IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

ROSALYN BELL,	)	
	)	
Plaintiff,	)	
	)	
v.	)	CASE NO. 2:10-CV-973-WKW
	)	[WO]
WYETH, INC., *et al*.,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

This lawsuit is one in a long line of actions alleging inadequate and illegal conduct on the part of the various pharmaceutical companies that "innovated, made, promoted, and sold" the prescription drug Reglan® or its generic counterpart, Metoclopramide ("MCP"). (Doc. # 105, at 1.) Plaintiff Rosalyn Bell contends that she ingested MCP in accordance with a prescription from her treating physician and developed a severe and incurable neurological disorder as a result. Ms. Bell alleges that her diagnosis is the proximate result of Defendants Wyeth, Inc. ("Wyeth"),[1] Pfizer, Inc. ("Pfizer"), Schwarz Pharma, Inc. ("Schwarz"),[2] Pliva

[1] As noted in Ms. Bell's Amended Complaint, Pfizer acquired Wyeth in a cash and stock merger on October 15, 2009. As a result of the merger, Pfizer acquired all of Wyeth's assets and assumed the full extent of Wyeth's liabilities. Pfizer is named in Ms. Bell's Amended Complaint solely as the successor to Wyeth's liability.

[2] Schwarz entered an Asset Purchase Agreement with Wyeth on December 27, 2001, whereby Schwarz purchased the rights and liabilities associated with Reglan subject to an indemnification provision.

USA, Inc. ("Pliva"), Watson Laboratories, Inc. ("Watson Laboratories"), Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals"), and Teva Pharmaceuticals USA's ("Teva") dissemination of "inaccurate, misleading, materially incomplete, false, and otherwise inadequate information concerning the potential effects of exposure to Reglan/MCP." (Doc. # 105, at 8.) She brings the following claims against each Defendant: strict liability (Count I), negligence and wantonness (Count II), breach of implied warranty (Count III), breach of express warranty (Count IV), fraud by misrepresentation (Count V), fraud by concealment, suppression, or omission of material facts (Count VI), and failure to adequately warn (Count VII).

Presently before the court is Defendants Pliva and Watson Laboratories' ("Generic Defendants")[3] Motion for Judgment on the Pleadings, in which they argue that Ms. Bell's claims against them are preempted by federal law. (Doc. # 117). The motion has been fully briefed. (Docs. # 118, 133, 144.) Upon consideration of the parties' arguments, the record, and the relevant case law, the court finds that the Generic Defendants' motion is due to be granted.

I. JURISDICTION AND VENUE

Subject-matter jurisdiction is proper pursuant to 28 U.S.C. § 1332. The parties do not contest personal jurisdiction or venue.

[3] Defendants Activis, Inc., f/k/a Watson Pharmaceuticals, and Teva – the other Generic Defendants – did not join in the present motion.

II. BACKGROUND

A. Facts

The FDA approved Reglan® in 1980 as a short-term therapy[4] for adults suffering from gastroesophageal reflux who did not respond to conventional therapy and to relieve the symptoms associated with acute and recurrent diabetic gastric stasis. Simply put, Reglan® was designed to increase the speed at which food travels through the digestive system. In 1985, pharmaceutical manufacturers began producing MCP – a generic version of Reglan®. MCP is equivalent to Reglan® in all therapeutically relevant aspects, including dosage, strength, and active ingredients.

Ms. Bell's physician prescribed her MCP in 2005, and she took the drug for approximately two years. In 2009, Ms. Bell was diagnosed with tardive dyskinesia ("TD"). TD is a neurological disorder that commonly causes "involuntary, repetitive movements of the extremities, lip smacking, grimacing, tongue protrusion, teeth grinding, rapid eye movements or blinking, puckering and pursing of the lips, and/or impaired and involuntary movement of the fingers." (Doc. # 105, at 9.) Ms. Bell suffers from one or more of these symptoms. At present, there is no known cure for TD, and its effects are rarely reversible.

