UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 17-cv-61800-BLOOM/Valle

ANITA ALLBRIGHT,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.
_____/

ORDER GRANTING MOTION TO DISMISS

THIS CAUSE is before the Court upon the Motion to Dismiss and Memorandum of Law in Support by Defendant Teva Pharmaceuticals USA, Inc. ("Teva" or "Defendant") on September 25, 2017. ECF No. [11] ("Motion"). The Court has carefully reviewed the Motion, all opposing and supporting materials, the record in this case and the applicable law, and is otherwise fully advised. For the reasons set forth below, the Motion is granted.

I. FACTUAL BACKGROUND[1]

Defendant Teva is a manufacturer of alendronate, the generic version of osteoporosis drug Fosamax. *See* ECF No. [5-1] ¶¶ 7, 18. The FDA approved Teva to manufacture this generic drug, a nitrogenous bisphosphonate, in September 1995. *Id.* ¶ 18. According to the Complaint, throughout the 1990's and 2000's, patients taking alendronate reported severe

[1] The Court accepts the well-pleaded factual allegations found in the complaint, ECF No. [5-1] ("Complaint") as true. *Am. Dental Ass'n v. Cigna Corp.*, 605 F.3d 1283, 1290 (11th Cir. 2010). The Court notes that Plaintiff's Complaint contains many paragraphs which repeat allegations found elsewhere in the Complaint. Accordingly, citations in this Order will reference some, but not all, of the paragraphs reflecting a particular fact or allegation unless context requires otherwise.

negative side effects, including osteonecrosis in the jaw, as well as other dental and bone complications. *Id.* ¶¶ 25, 30.

Plaintiff Anita Allbright ("Plaintiff" or "Allbright") was prescribed alendronate either sometime in 2008 or in September 2009. *Cf. id.* ¶¶ 27, 58 *with id.* ¶ 65. She took alendronate "on-and-off until January of 2015." *Id.* ¶ 66. In the months prior to when she ceased taking the drug, Allbright began experiencing symptoms affecting her jaw, mouth, and teeth with increasing severity. In November 2014, Allbright sought dental treatment for pain in the back of her jaw. *Id.* ¶ 67. On December 17, 2014, Allbright developed "a lump on the right side of her jaw" and "extreme swelling under her tongue," for which she was prescribed an antibiotic. *Id.* ¶ 68. On January 21, 2015, "a piece of [] Allbright's jaw bone was protruding during a routine dental cleaning," and on February 4, 2015, "another piece of jaw bone became dislodged." *Id.* ¶¶ 69–70. These bone pieces were subsequently pathologically evaluated and Allbright was diagnosed with "necrotic bone osteonecrosis of the jaw from bisphosphonates." *Id.* ¶¶ 70–71. In the months following of 2015, Allbright experienced tooth and jaw pain, shingles, painful lumps of the jaw, loss of teeth fixation, and a full tear and retraction of the supraspinatus tendon which required a reverse shoulder replacement. *Id.* ¶¶ 72–77. In May of 2017, Allbright re-fractured her right shoulder. *Id.* ¶ 78.

Plaintiff alleges that she has "developed osteonecrosis of the jaw and/or other jaw and bone injuries after ingesting alendronate." *Id.* ¶¶ 9, 65. "Before taking bisphosphonates, [Allbright] was asymptomatic and in reasonably good health." *Id.* ¶ 64. Allbright alleges that the injuries she has since sustained are "severe and permanent" (*id.* ¶ 10) and that her injuries will "continue into the indefinite future" (*id.* ¶ 16). Plaintiff "would not have taken these drugs if she had been informed of the unreasonable risk of osteonecrosis." *Id.* ¶ 14.

