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

LINDA WOODS,	]	
	]	
Plaintiffs,	]	
	]	**Case No.: 2:13-cv-543-KOB**
v.	]	
	]	
WYETH, LLC, *et al.*,	]	
	]	
Defendants.	]	
	]	
	]	

MEMORANDUM OPINION

This matter is before the court on "Defendants Pliva, Inc.; Barr Laboratories, Inc.; and Ranbaxy Pharmaceuticals, Inc.'s Renewed Motion for Judgment on the Pleadings" (doc. 185) and "Defendant Teva Pharmaceutical USA, Inc.'s Motion for Judgment on the Pleadings, or, in the Alternative, For Summary Judgment" (doc. 186).

In 2011, the United States Supreme Court held that failure to warn claims brought against a manufacturer of a generic drug are preempted by federal law because it would be impossible for a generic manufacturer to comply with both its federal and state law duties. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011) (explaining that if a manufacturer of a generic drug provided warnings beyond those provided by the manufacturer of the corresponding brand name drug, the generic manufacturer would violate federal law). Since that time, plaintiffs across the country have tried to plead their claims against generic manufacturers in a way that avoids *Mensing* preemption.

The Plaintiff in the instant case alleges that she developed tardive dyskinesia after

ingesting the generic drug metoclopramide. She argues that her claims are not preempted because they are based on the generic defendants' "failure to update" their labels to be consistent with the brand name labeling, rather than on their failure to provide additional or strengthened warnings. As will be discussed in greater detail in this Opinion, the court finds that the majority of the Plaintiff's claims against the generic manufacturers are preempted under *Mensing*. However, to the extent that the Plaintiff has stated a narrow set of claims, based on the generic manufacturers' "failure to update," that are not preempted, those claims still fail because Plaintiff has not shown proximate cause or pled her allegations with the necessary specificity. Therefore, this court finds, as many courts before it have found, that the Plaintiff's claims in the instant action against the manufacturers of the generic drug metoclopramide are preempted by federal law, or otherwise fail as a matter of law.

Accordingly, the court will GRANT Defendants Pliva, Barr, and Ranbaxy's Motion for Judgment on the Pleadings and Defendant Teva's Motions for Judgment on the Pleadings. Because the court will grant Teva's Motion for Judgment on the Pleadings, it will DENY as MOOT Teva's Motion for Summary Judgment.[1]

[1] The court does not reach the merits of Defendant Teva's Motion for Summary Judgment because it finds in this Opinion that Teva's Motion for Judgment on the Pleadings is due to be granted. However, alternatively, if the court were to consider evidence outside of the pleadings, Teva would also be entitled to summary judgment. Teva has presented evidence demonstrating that it updated its label on or about June 24, 2005, but that Woods did not take a pill manufactured by Teva until August 2007. Accordingly, because Teva's label was already updated by the time Woods ingested the pill Teva produced, Woods has no basis to bring a "failure to update" claim against Teva. Woods has acknowledged that this aspect of her claim against Teva is due to be dismissed. *See* (Doc. 193, at 2 ("Plaintiff concedes that its claim against Teva for 'failure to update' its label is due to be dismissed.")).

I. Standard of Review

Rule 12(c) provides 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). "Judgment on the pleadings is appropriate when material facts are not in dispute and judgment can be rendered by looking at 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) (citations omitted).

When ruling on a motion for judgment on the pleadings, the court should "accept the facts in the complaint as true and view them in the light most favorable to the nonmoving party." *Ortega v. Christian*, 85 F.3d 1521, 1524 (11th Cir. 1996) (citations omitted). However, the court "need not accept as true . . . conclusory legal allegations made in the complaint." *Andrx Pharma., Inc. v. Elan Corp.*, 421 F.3d 1227, 1230 n. 1 (11th Cir. 2005) (citing *Green Leaf Nursery v. E.I. DuPont De Nemours & Co.*, 341 F.3d 1292, 1304 n. 12 (11th Cir. 2003)). Thus, a Rule 12(c) motion "is subject to the same standard as a motion to dismiss under Rule 12(b)(6)." *Synovus Bank v. Summerford*, No. 2:12-cv-3598-VEH, 2013 WL 21679, at *2 (N.D. Ala. May 10, 2013) (quoting *Doe v. Myspace, Inc.*, 528 F.3d 413, 418 (5th Cir. 2008)); *see also Horsley v. Feldt*, 304 F.3d 1125, 1134 (11th Cir. 2002) (noting the similarities between Rule 12(c) and Rule 12(b)(6)).