Ms. Bell alleges that it was her prolonged ingestion of MCP that caused her to develop TD. The active ingredient in MCP works to block the transfer of

[4] Reglan® was never approved for use longer than twelve weeks.

dopamine within the brain, which in turn causes the brain to produce additional dopamine receptors. Ultimately, prolonged MCP ingestion may lead the areas within the brain that control movement to become hypersensitive to dopamine, potentially resulting in the development of a neurological movement disorder. "Studies have shown that up to 29% of patients who take [MCP] for several years develop [TD]." *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2572 (2011).

In her complaint, Ms. Bell alleges that Defendants had actual knowledge that the risk of developing TD or another neurological side effect from long-term use of Reglan® or MCP was "approximately 100 times greater" than the risk that Defendants disclosed to medical professionals. (Doc. # 105, at 10.) Ms. Bell contends that Defendants failed to warn doctors and patients of the risks associated with long-term use and even "encouraged long term use of the drug," concealing the drug's "true risks and the true prevalence of side effects." (Doc. # 105, at 10.) Had her treating physician been warned of the true risks of MCP, Ms. Bell asserts that her physician would have adjusted the prescription to avoid the risks associated with long-term use or not prescribed the drug at all.

B. <u>Procedural History</u>

This case has a protracted procedural history. Ms. Bell filed her initial complaint in November 2010. The Brand-Name Defendants[5] responded with a motion to dismiss. In the motion, they argued that Ms. Bell only ingested the

[5] The Brand-Name Defendants are Wyeth, Pfizer, and Schwarz.

generic MCP, and accordingly, she could not maintain products-liability claims against them as the manufacturers and sellers of Reglan®. After briefing the motion to dismiss, the Brand-Name Defendants moved to stay the action to allow the Eleventh Circuit to issue its opinion in *Simpson v. Wyeth, Inc*., No. 11-11197 (11th Cir.). The Brand-Name Defendants argued that *Simpson* presented the same issue existing in this case – namely, whether brand-name drug manufacturers can be held liable for harm caused by a generic drug manufactured and distributed by an unrelated generic manufacturer. The motion to stay was unopposed, and the court entered the stay on April 15, 2011.

Before the Eleventh Circuit issued its opinion, however, the *Simpson* plaintiffs moved to dismiss their appeal. As a result, the Brand-Name Defendants requested that this court certify the unresolved question to the Alabama Supreme Court. However, in another action pending in this court in which an identical legal issue was presented, the following question was certified to the Supreme Court of Alabama: "Under Alabama law, may a drug company be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture or distribution of a brand-name drug, by a plaintiff claiming physical injury from a generic drug manufactured and distributed by a different company?" *Weeks v. Wyeth, Inc*., No 1:10-CV-602-MEF, at 5 (M.D. Ala. Aug. 25, 2011) (Order certifying question to the Alabama Supreme Court).

Accordingly, this court kept the April 15, 2011 stay in place pending the conclusion of the certification process in *Weeks.*

On October 17, 2011, the Alabama Supreme Court agreed to answer the question certified in *Weeks*. On January 11, 2013, the Alabama Supreme Court issued its opinion, concluding that liability *could* extend to brand-name manufacturers and developers for fraud or misrepresentations made in connection with the manufacture and sale of a brand-name drug, by a plaintiff who was injured by the generic drug manufactured and distributed by a different company. The brand-name defendants in *Weeks*, however, timely moved for a rehearing, which the Alabama Supreme Court granted.

On August 15, 2014, the Alabama Supreme Court withdrew its January 11, 2013 opinion and issued a new opinion. Despite the issuance of a new opinion, the Alabama Supreme Court's legal determination largely was the same. For a second time, it concluded that liability *could* extend to brand-name manufacturers and developers for fraud or misrepresentations made in connection with the manufacture and sale of a brand-name drug, by a plaintiff who was injured by the generic drug manufactured and distributed by a different company. The brand-name defendants in *Weeks* again applied for rehearing, but the Alabama Supreme Court denied their application, and on September 3, 2014, a certificate of judgment was issued, making the determination as to the certified question final.

Upon the conclusion of the certification process in *Weeks*, the stay in this case was lifted, and a new scheduling order was entered. Ms. Bell filed an amended complaint on December 16, 2014. After the pleadings closed, the Generic Defendants responded with the now pending motion for judgment on the pleadings.