Plaintiff alleges that generic manufacturer Teva knew or should have known that alendronate was defectively designed because it was unreasonably dangerous and its foreseeable risks exceeded any benefits. Despite this knowledge, Defendant continued to manufacture, market, and distribute alendronate. ECF No. [5-1] ¶¶ 80-86. Plaintiff further alleges that Defendant failed to properly warn her and her physician of the risks of taking alendronate because Defendant (1) failed to investigate reports of negative side effect like those experienced by Allbright and conduct post-market surveys regarding those side effects; (2) concealed alendronate's negative side effects and its "unreasonably dangerous risks"; (3) provided misleading and incomplete information for publication in the packaging inserts of the drug and in the Physician's Desk Reference, a publication widely used and relied upon by physicians when prescribing medications; and (4) failed to update the labels of alendronate pursuant to direction by the FDA in 2004. *See id.* ¶¶ 11–14, 16, 26–27, 31, 33, 42, 45–47.

With regard to allegations regarding failure to update alendronate's labels, Plaintiff alleges that on August 25, 2004, in its post-marketing safety review of bisphosphonates including alendronate, the FDA advised Defendant that it "should amend the labeling for the respective bisphosphonates medication to specifically warn of the risk of osteonecrosis of the jaw." *Id.* ¶ 40. According to the Complaint, Defendant "has refused to accede to the FDA request timely and to this day still does not adequately and/or specifically warn of the exceptional medical complication risk of osteonecrosis of the jaw in the label for alendronate." *Id.*¶ 41.[2] FDA cited Teva for violating federal regulations by overstating the benefits of alendronate and minimizing its risks. *Id.* ¶ 43. The Complaint also alleges that Teva failed to

[2] Teva argues in its Motion that it timely updated its labels to match the FDA approved amendments to the brand name label in early 2010. However, for the purposes of the Motion, the Court treats Plaintiff's allegations as true.

engage in the FDA's process of implementing stronger warnings, known as the "changes being effected" or CBE process. ECF No. [5-1] ¶ 35.

Based on these allegations, Plaintiff originally filed her Complaint in the Seventeenth Judicial Circuit in and for Broward County, Florida on August 11, 2017. ECF No. [5-1]. Plaintiff asserts three causes of action against Defendant: Count I: Strict Liability – Defective Design; Count II: Strict Liability – Failure to Warn; and Count III: Negligence. *Id.* On September 18, 2017, Defendant timely removed the action to this Court based on diversity. ECF No. [1]. Defendant now moves to dismiss the Complaint under Federal Rule of Civil Procedure 12(b)(6) because the claims asserted by Allbright are preempted by federal law.

II. LEGAL STANDARD

A. Motion to Dismiss

A motion to dismiss under Rule 12(b)(6) challenges the legal sufficiency of a complaint. See Fed. R. Civ. P. 12(b)(6). To survive such a motion, a claim "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' " *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Although this pleading standard "does not require 'detailed factual allegations,' . . . it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation," meaning that a plaintiff is required to plead sufficient "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 556–56). Thus, while a court must accept well-pleaded factual allegations as true, "conclusory allegations . . . are not entitled to an assumption of truth—legal conclusions must be supported by factual allegations." *Randall v. Scott*, 610 F.3d 701, 709–10 (11th Cir. 2010). When considering a motion to dismiss, the Court construes the

pleadings broadly and views the allegations in the complaint in the light most favorable to the plaintiff. *Bishop v. Ross Earle & Bonan, P.A.*, 817 F.3d 1268, 1270 (11th Cir. 2016) (quoting *Hill v. White*, 321 F3d 1334, 1335 (11th Cir. 2003).

B. Federal Preemption of State Tort Law

Under the Supremacy Clause, federal law "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. A "federal statute may preempt state law either expressly, by the statute's language, or implicitly, by the statute's structure and purpose." *Goodlin v. Medtronic*, Inc., 167 F.3d 1367, 1371 (11th Cir. 1999) (citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (finding state law claims expressly preempted by the Medical Device Amendments, 21 U.S.C. § 360c *et seq*., to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq*. for the pre-market approval process for new devices). "In the absence of an express command, federal law will preempt state law if that law actually conflicts with federal law or if the federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it." *Id.* (internal quotations and citations omitted). Thus, where state and federal law "directly conflict," state law must give way. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617–18 (2011) (quoting *Wyeth v. Levine*, 555 U.S. 555, 583 (2009)). A state and federal law conflict where 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).