The Eleventh Circuit has explicitly applied the *Twombly* standard to a Rule 12© motion for judgment on the pleadings, noting that dismissal is appropriate 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) (quoting *Bell Atlantic Corp. v.*

Twombly, 550 U.S. 544, 556, 570 (2007)).

II. Statement of Facts

Plaintiff Linda Woods brings the instant action against various brand name and generic manufacturers of the prescription drug Reglan, or metoclopramide, for personal injuries she claims to have suffered as a result of her ingestion of the generic drug metoclopramide. Woods asserts claims for fraud/misrepresentation by misstatement or omission; strict liability/Alabama Extended Manufacturers Liability Doctrine ("AEMLD"); failure to warn; breach of implied warranty; breach of express warranty; negligence and wantonness; and negligence/violation of FDA requirements.

Defendants Wyeth LLC; Wyeth Pharmaceuticals, Inc.; Pfizer, Inc.; Schwarz Pharma, Inc.; and Alaven Pharmaceutical, LLC manufactured the brand name drug Reglan, and are collectively referred to in Woods's Complaint as the "brand name defendants." Defendants Teva Pharmaceuticals USA, Inc.; PLIVA, Inc.; Barr Laboratories, Inc.; and Ranbaxy Pharmaceuticals, Inc. manufactured the generic version of Reglan, called metoclopramide, and are collectively referred to as the "generic defendants." The generic defendants filed the Motions that are the subject of this Opinion.

In the early 1980s, after receiving FDA approval, A.H. Robins Company, Wyeth's predecessor, first marketed the prescription drug Reglan in the United States. Five years later, the patent protection for Reglan expired, and manufacturers began filing Abbreviated New Drug Applications ("ANDAs"), so that they could make generic versions of the drug metoclopramide. The FDA requires generic manufacturers filing ANDAs to submit a label for metoclopramide "identical in all material aspects to the reference listed drug label." (Doc. 151, ¶ 55). The generic

defendants acted in accordance with this process and submitted labels that matched those of Reglan. The generic defendants then began selling metoclopramide with labels identical to the labels on the brand name drug Reglan.[2]

Woods alleges that the warnings provided by the brand name defendants and the generic defendants on the labels of Reglan and metoclopramide were inadequate and that the generic defendants "knew or should have known that the risks of the drug were significantly understated on the label, but they took no steps to warn the relevant community of prescribing doctors about the true risks." (Doc. 151, ¶ 57). Woods contends that the risk of patients developing tardive dyskinesia or other extrapyramidal side effects (involuntary repetitive movements) when using Reglan long term was "approximately 100 times greater than disclosed" by the defendants. (*Id.*, ¶ 49).

Woods also alleges that the brand name defendants "knowingly, intentionally and negligently disseminated misleading information to physicians' across the country, through a publication known as the *Physicians' Desk Reference*," and that "[n]o Defendant after 2002 published any warning about the drug in the *Physicians' Desk Reference*." (Doc. 151, ¶ 44, 65).

In 2003, the FDA approved the addition of information on the labels for Reglan/metoclopramide directed towards the safe use of the drug in geriatric patients. In 2004, the FDA approved the addition of bolded warnings on the label for the brand name drug Reglan. The 2004 additional warnings included a statement that therapy with the drug Reglan "should not exceed 12 weeks in duration." (Doc. 151, ¶ 76).

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[2] In the Federal Food, Drug, and Cosmetic Act, the FDA defines "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

Woods alleges that the generic defendants failed to update their labels to include the new 2004 warning in a timely manner. Specifically, Woods alleges that Teva took 14 months to update its labels; and that the PLIVA Defendants, and the Barr Defendants, as their successors in interest, did not update their labels with the 2004 revision. Woods also alleges that the Teva, PLIVA, and Barr Defendants failed to send direct correspondence concerning the 2004 revisions in the form of "Dear Doctor" letters to healthcare professionals.[3]

In February 2009, the FDA required manufacturers of Reglan/metoclopramide to place a black boxed warning on the label of the drug. The black boxed warning states that "[p]rolonged treatment (greater than 12 weeks) with metoclopramide should be avoided in all but rare cases . . . ." (Doc. 151, ¶ 77). The FDA also required the manufacturers to "implement a Risk Evaluation and Mitigation Strategy" because "the FDA determined that use of Reglan/metoclopramide 'pose[s] a serious and significant public health concern requiring the distribution of a Medication Guide.[4]'" (*Id.*) (alteration in original).