III. STANDARD OF REVIEW

The Federal Rules of Civil Procedure provide that "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." Fed. R. Civ. P. 12(c). A judgment on the pleadings is limited to consideration of "the substance of the pleadings and any judicially noticed facts." *Bankers Ins. Co. v. Fla. Residential Prop. & Cas. Joint Underwriting Ass'n*, 137 F.3d 1293, 1295 (11th Cir. 1998). In evaluating a motion for judgment on the pleadings, the court must review the factual allegations in the light most favorable to the non-moving party. *Cannon v. City of W. Palm Beach*, 250 F.3d 1299, 1301 (11th Cir. 2001). However, the court need not credit a nonmoving party's legal contentions. *See CompuCredit Holdings Corp. v. Akanthos Capital Mgmt., LLC*, 661 F.3d 1312, 1314 (11th Cir. 2011). A judgment on the pleadings pursuant to Rule 12(c) is appropriate when "no issues of material fact exist, and the movant is entitled to judgment as a matter of law[,]" *Ortega v. Christian*, 85 F.3d 1521, 1524 (11th Cir. 1996), or when "the complaint lacks sufficient factual matter to state a facially plausible claim for relief that allows the court to draw a reasonable

inference that the defendant is liable for the alleged misconduct." *Jiles v. United Parcel Serv., Inc.*, 413 F. App'x 173, 174 (11th Cir. 2011) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556, 570 (2007)).

IV. DISCUSSION

The Generic Defendants' motion for judgment on the pleadings is grounded singularly upon an assertion that Ms. Bell's state-law tort claims are preempted by federal law. They specifically contend that the federal-labeling requirements imposed on generic-pharmaceutical manufacturers directly conflict with state-tort liabilities and that these conflicting obligations mandate the dismissal of Ms. Bell's claims against them on the basis of preemption. In response, Ms. Bell argues that the preemption doctrine is not applicable because the Generic Defendants chose not to comply with federal law. Because the Generic Defendants failed to comply with the federal requirements, Ms. Bell asserts that they could have complied with the state laws, avoiding true conflict and bringing this action outside the scope of federal preemption.

A. Federal Pharmaceutical Regulations

The labeling of pharmaceuticals is heavily regulated by federal law. Before a pharmaceutical manufacturer may market any new drug to the public, it must first acquire federal approval. To acquire federal approval, the 1962 Drug Amendments to the Federal Food, Drug, and Cosmetic Act require that a manufacturer prove that the new drug "is safe and effective and that the proposed

label is accurate and adequate." 21 U.S.C. §§ 301 *et seq*.; *Mensing*, 131 S. Ct. at 2574.

For a period of time, all manufacturers had to complete the same approval process, whether the manufacturer was seeking to market an entirely new pharmaceutical or merely a new, generic version of an existing drug. *Mensing*, 131 S. Ct. at 2574. Because successfully completing the approval process inherently required "costly and lengthy clinical testing" ill-suited to the development of a thriving generic-pharmaceutical industry, in 1984 Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Amendments, which drastically altered the approval process for new generic pharmaceuticals. 21 U.S.C. § 355(j); *Mensing*, 131 S. Ct. at 2574.

Pursuant to the Hatch-Waxman Amendments, manufacturers of brand-name drugs and manufacturers of generic drugs face two different sets of obligations when seeking federal approval of new pharmaceuticals. Brand-name drug manufacturers must prove that the proposed label is "accurate and adequate." 21 U.S.C. § 355(b)(1), (d); *Mensing*, 131 S. Ct. at 2574. The manufacturers of generic drugs, on the other hand, are not independently required to demonstrate the accuracy or adequacy of their labels. Rather, generic-drug manufacturers are obligated to ensure that their proposed warning label is identical to the label of the corresponding brand-name drug.

B. The Arguments of the Parties

It is upon this "sameness" requirement that the Generic Defendants rest their federal-preemption argument. They contend that each of Ms. Bell's claims is grounded upon a theory that the Generic Defendant failed to adequately warn and/or properly design MCP. The Generic Defendants argue, however, that they were unable to strengthen MCP's warning labels or alter the drug's design without violating federal law. In conclusion, the Generic Defendants assert that, because the state-tort laws conflict with their federal-law obligations, the state laws are preempted and Ms. Bell's claims against them are due to be dismissed.