However, a court's determination of whether state law is preempted by federal law should be examined through the lens of two broad presumptions. First, "[i]n all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, [the court] starts with the assumption that the historic police powers of the

States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Wyeth*, 555 U.S. at 565 (2009) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). Second, and relatedly, "the purpose of Congress is the ultimate touchtone in every case," *Lohr*, 518 U.S. at 485 (citations and internal modifications omitted), such that any "preemption provision and [the] surrounding statutory framework[] . . . provide [the] primary guide for discerning Congressional intent regarding the scope of preemption." *Goodlin*, 167 F.3d at 1372.

Here, Plaintiff benefits from the presumption against preemption because states have traditionally regulated matters of health and safety affecting their citizens. *See In re Fosamax Prod. Liab. Litig.*, 742 F. Supp. 2d 460, 475–76 (S.D.N.Y. 2010) (finding no implied preemption of FDA and Florida state law for *brand name* manufacturer of alendronate). However, over the last century, Congress has enacted significant and wide-sweeping public health laws which regulate drugs such as alendronate. In 1906, Congress passed the Federal Food and Drugs Act, ch. 3915, 34 Stat. 768, which prohibited the manufacture or interstate shipment of adulterated or misbranded drugs. *Wyeth*, 555 U.S. at 566 (finding no preemption for a *brand name* manufacturer). In the 1930s, it passed the Federal Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040, as amended, 21 U.S.C. § 301 *et seq.*, which among other regulations, required pre-market approval for new drugs prior to distribution. *Id.*

Despite this far-reaching regulation to "protect the public health and assure the safety, effectiveness, and reliability of drugs," Congress also took steps to preserve state law. *Wyeth*, 555 U.S. at 567. For example, the 1962 amendments "added a saving clause, indicating that a provision of state law would only be invalidated upon a 'direct and positive conflict' with the FDCA." *Id.* Accordingly, "state common-law suits continued unabated despite FDA

regulation." *Id.* (quoting *Riegel v. Medtronic, Inc.*, 552 U.S. 310, 340 (2008) (Ginsburg, J., dissenting) (internal modifications and quotation marks omitted).

The FDCA places ongoing duties to on brand name manufactures to investigate the safety and design of its drugs post-market, conduct post-market surveillance of its drugs, and to "change its drug label based on safety information that becomes available after a drug's initial approval." *Id.* at 570 (citing 121 Stat. § 901(a)). Indeed, "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." *Id.* at 570–71 (finding no preemption where *brand name* manufacturer failed to demonstrate compliance with both federal and state regulations was impossible). There are several processes by which a brand name manufacturer may update labels, some unilateral and some requiring FDA approval. Thus, courts examining whether state common law obligations of a brand name manufacturer are preempted by federal law have generally found that obligations placed on brand name manufacturers and avenues to fulfill those obligations allowed by the FDA do not pose the "direct conflict" as required to find preemption. *See, e.g.*, *Wyeth*, 555 U.S. at 581 (2009) (finding no preemption where brand name manufacturer failed to demonstrate compliance with both federal and state regulations was impossible); *In re Fosamax*, 965 F. Supp. 2d at 413; *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 475 (5th Cir. 2014) (finding failure to warn claims preempted under *Mensing*).