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[3] Woods's Amended Complaint does not contain any specific allegations as to whether generic defendant *Ranbaxy Pharmaceuticals* updated its label in a timely manner or sent "Dear Doctor" letters to healthcare professionals. *See* (Doc. 151, ¶¶ 81-91 (discussing the actions taken by the PLIVA, Teva, and Barr Defendants)). Woods does generally allege that "the Generic Defendants failed to communicate any warning about Reglan/MCP to the doctor(s) who prescribed the drug to Linda Woods" and "[t]he Generic Defendants failed to conform their package inserts . . . to the FDA-approved label." (*Id.*, ¶¶ 65-66).

These generalized allegations would likely be insufficient to meet the pleading standards of Rule 8 of the Federal Rules of Civil Procedure. However, Ranbaxy did not raise this point in its Motion for Judgment on the Pleadings. Because Ranbaxy did not raise the issue, and because the court finds that its Motion is due to be granted regardless, the court does not address the sufficiency of these allegations.

[4] "Medication Guides are paper handouts that come with many prescription medicines. The guides address issues that are specific to particular drugs and drug classes, and they contain FDA-approved information that can help patients avoid serious adverse events." *Medication Guides,* U.S. Food and Drug Administration (last updated Apr. 25, 2016),

From approximately 2005 to 2009, Woods's doctors prescribed the brand name drug Reglan to her, without expressly prohibiting her pharmacies from dispensing the generic drug as a substitute. Woods's pharmacies then filled and refilled her prescriptions with the generic version of the drug, metoclopramide. Woods admits that the fact that she ingested generic products manufactured by the generic defendants "was happenstance, due solely to actions of her pharmacies." (Doc. 151, ¶ 66).

After ingesting metoclopramide, Woods contracted tardive dyskinesia, an incurable neurological movement disorder, and Parkinsonism. Woods alleges that, had the brand name defendants and generic defendants properly warned her doctors of the risks of taking metoclopramide, her doctors would not have prescribed the drug, and Woods would have not have experienced these adverse health effects.

III. Discussion

A. Failure to Provide Additional Warnings on Labels

First, to the extent that Woods alleges that the warning labels on metoclopramide were inadequate and that the generic defendants should have provided additional warnings on its labels, *beyond those the FDA approved for Reglan*[5], the generic defendants are entitled to

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http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm.

[5] This Section of the court's Opinion applies only to Woods's claims that the generic defendants should have provided additional warnings *that went beyond those provided by* the brand name manufacturers. The court addresses Woods's claims that the generic defendants should have *updated* their labels and provided warnings *that were consistent* with the brand name labels in Section III© of this Opinion.

judgment on the pleadings.[6] The United States Supreme Court has made clear that such claims are preempted by federal law. *See Mensing*, 564 U.S. 604.

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the requirements for obtaining FDA approval vary greatly depending on whether the manufacturer is seeking approval for a new drug or is applying to manufacture a generic version of an already approved drug. A manufacturer seeking approval of a new drug must demonstrate that the drug is safe and effective, and that the proposed labeling of the drug is accurate and adequate. *See* 21 U .S.C. § 355(b); 21 U.S.C. § 352(f)(2). In contrast, a generic manufacturer seeking FDA approval must only demonstrate that the generic drug is chemically and practically the bioequivalent of the brand-name drug and that the labeling is the same as that approved for the brand-name drug. *See* 21 U.S.C. 355(j)(2)(A); *see also Dreher v. Wyeth Pharm.*, No. 2:14-cv-00280-KOB, 2015 WL 3948961, at *1 (N.D. Ala. June 29, 2015).