Ms. Bell counters the Generic Defendants' arguments by contending that the Generic Defendants cannot rely on federal preemption because they "chose not to comply with the applicable federal law" when they failed to update their labels. Because the Generic Defendants did not comply with the federal labeling requirements, Ms. Bell asserts that they could have complied with Alabama's tort laws. Accordingly, she argues that there is no real conflict and, therefore, no preemption defense available.

C. Analysis

A defense of federal preemption is grounded upon the Supremacy Clause of the United States Constitution. The Supremacy Clause states that "the Laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const.,

art. VI, cl. 2. The Supreme Court has interpreted this constitutional mandate to require any state law, including those creating state-tort duties, to give way when the state law is in direct conflict with a federal law. *Mensing*, 131 S. Ct. at 2577. ("Where state and federal law 'directly conflict,' state law must give way." (quoting *Wyeth v. Levine*, 555 U.S. 555, 583 (2009))). The Supreme Court has explained that state and federal law directly conflict for preemption purposes when it is "impossible for a private party to comply with both state and federal requirements." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995).

To be sure, this is not the first case in which a court has been tasked with determining whether state-tort laws directly conflict with the federal laws regulating pharmaceuticals. The Supreme Court addressed a similar preemption defense brought on behalf of the generic manufacturers of MCP in 2011. In *Mensing*, plaintiffs similarly situated to Ms. Bell alleged that the long-term use of MCP had caused them to develop TD and that the generic manufacturers of MCP were liable under state-tort laws "for failing to provide adequate warning labels." 131 S. Ct. at 2573. Specifically, they contended that, "despite mounting evidence that long term [MCP] use carries a risk of [TD] far greater than that indicated on the label, none of the [m]anufacturers had changed their labels to adequately warn of that danger." *Id.* (internal quotation marks omitted).

The *Mensing* defendants countered the plaintiffs' claims with a theory of federal preemption. Like the Generic Defendants in the present action, the

Mensing defendants explained that "federal statutes and FDA regulations required them to use the same safety and efficacy labeling as their brand-name counterparts," and, accordingly, it was impossible for them "to simultaneously comply with both federal law and any state tort-law duty that required them to use a different label." *Id*. With these contentions in place, the Supreme Court examined whether the *Mensing* defendants had an avenue by which they could comply with both federal drug regulations and state-tort laws.

Relying heavily on the FDA's interpretations of the federal requirements imposed upon generic pharmaceutical manufacturers, the Supreme Court determined that the *Mensing* defendants were without a viable means of complying with both state and federal law. Specifically, the Supreme Court determined that federal law prohibited the generic manufacturers from unilaterally changing their labels via the "changes-being effected" process or providing heightened warnings directly to physicians via "Dear Doctor" letters. *Id*. at 2575. Accordingly, the Supreme Court concluded that federal law preempted the *Mensing* plaintiffs' failure-to-warn state-tort claims.

Two years later, the Supreme Court extended its holding in *Mensing*, concluding that federal pharmaceutical regulations also preempted state-tort claims against generic manufacturers based upon design-defect theories. *See Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013). The Supreme Court neglected the First Circuit's rationale that *Mensing* was distinguishable because the generic

manufacturer could have complied with state design-defect laws and federal regulations simultaneously by choosing to not make the drug at all. It determined that a "stop-selling" rationale was "incompatible with . . . pre-emption jurisprudence." *Id*. at 2477. The Court ultimately concluded that state-tort laws that require generic manufacturers to "render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws" and preempted accordingly. *Id*. at 2479.

