at 2571, 180 L.Ed.2d 580, 79 USLW 4606 (2011).
[9] Rec. Doc. 129, p.6.
[10] Rec. Doc. 129, p.5.
[11] *Morris v. PLIVA, Inc.*, 713 F.3d 774 (5th Cir. 2013).

Plaintiffs argue that *Morris* is distinguishable from the pending matter and that the U.S. Supreme Court's decision *Mutual Pharmaceutical Co., Inc. v. Bartlett*[12] provides further support for this Court's prior *Ruling*.

II. LAW AND ANALYSIS

The Fifth Circuit has explained that where a "motion to reconsider concerns only interlocutory rulings, the appropriate vehicle for making the motion is the Rule 54(b) grant of discretion to the district courts."[13] The meaning of Rule 54(b) in its simplest terms is "that a court retains jurisdiction over all the claims in a suit and may alter any earlier decision at its discretion until final judgment has been issued on a claim or on the case as a whole."[14] "Although courts are concerned with principles of finality and judicial economy, 'the ultimate responsibility of the federal courts, at all levels, is to reach the correct judgment under law.'"[15] Moreover, "rulings should only be reconsidered where the moving party has presented substantial reasons for reconsideration."[16] "There are three major grounds justifying reconsideration: (1) an intervening change in controlling law; (2) the availability of new evidence; and (3) the need to correct clear error or prevent manifest injustice."[17]

In the present matter, because a final judgment has not been issued, Defendants' *Motion for Reconsideration* is properly considered under Rule 54(b). Defendants are seeking reconsideration based on an intervening change or

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[12] 133 S.Ct. 2466 (U.S. June 3, 2013)
[13] *Livingston Downs Racing Assoc., Inc. v. Jefferson Downs Corp., et al.*, 259 F.Supp. 2d 471, 474-75 (5th Cir. 2002).
[14] *Id.* at 475.
[15] *Keys v. Dean Morris*, LLP, 2013 WL 2387768, *1 (M.D.La. May 30, 2013)(quoting *Georgia Pacific, LLC v. Heavy Machines, Inc.*, 2010 WL 2026670, at *2 (M.D.La. May 20, 2010)).
[16] *State of La. v. Spring Communications Co.*, 899 F.Supp. 282, at 284 (M.D.La. 1995).
[17] *J.M.C. v. Louisiana Bd. of Elementary and Secondary Educ.*, 584 F.Supp.2d 894, 896 (M.D.La. Oct. 20, 2008)(quoting *Shields v. Shetler*, 120 F.R.D. 123, 126 (D.Colo. 1988)).

interpretation of the law as set forth in the recent Fifth Circuit's opinion, *Morris v. Pliva* (hereinafter *"Morris"*).[18] Therefore, the Court shall grant Defendants' motion for reconsideration and reconsider the Court's prior ruling herein.

The Court finds that Plaintiffs' reliance on the Supreme Court decision, *Mutual Pharmaceutical Co., Inc. v. Bartlett*, (hereinafter "Bartlett")[19] is misplaced. *Bartlett* is factually distinguishable from the remaining claim before this Court. In its analysis, the Supreme Court also considered the principle of preemption referencing *PLIVA* for the position that "federal law prevents generic drug manufacturers from independently changing their drugs' labels."[20] In *Bartlett*, the Supreme Court further applied these preemption principles in finding that a state law warning-based design-defect cause of action was preempted with respect to FDA-approved drugs sold in interstate commerce, because it was impossible for the generic drug manufacturer to comply with its state-law duty to strengthen its drug labels and its federal-law duty not to unilaterally alter its drug label.[21]

In contrast, the Court finds that the facts and legal issues presented to the *Morris* Court are directly on point to those in the pending matter. In *Morris*, the plaintiffs sued generic drug manufacturers, including PLIVA and TEVA, for injuries allegedly related to use of the drug metoclopramide (brand-name Reglan). Plaintiffs specifically alleged that the defendants were "liable for failing to convey FDA-approved information; information communicated by generic manufacturers that is consistent with the brand-

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[18] *Morris v. PLIVA, Inc.*, 713 F.3d 774 (5th Cir. 2013).
[19] 133 S.Ct. 2466, 186 L.Ed.2d 607, 81 USLW 4538 (2013).
[20] Id. at 2470.
[21] In *Mutual Pharmaceuticals Co., Inc. v. Bartlett*, the Supreme Court held that "state-law design-defect claims that turn on the adequacy of a drug's warnings are pre-empted by federal law under PLIVA." *Id.* at 2469. The Court also noted that "[g]eneric manufacturers are also prohibited from making any unilateral changes to a drug's label" under the Code of Federal Regulations. 21 C.F.R. §§ 314.94(a)(8)(iii), 314.150(b)(10).

name labeling does not violate the duty of sameness."[22] The Fifth Circuit affirmed the district court's finding that plaintiffs' only factually supported claim for failure to warn—failure to communicate FDA-approved information and update or adopt FDA-approved warning labels—was preempted by *Mensing*. The Fifth Circuit further explained:

> [F]ailure to 'communicate' extends beyond just a labeling change. To avoid liability, the manufacturer must take affirmative steps to alert consumers, doctors, or pharmacists of changes in the drug label. Because the duty of sameness prohibits the generic manufacturers from taking such action unilaterally, they are dependent on brand-names taking the lead...Under federal law, the inquiry is whether the brand-name manufacturers sent out a warning...Because no brand-name manufacturer sent a warning based on the 2004 label change, the generic manufacturers were not at liberty to do so.[23]