The Supreme Court in *Mensing* explained that after the initial FDA approval, generic drug labels must continue to be the same as their brand name counterparts. The court explained, "generic drug manufacturers have an ongoing federal duty of 'sameness'," which requires the generic drug's labeling to be the same as the brand name drug's labeling. *Mensing*, 564 U.S. at 613. The Court rejected arguments that the generic manufacturers could have used the FDA's

[6] The court's analysis applies not only to Woods's failure to warn claim in Count III of her Amended Complaint, but also to the other six Counts in Woods's Amended Complaint. Each of Woods's claims is premised on the defendants' failure to warn her prescribing physicians of the risks of using metoclopramide. *See Guarino v. Wyeth*, 719 F.3d 1245, 1249 (11th Cir. 2013) (finding, in an action with claims for negligence, strict liability, breach of warranty, misrepresentation and fraud, and negligence per se, that, "[b]ecause each of [the plaintiff's] claims against [the generic manufacturer] is premised upon an allegedly inadequate warning, they are all preempted by federal law.").

changes-being-effected ("CBE") process to change their labels. The CBE process allows drug manufacturers to "add or strengthen a contraindication, warning, [or] precaution" to their labels. 21 C.F.R. § 314.70(c)(6)(iii)(A). However, the FDA explained that generic manufacturers could not use the CBE process to *unilaterally* strengthen their warning labels, and that FDA approval for the drug could be withdrawn if the generic drug's label was no longer consistent with the brand name drug's label. *Mensing*, 564 U.S. at 614.

Accordingly, the Supreme Court found that state law tort claims, which impose a higher duty on generic drug manufacturers to provide adequate warnings in their labels, directly conflict with the federal requirement that generic drug manufacturers' labels be the same as the corresponding brand name label. *Mensing*, 564 U.S. at 608, 618. Consequently, Woods's claims based on the generic drug manufacturers' failure to provide additional warnings are preempted by federal law because it is "impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same." *Id.* at 618.

Therefore, to the extent that Woods alleges that the generic defendants had a duty to provide additional warnings on their labels to warn doctors about the risks of contracting tardive dyskinesia, Woods's claims are preempted.[7]

[7] It does not appear that Woods intends to bring claims against the generic defendants based on a design defect. However, in her Amended Complaint, Woods occasionally makes references to the drug being defective in the way that it was designed. The United States Supreme Court has explained that design defect claims brought against generic manufacturers are also preempted by federal law because the manufacturer would have to change the product's design or labeling to comply with state law, neither of which could it do without violating federal law. *See Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2474-76 (2013). Accordingly, to the extent that Woods does intend to assert design defect claims against the generic defendants, those claims are also preempted.

B. Failure to Send "Dear Doctor" Letters

Next, to the extent that Woods alleges that the generic defendants could have satisfied their state law duties by sending "Dear Doctor" letters to healthcare professionals to warn them of the risks of using Reglan/metoclopramide or to notify them of changes made to the labeling of the brand name drug Reglan, those claims are also preempted.

The Supreme Court in *Mensing* established that generic manufacturers may not place additional warnings on their labels or send additional warnings directly to doctors in the form of "Dear Doctor" letters. 564 U.S. at 615 (explaining that "[a] Dear Doctor letter that contained substantial new warning information would not be consistent with the drug's approved labeling," and that "if generic drug manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'").

Woods, however, contends that the holding of *Mensing* only applies to "Dear Doctor" letters that contain "substantial new warning information," and that the generic defendants could have sent "Dear Doctor" letters regarding the 2004 updates that were "consistent with and not contrary to" the approved labeling for the brand name drug.

Eleventh Circuit precedent, however, holds otherwise. In a case that is factually similar to the present case, *Guarino v. Wyeth,*[8] the Eleventh Circuit found that such claims are also preempted by federal law. 719 F.3d 1245 (11th Cir. 2013). The Eleventh Circuit adopted the

[8] Both cases involve a plaintiff who took generic metoclopramide for over twelve weeks, developed tardive dyskinesia, and tried to hold generic manufacturers liable for a failure to communicate with doctors following the 2004 updates to the Reglan label. *See Guarino*, 719 F.3d 1245.

reasoning of the Fifth Circuit and found 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.'" *Guarino,* 719 F.3d at 1249 (quoting *Morris v. PLIVA, Inc.*, 713 F.3d 774, 776-77 (5th Cir. 2013) (per curiam)).

