UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

MARIA LUISA GARZA, *et al*,	§	
	§	
Plaintiffs,	§	
VS.	§	CIVIL ACTION NO. 2:12-CV-198
	§	
WYETH LLC; fka WYETH; dba WYETH, INC., *et al*,	§	
	§	
	§	
Defendants.	§	

ORDER

Maria Luisa Garza, along with her husband Oscar Garza, Sr. (together Garza), sued Watson Pharma, Inc. and Watson Laboratories, Inc. (jointly Watson), alleging that Maria Luisa Garza suffers from tardive dyskinesia as a result of ingesting metoclopramide (the generic equivalent of Reglan) over an extended period of time, starting in 2007. D.E. 72, p. 7. She alleges that Watson, which manufactured and sold the metoclopramide she ingested, failed to update its labeling in 2003, 2004, and 2009 to include warnings that had been required for the brand-name drug, Reglan.

This Court granted the motion to dismiss filed by the manufacturers in this case, with one exception. D.E. 99. This Court permitted Garza to go forward on a "failure to update" theory against Watson, based on a reading of the preemption holding in *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011). D.E. 99, pp. 4-7 (Part A, "Mensing"). On the same date, this Court stayed the prosecution of this case in deference to *Del Valle v. Qualitest Pharmaceuticals, Inc.*, No. 12-41148, which was pending in the Fifth Circuit with a challenge related to this issue. D.E. 98.

On February 21, 2014, the Fifth Circuit issued its opinion in *Del Valle* and another virtually identical case, rejecting the state law "failure to update" theory and interpreting

Mensing to require federal preemption of the question. *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 477-78 (5th Cir. 2014) (per curiam). *See also Morris v. PLIVA, Inc.*, 713 F.3d 774 (5th Cir. 2013) (per curiam); *Johnson v. Teva Pharmaceuticals USA, Inc.*, 758 F.3d 605 (5th Cir. 2014). If applied here, federal preemption would eliminate Garza's private right of action under state law. 21 U.S.C. § 337 (all proceedings to enforce the Food, Drug, and Cosmetics Act (FDCA) must be brought by the United States or, in some cases, by a State). Before the Court is Watson's Motion for Reconsideration (D.E. 106), asking this Court to reconsider its prior ruling in light of the new Fifth Circuit opinions and to dismiss this action. For the reasons set out below, the motion is GRANTED, the Court VACATES Part A of its prior Order (D.E. 84, pp. 4-7) as incorporated into its Order (D.E. 99, p. 4) and SUBSTITUTES this analysis in its stead.

THE PLEADINGS

In relevant part, Garza has pled that the Food and Drug Administration (FDA) approved a warning for Reglan/metoclopramide in 2003 regarding geriatric use. In 2004, the FDA approved a warning that therapy with the drug "should not exceed 12 weeks in duration." D.E. 72, p. 9. Garza further states that, because those warnings were inadequate, in 2009 the FDA ordered a black box warning that "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." *Id*. She also alleges that the FDA determined that the public health risk was so significant as to require a Medication Guide in 2009. *Id*. Neither the warnings nor the Medication Guide were available to Garza. *Id*.

Garza alleges that Watson was governed by the Code of Federal Regulations with respect to its duty to provide adequate warnings. *Id*. at 16. More specifically, she notes that, under FDA regulations, when the FDA approves a label change for a brand-name drug, manufacturers of the

generic equivalent, such as Watson, must follow the new labeling requirement. *Id*. at 17-18. Her claims against Watson are based on its failure to comply with those regulations and provide the necessary warnings that metoclopramide should not be ingested for more than 12 weeks and that it could cause tardive dyskinesia. She also alleges that these issues are covered by state law duties to exercise reasonable care in marketing metoclopramide and to monitor safety issues and make additional disclosures as needed to avoid liability for an unreasonably dangerous product. *Id*. at 19-21.

THE *LASHLEY/DEL VALLE* TRIO OF CASES

The Fifth Circuit's decision in *Lashley* considers nearly identical claims regarding the generic manufacturer's failure to update its labeling on metoclopramide to conform to the FDA's approval of changes to name-brand labeling. Noting that generic manufacturers are governed by federal regulations that require them to send out the same warnings as the name-brand manufacturers, and no greater warnings, and noting that the name-brand manufacturers had not sent out the new warnings in 2004, the Fifth Circuit held that the generic manufacturers could not comply with both federal regulations and claimed state law duties.

> In *Mensing*, as here, the Supremacy Clause—not a statute—made it impossible for the generic defendant to do what state law required of it and, therefore, the state law claim was preempted. In these types of cases, the inquiry is not whether there is a "parallel" claim where one looks for absence of conflict with the statute; the inquiry is whether the state law claim is impliedly preempted.

Lashley, *supra* at 476 (footnote omitted).

In this regard, the *Lashley* opinion specifically distinguishes the analysis applicable to generic manufacturers from that applicable to name-brand manufacturers. Generic manufacturers' hands are tied by the FDCA in that they must use the same formulation for pharmaceuticals and conform to the name-brand labeling and no more. To measure their

compliance with the law, one looks to those federal requirements, the FDA's approvals, and the name-brand manufacturers' actions. None of these issues requires the analysis of a duty to consumers and, in fact, a duty to consumers measured by state law requirements and what a "reasonably prudent person" would do under the same or similar circumstances may well differ from the FDA's regulatory actions. This conflict is resolved through the Supremacy Clause in favor of the federal regulatory scheme.