Based on the foregoing, the *Morris* Court found that Plaintiffs' claims were preempted because it would be impossible for the defendants to "comply with both state law duty to warn and the federal law duty of sameness."[24] The court further explained that a claim for breach of a federal labeling obligation would "sound exclusively in federal (not state) law, and is preempted."[25]

The Court finds that *Morris v. Pliva* is controlling and binding precedent. In its earlier *Ruling*, this Court concluded that generic drug manufacturers, such as the Defendants, could send "Dear Doctor" letters or other forms of communication to notify a prescribing physician of newly updated changes to the brand-name drug's labeling without "run[ning] afoul of any federal law."[26] The Court now finds, however, that its previous conclusion is contradictory to *Morris* wherein the Fifth Circuit explained that the duty of sameness prohibits generic manufacturers from taking labeling action

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[22] *Morris,* 713 F.3d, at 777.
[23] *Id.*
[24] *Id.*
[25] *Id.*
[26] Rec. Doc. 129, p. 7.

unilaterally.[27] Hence, federal law requires that the generic manufacturers must follow the lead of the brand name manufacturers. Based on the allegations in Plaintiffs' *Second Amended Complaint*, none of the Defendants, generic or brand-name manufacturers, provided updated labels to include the addition of warnings of Reglan/metoclopramide regarding geriatric or long-term use.[28] Hence, generic manufacturer Defendants PLIVA and Watson Laboratories, Inc. were prohibited from acting unilaterally, and therefore could not possibly comply with both state and federal law.

The Court further finds that its earlier conclusion—that Plaintiffs' "failure to update" claim is based in state law as opposed to federal law—also runs afoul to *Morris*, where the Fifth Circuit clearly explained that a breach in tort for a federal labeling obligation sounds solely in federal law. Contrary to our earlier position, the Court finds that it is significant that Plaintiffs have admitted that un-updated labels would have been inadequate even if included in the newly mandated FDA labels.[29] As in *Morris*, it would be "logically incoherent to contend" the Defendants had a duty to apply un-updated labels when the Plaintiffs have admitted that these labels would have been inadequate.

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[27] 713 F.3d at 776-777.

[28] In their *Second Amended Complaint*, Plaintiffs alleged that "all Defendants failed to alert the medical community and consumers to the addition of warnings to the labeling of Reglan/metoclopramide regarding geriatric and long-term use. As a result, plaintiff and his physicians were unaware of the fact that therapy with metoclopramide should not exceed 12 weeks in duration due to the risk of neurological injury, and prescribed and ingested the drug for a much longer period of time." Rec. Doc. 113, p. 14, ¶3.65. In their *Memorandum in Opposition to Defendants' Motion to Dismiss*, Plaintiffs similarly argued that "during the time that Plaintiff's physician was prescribing him metoclopramide, no manufacturer defendant had communicated the warning that therapy with metoclopramide 'should not exceed 12 weeks in duration.'" Rec. Doc. 119, p. 20.

[29] For instance, Plaintiffs alleged in their *Second Amended Complaint* that "the package insert for metoclopramide states that the frequency of developing any movement side effect is '1 in 500', and that these side effects are 'rare' when compared to similar drugs. The package insert also states that metoclopramide is safe for 'recurrent' use, and that long-term use of the drug 'has not been evaluated.' These representations induced plaintiff's physician to prescribe the drug to plaintiff, and induced plaintiff to ingest the metoclopramide for long periods of time, resulting in severe injury." Rec. Doc. 113, p. 15, ¶3.70.

Accordingly, the Court finds that based on the recent Fifth Circuit decision, *Morris v. PLIVA, Inc.*, Plaintiffs' remaining claim for failure to warn is preempted under federal law and shall be dismissed.

III. CONCLUSION

Accordingly, Defendants', PLIVA, Inc. and Watson Laboratories, Inc., *Motion for Reconsideration* is hereby GRANTED. The Court's Ruling of March 6, 2012, is hereby AMENDED for the reasons set forth above, and Plaintiffs' remaining claims against Defendants PLIVA, Inc. and Watson Laboratories, Inc. for failure to warn under the Louisiana Products Liability Act (LPLA), based on the theories of failure to communicate and update to include an FDA-approved label on their generic drug products are hereby DISMISSED with prejudice. This *Ruling* has no bearing on Plaintiffs' remaining claims against Defendant, Wyeth LLC,[30] individually and as successor-in-interest to ESI-Lederle, Inc.[31]

Baton Rouge, Louisiana, this 11th **day of December, 2013.**

SHELLY D. DICK, DISTRICT JUDGE
MIDDLE DISTRICT OF LOUISIANA

[30] Formerly known as Wyeth, Inc. Rec. Doc. 27, p.1; Rec. Doc. 78, p.1; Rec. Doc. 116, p. 1.
[31] According to the *Answers* filed on behalf of Defendant Wyeth LLC, "ESI Lederle Inc. is a former division of American Home Products Corporation ("AHPC"). AHPC is now Wyeth. ESI Lederle Inc. dissolved on December 15, 1998." Rec. Doc. 27, p.1; Rec. Doc. 78, p.1; Rec. Doc. 116, p. 1.