The Fifth Circuit explained that, because generic manufacturers are bound to the "duty of sameness" under federal law,

> the inquiry is whether the brand-name manufacturers sent out a warning, not whether the proposed warning to be disseminated contains substantially similar information as the label. Because no brand-name manufacturer sent a warning based on the 2004 label change, the generic manufacturers were not at liberty to do so.

Morris, 713 F.3d at 777.

Similarly, the generic defendants in the instant case were not at liberty to unilaterally send "Dear Doctor" letters, even ones that were consistent with the information contained in the labels approved for the brand name drug.

Woods spends much of her brief arguing why the Eleventh Circuit's decision in *Guarino* is incorrect; however, this court may not second guess the decision of the Eleventh Circuit. *See, e.g.*, *In re Hubbard*, 803 F.3d 1298, 1309 (11th Cir. 2015) (finding that district court "transgressed the fundamental rule that courts of this circuit are bound by the precedent of this circuit" when it overlooked a binding Eleventh Circuit decision). The Eleventh Circuit's decision is binding, and this court must apply its holding. In *Guarino*, the plaintiff's claims based on a failure to send "Dear Doctor" letters were preempted, and likewise, so are Woods's.

C. Failure to Update Labels

Woods next argues that her claims are not preempted because they are based on the

generic defendants' failure to update their labels in a timely manner *after* the FDA approved additional warnings on the label for the brand name drug. The court finds that a narrow set of Woods's claims based on a failure to update are not preempted; however, these claims still fail as a matter of law.

1. Preemption

The court in *Mensing* explained that a claim is preempted when "it is 'impossible for a private party to comply with both state and federal requirements.'" *Mensing*, 564 U.S. at 618 (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)). Woods contends that her claims are not preempted because it would have been possible for the generic defendants to comply with both state and federal law by updating their labels promptly after the FDA approved the 2004 changes to the label of the brand name drug.

The Eleventh Circuit has not yet addressed this argument; however, the Sixth Circuit has found under similar circumstances that a plaintiff could bring a "failure to update" claim against a generic manufacturer that would fall outside the scope of federal preemption. *See Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013). In *Fulgenzi*, the plaintiff took generic metoclopramide and developed tardive dyskinesia, much like the plaintiff in the instant case. Also like the plaintiff in the instant case, the plaintiff in *Fulgenzi* argued that her claims against the generic manufacturer were not preempted because the generic manufacturer could have updated its label following the 2004 changes to the Reglan label, and thereby comply with both state and federal law. The court in *Fulgenzi* agreed with the plaintiff, finding that it would have been possible for the generic manufacturer to update its label in 2004 and satisfy both state and federal law. *Id.* at 584.

The Sixth Circuit, however, noted that the plaintiff's claims against the generic manufacturer were limited. The plaintiff could argue only that the generic manufacturer violated state law by failing to update its label to be consistent with the brand name label, not that it should have provided any additional warning beyond those provided by the brand name manufacturer. The court explained:

> We note at this point that Fulgenzi's claims survive only to the extent PLIVA's actions were permitted by federal law. She cannot claim that PLIVA should have included an aggressive black-box warning; any such allegations are preempted under *Mensing.* Instead, she is left to argue only that PLIVA's warning was inadequate to the extent that it did not include the language contained in the updated Reglan label from 2004.

Id.

Several other courts have followed the Sixth Circuit's lead and have found that narrow failure to update claims fall outside the scope of preemption. *See*, *e.g., In re Fosamax Prod. Liab. Litig.*, 965 F. Supp. 2d 413, (S.D.N.Y. 2013) ("In this case, as in *Fulgenzi*, it was possible for the Generic Defendants to comply with their federal duty to match their labels to the Fosamax label, while also satisfying their state tort law duty to adequately warn consumers of alendronate sodium."); *Phelps v. Wyeth, Inc.*, 931 F. Supp. 2d 1055, 1061 (D. Or. 2013) ("[B]ecause plaintiffs' state-law claim does not make it impossible for Pliva to comply with federal law, no conflict exists and preemption is not warranted."); *Johnson v. Teva Pharma. USA, Inc.*, No. 2:10 CV 404, 2012 WL 1866839, at *3 (W.D. La. May 21, 2012) ("[I]mpossibility preemption would not apply to any requirement . . . that the Generic Defendants update their product labels to reflect labeling changes made by the brand name manufacturer."); *Franzman v. Wyeth LLC*, 451 S.W.3d 676, 688 (Mo. Ct. App. 2014) ("[I]t was not impossible for the Generic Defendants to comply with their duties under Kentucky state law and fulfill their duty under the FDCA and its

accompanying regulations by updating their label to conform to the Reglan legal revision of 2004.").