Recently, the Eleventh Circuit applied the Supreme Court's holdings in *Mensing* and *Bartlett*. In *Guarino v. Wyeth, LLC*, 719 F.3d 1245 (11th Cir. 2013), a plaintiff appealed from a district court's dismissal of her claims in favor of a generic manufacturer of MCP. The district court had explicitly relied upon the Supreme Court's decision in *Mensing*, and on appeal, the plaintiff argued that *Mensing* was distinguishable because her negligence claim was based upon a "failure to communicate" theory. *Id*. at 1247–48. Addressing the plaintiff's artful attempt to overcome federal preemption, the Eleventh Circuit spoke to the scope of *Mensing*, explaining that any state law cause of action grounded upon a generic manufacturer's taking unilateral action is preempted because the federal law "duty of sameness" makes generic manufacturers dependent upon brand-name manufacturers. *Id*. at 1249.

The Generic Defendants argue that *Mensing*, *Bartlett*, and *Guarino* control the entirety of Ms. Bell's action against them. Ms. Bell asserts, however, that her

claims against the Generic Defendants are easily distinguishable from the claims asserted in *Mensing* and the related cases. She argues that the Generic Defendants, on their own, "prior to [her] ingestion of [MCP], chose not to fulfill federal law" when they failed to update the package inserts to match the inserts that accompanied the name-brand Reglan®. (Doc. # 133, at 8.) Accordingly, she contends that by unilaterally deciding to ignore the federal duty of "sameness," the Generic Defendants should not now be able to cloak themselves in that duty for preemption purposes. As support for this argument, Ms. Bell highlights the Sixth Circuit's analysis in *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013).[6]

In *Fulgenzi*, the Sixth Circuit was tasked with applying *Mensing* to facts largely analogous to those presented in this case. Specifically, the plaintiff in *Fulgenzi* argued that federal preemption was not available to the generic manufacturer because it "failed to update its labels as required by federal law—rendering compliance with both federal and state duties no longer impossible." 711 F.3d at 580. Finding the plaintiff's argument persuasive, the Sixth Circuit concluded that the generic manufacturer not only could have acted unilaterally to update its labeling to conform to that of the brand-name manufacturer, but it was required to do so under federal law. *Id.* at 584. Accordingly, it held that the

[6] The Eleventh Circuit addressed *Fulgenzi* when rendering its decision in *Guarino*. In a footnote, the Eleventh Circuit explained that its decision "was not to the contrary" of the Sixth Circuit's holding in *Fulgenzi*. *Guarino*, 719 F.3d at n.2. Rather, it noted that the plaintiff in *Guarino* had failed to allege that the generic manufacturer had not updated its label, as allowed by federal law. *Id.*

plaintiff's claims were allowed to go forward in a limited fashion. While the plaintiff could not proceed as to any claims based upon the generic manufacturer's failure to act independently of the brand-name manufacturers, her claims challenging the generic manufacturer's warning survived "to the extent that [the warning] did not include the language contained in the updated Reglan label from 2004." *Id*.

While Ms. Bell hinges her opposition to the Generic Defendants' motion for judgment on the pleadings upon the Sixth Circuit's reasoning in *Fulgenzi*, she fails to appreciate the limited nature of *Fulgenzi's* holding. The *Fulgenzi* court did not conclude that federal preemption was inapplicable to the entirety of the plaintiff's claims. Rather, the Sixth Circuit determined that federal-preemption law did not prohibit the plaintiff from pursuing a single, narrow state-tort law claim. Specifically, the plaintiff was able to proceed on her claim that the generic manufacturers violated state-tort law when they failed to provide a durational warning on the labeling, as was allowed (even required) under federal regulations because the brand-name manufacturers already had added the language to their labels.

Accordingly, while Ms. Bell argues that the Generic Defendants' failure to comply with federal law should leave her claims entirely outside the scope of federal preemption, the Supreme Court, the Eleventh and Sixth Circuits, and the Supreme Court of Alabama all make clear that generic manufacturers cannot be