While Garza suggests that a "failure to update" claim is qualitatively different from a state law "failure to warn" claim, the act of "updating" cannot be measured by state law expectations but can only be governed by FDA and name-brand manufacturers' actions and the generic manufacturer's duty of sameness. From *Morris* through *Johnson*, the Fifth Circuit has been consistent: "a claim that [the generic manufacturer] breached a federal labeling obligation sounds exclusively in federal (not state) law, and is preempted." *Morris*, 713 F.3d at 777; *Lashley*, 750 F.3d at 474; *Johnson*, 758 F.3d at 612.

On their face, the *Lashley/Del Valle* trio of cases requires dismissal of Garza's remaining failure to update theory against Watson.

GARZA'S CHALLENGES

Garza challenges this conclusion with four arguments: (1) the motion to reconsider is procedurally improper; (2) Garza has not pled that the 2004 warnings approved by the FDA were inadequate; (3) *Mensing* does not require preemption and the Fifth Circuit cases are distinguishable; and (4) Watson's motion for summary judgment is premature because the parties have not had a chance to complete discovery. The Court rejects each of the arguments, in turn, below.

Courts have the power to reconsider rulings at any time during their plenary jurisdiction. *E.g., Melancon v. Texaco, Inc*., 659 F.2d 551, 553 (5th Cir. 1981). This Court reserved the power to do so on this very issue when it stayed prosecution of this case pending the outcome of *Del Valle*. Now that the Fifth Circuit has clarified the law, this Court is bound to follow its determination. *See generally, Central Pines Land Co. v. United States*, 274 F.3d 881, 893 (5th Cir. 2001) (discussing binding nature of Fifth Circuit panel decisions even as to other panels of the Fifth Circuit). The Court rejects Garza's challenge to reconsideration as a procedural matter.

Garza argues that she did not plead that the 2004 warnings were inadequate. She does this because an alternate holding in *Morris* was that it is "logically incoherent" to sue a drug manufacturer for failure to provide an inadequate warning. *Morris*, 713 F.3d at 777. As set out above, this Court has noted that Garza did, in fact, claim that the 2003 and 2004 warnings were inadequate, thus creating the need for the 2009 warnings. D.E. 72, p. 9.

However, even if Garza were permitted to amend her pleading to omit such a claim, the Fifth Circuit's decision that preemption applies is separate and apart from the "logically incoherent" observation. As already discussed, the preemption decision is based on the fact that generic manufacturers are bound—through the duty of sameness—by what the FDA and brand-name manufacturers do, not by what a reasonably prudent person would do under the same or similar circumstances or by any other measure. Therefore, any claim addressing a generic manufacturer's failure to warn is preempted, whether or not it involves a complaint that omitted warnings were, themselves, insufficient in whole or in part.

Garza suggests that *Mensing* does not require preemption under the facts of this case and that this Court should hold fast to its prior opinion on the matter. Her only reasoning is that *Morris* and *Johnson* involved different states' products liability law and that the FDA duty of

sameness does not govern a "failure to update" theory. First, Garza does not articulate how the state law in *Morris* and *Johnson* allegedly differs from Texas law such that a different result would obtain in Texas. The Court determines that the preemption determination with respect to the evaluation of a generic manufacturer's duty does not depend on the particular provisions of any specific state law deemed to be in conflict. Rather, the preemption decision is based on the duty of sameness and the FDA's regulatory scheme, which is consistent throughout the country, preempting any alternative measure of conduct.

With respect to *Del Valle*, Garza argues that the facts of the cases are distinguishable. In *Del Valle*, the generic manufacturers had adopted the brand-name manufacturer's FDA-approved labels and the preempted claim was that they should have been required to do more. Here, in contrast, the claim is that Watson failed to adopt the brand-name manufacturer's label and that the state law claims are appropriate to enforce that duty. This is a distinction without a difference from a preemption point of view. That is because, regardless of whether the claim is that the generic manufacturers did not comply with the duty of sameness or that they should have exceeded the minimum required by the duty of sameness, it is the duty of sameness—a federal statutory construct—that governs, rather than any alternative state law measure of the adequacy of warnings.

Last, the Court holds that the summary judgment motion is not premature. The preemption decision is not evidence-based but is rather a question of law. There is no need for additional discovery under Fed. R. Civ. P. 56(d), (e) and Garza has not indicated what discovery she would seek on this issue.

CONCLUSION

For the reasons set out above, the Court GRANTS the motion to reconsider (D.E. 106), VACATES Part A of its prior Order (D.E. 84, pp. 4-7) as incorporated into its Order (D.E. 99, p. 4) and SUBSTITUTES this analysis in its stead, and DISMISSES all claims against Watson.

ORDERED this 27th day of January, 2015.

NELVA GONZALES RAMOS
UNITED STATES DISTRICT JUDGE