Fulgenzi's holding does not conflict with Eleventh Circuit precedent. In *Guarino*, the Eleventh Circuit explained that

> [t]he Sixth Circuit's recent decision in *Fulgenzi v. PLIVA, Inc*., 711 F.3d 578 (6th Cir. 2013), is not to the contrary. In *Fulgenzi*, the plaintiff alleged that the generic manufacturer failed to update its label when the brand manufacturer strengthened the Reglan warning; therefore, the claim against the generic manufacturer was not preempted because "not only could [the generic manufacturer] have independently updated its labeling to match that of the branded manufacturer . . . it had a federal duty to do so." *Id.* at 584. In the present case, Guarino does not allege that Teva failed to update its label once the Brand Manufacturers strengthened it, so *Fulgenzi* is inapplicable.

Guarino, 719 F.3d at 1250 n. 2 (alteration in original); *see also Bell v. Wyeth, Inc.*, 117 F. Supp. 3d 1355, 1364 (M.D. Ala. 2015) ("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.").

Fulgenzi applies to the present case because Woods has alleged that the generic defendants failed to updated their labels once the brand name defendants had strengthened it.

The generic defendants contend that they could not have complied with their state law duties because Woods has asserted that the labels were not adequate until 2009 when they included the black boxed warnings. *If* Woods had alleged that *only* the 2009 black boxed warning provided an adequate warning, sufficient to satisfy the defendants' state law duties, then her claims against the generic defendants would not be viable because the generic defendants would

not have been able to provide this black boxed warning without violating federal law. *See Bell*, 117 F. Supp. 3d at 1365 ("[The plaintiff] 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, [the plaintiff] contends that, even if the Generic Defendants had fulfilled their federal updating obligation, they would not have satisfied 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.").

However, although Woods discusses the 2009 black boxed warning in her Complaint, she has artfully avoided stating that either the 2009 warning was the only "good" warning, or that the 2003 and 2004 revisions to the label were inadequate as they relate to her claims against the generic defendants. Thus, Woods has not limited herself to arguing that only the 2009 label provided an adequate warning.

The court finds, therefore, that, taking the allegations in her Complaint as true, Woods has set out a narrow claim that falls outside the scope of federal preemption. Woods has alleged 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." *Bell*, 117 F. Supp. 3d at 1364. That is, Woods has alleged that the generic defendants could have satisfied both their federal and state law duties by updating their labels to be exactly the same as the brand name labels following the 2004 changes.

However, like the plaintiff's claims in *Fulgenzi*, Woods's claims avoid preemption "only

to the extent [the generic defendants'] actions were permitted by federal law." 711 F.3d at 584. Woods's claims survive preemption only to the extent that she argues that the generic defendants' warnings were inadequate because they did not include the language contained in the 2004 update to the Reglan label.

The generic defendants' argument that Woods's claims are impliedly preempted because the duty to update prescription drug labeling arises under federal law, and no private right of action exists to enforce the requirements of the FDA lacks merit. Woods's claims are not premised on the generic defendants' violation of federal law. Although "the alleged breach arises from the same act, . . . the legal basis is different." *Fulgenzi*, 711 F.3d at 587; *see also In re Fosamax*, 965 F. Supp. 2d at 418 ("[T]he federal duty of sameness is not 'a critical element' in plaintiffs' cases"). Woods's state law claims do not rely on the federal duty of "sameness" as an element; rather, they rely on independent state law duties. Therefore, her failure to update claims are not impliedly preempted.

2. Sufficiency of Pleading

a. Causation

However, even though the court finds that Woods has pled claims that are not preempted by federal law, her claims still fail as a matter of law because she has failed to allege facts sufficient to show that the generic defendants' actions proximately caused her injuries.

Under Alabama's learned-intermediary doctrine, a prescription drug manufacturer has "'an obligation to advise the *prescribing physician* of any potential dangers that may result from the drug's use.'" *Allain v. Wyeth*, No. 2:14-cv-00280-KOB, 2015 WL 178038, at *6 (N.D. Ala. Jan. 14, 2015) (quoting *Stone v. Smith, Kline, & French Labs.*, 447 So. 2d 1301, 1304 (Ala.