held liable for violating state-tort laws in failing to take unilateral actions that would be prohibited by federal law. *Mensing*, 131 S. Ct. at 2577–78 ("We find impossibility here. It was not lawful under federal law for the Manufacturers to do what state law required of them."); *Guarino*, 719 F.3d at 1249 (agreeing with the Fifth Circuit, that "[w]hether a warning is placed on the label on the bottle or in letters to distributors, any state law duty requiring generic manufacturers to act unilaterally in this area is preempted by federal law" (quoting *Morris v. PLIVA, Inc.*, 713 F.3d 774, 776–77 (5th Cir. 2013))); *Fulgenzi*, 711 F. 3d at 588 ("Under *Mensing*, [the plaintiff's] claims are viable only to the extent [the generic manufacturer's] actions were permitted by federal law."); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 677 (Ala. 2014) ("The Supreme Court in [*Mensing*] held that it would have been impossible for the generic manufacturers to change their warning labels without violating the federal requirement that the warning on a generic drug must match the warning on the brand-name version, preempting failure-to-warn claims against generic manufacturers."). Applying that principle, to the extent Ms. Bell seeks to hold the Generic Defendants liable for actions that would have been prohibited by federal law, her claims are due to be dismissed under a straightforward application of *Mensing*.

This court is left with the singular task of determining whether Ms. Bell may proceed on a claim that the Generic Defendants violated state-tort law when they failed to provide a durational warning on the labeling. As discussed in *Guarino*,

such a claim could potentially survive *Mensing* and federal preemption because the Generic Defendants were allowed (even required) under the federal regulations to incorporate the durational warning since the brand-name manufacturers already had added that language to their labeling. A close review of Ms. Bell's Amended Complaint, however, makes clear that, unlike the *Guarino* plaintiffs, Ms. Bell has not pled a failure-to-update claim sufficiently narrow to escape federal preemption.

As Ms. Bell has acknowledged, preemption will attach when "it is 'impossible for a private party to comply with both state and federal requirements.'" *Mensing*, 131 S. Ct. at 2577 (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)). Stated differently, if complying with a state's laws would require a "party to violate federal law," then the state laws "are pre-empted and, thus, are 'without effect.'" *Bartlett*, 133 S. Ct. at 2470 (*quoting Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). In turn, to present a viable state-tort claim that falls outside the scope of federal preemption, Ms. Bell would have to allege that (1) the Generic Defendants violated their state-tort duties, and that (2) the Generic Defendants could have taken actions in line with their federal-law obligations that would have also allowed them to discharge their state-law duties. More specifically, she would have to allege that, if the Generic Defendants had updated their labels in accordance with federal law to incorporate a durational warning, then they would have been able to comply fully with their state tort-law obligations.

Ms. Bell, however, does not make such a claim. Rather, throughout her Amended Complaint, Ms. Bell repeatedly asserts that the federally compliant labeling, as implemented by the Brand-Name Defendants in 2004, failed to fully comply with state law. As a result, Ms. Bell contends that, even if the Generic Defendants had fulfilled their federal updating obligation, they would not have satisfied state law. Because Ms. Bell's claims, all of which are grounded upon failure-to-warn and defective-design theories,[7] allege state-law violations that the Generic Defendants could not have remedied without violating federal-pharmaceutical obligations, the claims are preempted. *See Mensing*, 131 S. Ct. at 2577 ("We find impossibility here. It was not lawful under federal law for the Manufacturers to do what state law required of them. And even if they had fulfilled their federal duty . . . , they would not have satisfied the requirements of state law."); *Morris*, 713 F.3d at 777 ("[I]t is logically incoherent to contend that [the generic manufacturer] had a duty to apply the 2004 warning label when appellants also assert repeatedly that no labels predating 2009 were adequate.").

[7] In responding to the Generic Defendants' motion for judgment on the pleadings, Ms. Bell clarifies that she is not seeking to hold the Generic Defendants accountable for failing to comply with the federal law that requires generic manufactures to maintain the same labeling as that of their brand-name counterparts. She repeatedly emphasizes that all of her claims are based upon alleged violations of state law and that she is not pursuing a "failure-to-update" claim. Ms. Bell explains that the Generic Defendants' failure to update its labeling was discussed only tangentially as a means of establishing why her claims were outside the reach of a preemption defense.

V. CONCLUSION

Based on the foregoing analysis, it is ORDERED that Defendants Pliva and Watson Laboratories' Motion for Judgment on the Pleadings (Doc. # 117) is GRANTED.

DONE this 3rd day of August, 2015.

/s/ W. Keith Watkins
CHIEF UNITED STATES DISTRICT JUDGE