1984). "The prescribing physician then acts as a 'learned intermediary' between the patient and drug manufacturer." *Id.* (citing *Nail v. Publix Super Markets, Inc.,* 72 So. 3d 608, 614 (Ala. 2011); *Batchelor v. Pfizer, Inc.,* No. 2:12-cv-908-WKW, 2013 WL 3873242, at *2 (M.D. Ala. July 25, 2013) ("Defendant had no duty to warn Plaintiff, only to warn her physicians adequately and honestly . . . .")).

Here, Woods has alleged that the generic defendants failed to provide adequate warnings to her physicians; however, she has not shown causation. If a plaintiff alleges that the defendants failed to adequately warn her prescribing physicians, she still must plead facts sufficient to show a causal connection between the defendants' allegedly inadequate warnings and the prescribing physicians' actions.

The Eleventh Circuit has explained that, under Alabama law,

> [t]he failure of the manufacturer to provide the physician with an adequate warning of the risks associated with a prescription product is not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated. Thus, the causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had "substantially the same" knowledge as an adequate warning from the manufacturer should have communicated to him.

Bodie v. Purdue Pharma Co., 236 F. App'x 511, 519 (11th Cir. 2007) (quoting *Christopher v. Cutter Labs*, 53 F.3d 1184, 1192 (11th Cir. 1995)).

In the instant case, Woods's doctors *prescribed her the brand name drug Reglan* – not the generic drug metoclopramide – from 2005 to 2009. The labels for Reglan already contained the 2004 warnings at the time that Woods's doctors prescribed her Reglan. Thus, Woods's doctors had already gleaned "substantially the same" knowledge about the effects of using

Reglan/metoclopramide from the 2004 updates to the Reglan label that they would have gained from an identical update to the labels of the generic version of the drug.

The Eighth Circuit has affirmed dismissals of claims against generic manufacturers under similar circumstances. In *Bell v. Pfizer, Inc.*, the plaintiff's physician similarly prescribed her Reglan, not generic metoclopramide. 716 F.3d 1087, 1097 (8th Cir. 2013). The Eighth Circuit explained that "[b]ecause [the plaintiff's] physician prescribed Reglan and relied on its labeling, there is nothing to indicate [the generic defendant's] failure to update its warning affected [the plaintiff's] physician's prescribing decision or [the plaintiff's] injury in any way." *Id.*; *see also Fullington v. Pfizer, Inc.*, 720 F.3d 739, 747 (8th Cir. 2013) (citing *Bell*, 716 F.3d at 1097-98) ("Bell's prescribing physician had independent knowledge of the risk the updated metoclopramide label would have communicated, and so this court determined that Bell failed to articulate a causal link between her injury and PLIVA's failure to update its labeling.").

Similarly, in the instant case, because Woods's physicians prescribed her Reglan, not generic metoclopramide, Woods has not shown that her physicians relied on the labeling of generic metoclopramide.

Woods contends that a comparison of the instant case to *Bell* or *Fullington* is inappropriate because the plaintiffs in those cases admitted that their physicians had relied on the representations made by the brand name manufacturers. Woods argues that her case is distinguishable because, while she admits that her doctors prescribed her the brand name drug Reglan, she has not alleged that her doctors relied on the labeling or representations made by the brand name manufacturers.

A review of Woods's Amended Complaint shows otherwise. In her Amended Complaint,

Woods alleges that

> - The Brand Name Defendants . . . intentionally and fraudulently misled the medical community, physicians, plaintiff's physicians and plaintiff about the risks associated with long term, pediatric, and/or short term use of metoclopramide. (Doc. 151, ¶ 43).
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> - The Brand Name Defendants then knowingly, intentionally and negligently disseminated misleading information to physicians' [sic] across the country . . . . (*Id.*, ¶ 44).
>
> - *Because of the misleading information that the Brand Name Defendants provided to physicians* and the FDA about the true risks associated with the use of Reglan, metoclopramide HCL and/or metoclopramide and because of the failure of the Brand Name Defendants to adequately inform physicians generally, including plaintiffs' physicians, about the true risks associated with the use of Reglan, metoclopramide HCL and/or metoclopramide, plaintiffs' physicians never informed them of any side effects associated with Reglan, metoclopramide HCL, metoclopramide before the February 26, 2009 FDA required warning. (*Id.*, ¶ 48) (emphasis added).

These allegations, taken as true, demonstrate that Woods's physicians relied on the labeling and representations *made by the brand name defendants* when they prescribed her the brand name drug Reglan.

Woods does not allege that her physicians prescribed Reglan *because of* any labeling or representations *made by the generic defendants*. Woods does make generalized allegations applicable to all defendants, such as "had the Plaintiff's physician(s) been warned *by any Defendants* of the true risks of Reglan/MCP, . . . the doctor(s) would not have prescribed the drug to the Plaintiff" and "[b]ecause of the misleading information *the Defendants* provided to physicians . . ., Plaintiff Linda Woods's physician(s) never informed her of the true risks . . . ." (Doc. 151, ¶¶ 67, 105) (emphasis added).

However, these sweeping allegations are insufficient to show a causal connection between the generic defendants' actions and the physicians' decisions to prescribe Reglan to Woods. *See Allain*, 2015 WL 178038, at *4 ("Plaintiff consistently lumps the Defendants into an undifferentiated group and makes broad sweeping allegations against all Defendants, failing to cite any specific factual instances for support. Such 'naked assertions' without supporting factual allegations are insufficient to survive a motion to dismiss.") (citations omitted); *see also Simpson v. Sanderson Farms, Inc.*, 744 F.3d 702, 708 (11th Cir. 2014) ("A plaintiff cannot rely on 'naked assertion[s] devoid of further factual enhancement.'") (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)) (alteration in original).

Woods provides no factual support for her generalized allegations that her physicians prescribed Reglan because of the defendants', and specifically the generic defendants', representations. Woods has not alleged that her physicians ever saw the package inserts or labeling for the generic drug metoclopramide, much less that they relied on those labels. As a result, Woods has not shown that the generic defendants' failure to update their labels in 2004 affected in any way her physicians' choice to prescribe her with Reglan. Accordingly, the court finds that Woods has failed to plead facts sufficient to show proximate cause.

b. Fraud

In addition to being deficient under the pleading standards of Rule 8 of the Federal Rules of Civil Procedure, Woods's fraud claim in Count II of her Amended Complaint fails to meet the heightened pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure. ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.") When pleading a fraud claim, to satisfy the requirements of Rule 9(b), "a

plaintiff must allege: '(1) the precise statements, documents, or misrepresentations made; (2) the time, place, and person responsible for the statement; (3) the content and manner in which these statements misled the [p]laintiff; and (4) what the defendants gained by the alleged fraud.'" *Am. Dental Ass'n v. Cigna Corp.*, 605 F.3d 1283, 1291 (11th Cir. 2010) (quoting *Brooks v. Blue Cross & Blue Shield of Fla., Inc.*, 116 F.3d 1364, 1380-81 (11th Cir. 1997)).

Woods has failed to meet this heightened pleading standard. While Woods makes allegations about the information that "the Defendants" as a whole provided to her physicians, she fails to identify with specificity which Defendants provided that information to her physicians, what information they provided, when they provided that information, or how her physicians relied upon and were mislead by those communications. Accordingly, Woods's blanket allegations against "the Defendants" are insufficient under Federal Rule of Civil Procedure 9(b) to state a claim for fraud against the generic defendants.

IV. Conclusion

Because Woods's claims against the generic defendants are preempted by federal law or otherwise insufficiently pled under Rule 8 or Rule 9 of the Federal Rules of Civil Procedure, the generic defendants are entitled to judgment on the pleadings as to each of Woods's claims in her Amended Complaint.

Therefore, the court will GRANT both of generic defendants' Motions for Judgment on the Pleadings (docs. 185 & 186) and will DISMISS WITH PREJUDICE all of Woods's claims against generic defendants Barr Laboratories; Pliva, Inc.; Ranbaxy Pharmaceuticals, Inc.; and Teva Pharmaceuticals, USA, Inc.

Additionally, because the court will grant Teva's Motion for Judgment on the Pleadings,

it will DENY as MOOT Teva's Motion for Summary Judgment.

DONE and ORDERED this 29th day of April, 2016.

KARON OWEN BOWDRE
CHIEF UNITED STATES DISTRICT JUDGE