No so for generic manufactures. Unlike the obligations on brand name manufacturers, Congress has sharply distinguished the duties placed on generic manufactures like Defendant Teva. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch–Waxman Amendments to the FDCA, to allow generic drugs to forego the FDA's onerous approval process so that generic drugs could enter the market faster

and for lower cost. *See Tsavaris v. Pfizer, Inc.*, 154 F. Supp. 3d 1327, 1333 (S.D. Fla.), *appeal dismissed* (May 12, 2016) (citations omitted). Under the Hatch–Waxman Amendments, generic manufacturers may obtain FDA approval to manufacture, market, and sell a drug by demonstrating equivalence to a drug that has already undergone clinical trials and been approved by the FDA. 21 U.S.C. § 355(j)(2)(A). Once a generic is approved, the generic manufacturer has a "duty of sameness"—that is, that "the warning labels of a brand-name drug and its generic copy must always be the same." *Mensing*, 564 U.S. at 616; *see also* 21 U.S.C. §§ 355(j)(2)(A)(v) & (j)(4)(G); 21 C.F.R. §§ 314.94(a)(8) & 314.127(a)(7). In essence, the "manufacturers of generic medications gain authorization to market their products by demonstrating that those products are equivalent to the previously authorized name brand versions in a number of ways, including formulation and labeling. Generics must maintain this equivalence to maintain authorization." *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 475 (4th Cir. 2014) (citing 21 U.S.C. § 355(j)). "The FDA interprets these regulations as imposing an ongoing duty for generic manufacturers to update their product labels to ensure the sameness of the generic and name-brand drug labels." *In re Fosamax*, 965 F. Supp. 2d at 416 (citing *Mensing*, 564 U.S. at 616; 57 Fed. Reg. 17961 (1992) ("Abbreviated New Drug Application (ANDA) product's labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for ANDA approval")). Thus, unlike a brand name, a generic manufacturer may not unilaterally change a drug's label, design or formulation.

Several recent Supreme Court cases control the preemptive effect of the FDCA on generic manufacturers. In *Mensing*, the Supreme Court addressed the preemptive effect of the FDCA on state tort law for a generic manufacturer. There, plaintiff alleged claims against the generic manufacturer of metoclopramide based on a state law theory of failure to adequately

warn of the risk of developing a severe neurological disorder. *Mensing*, 564 U.S. at 608. The Supreme Court held that plaintiff's failure to warn claims were preempted by federal law because "it was 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.

Subsequently in *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013), the Supreme Court held that claims for design defect against a generic manufacturer based on flawed chemical compounds, proposed label changes, or failure to exit the market based on alleged risks of the drug in question were all preempted by federal law. *Id.* at 2473 ("[I]t was impossible for Mutual to comply with both its state-law duty to strengthen the warnings on [generic NSAID] sulindac's label and its federal-law duty not to alter sulindac's label. Accordingly, the state law is pre-empted.").

While the Supreme Court has conclusively found that failure to warn and design defect claims against a generic manufacturer are preempted, claims based on a generic manufacturer's failure to *update* labels consistent with its "sameness" duty are not preempted. *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 584 (6th Cir. 2013) ("In our case, not only could PLIVA have independently updated its labeling to match that of the branded manufacturer through the CBE process, . . . but it had a federal duty to do so, 21 C.F.R. § 314.150(b)(10). As a result, compliance with federal and state duties was not just possible; it was required."); *In re Fosamax*, 965 F. Supp. 2d at 417 ("This Court joins the majority of other jurisdictions in finding that 'failure to update' claims against the Generic Defendants are not preempted."); *Phelps v. Wyeth, Inc.*, 938 F. Supp. 2d 1055, 1061 (D. Or. 2013) ("Unlike the failure to warn claim in *Mensing*, plaintiffs do not claim that Pliva was required to use a different or stronger warning label; they merely claim that, under Oregon law, Pliva was negligent by failing to update its label to match

the name-brand label—a requirement that is consistent with the FDCA. Thus, because 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 Pharm. USA, Inc.*, No. 2:10 CV 404, 2012 WL 1866839, at *13 (W.D. La. May 21, 2012), *aff'd*, 758 F.3d 605 (5th Cir. 2014) ("[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"); *Cooper v. Wyeth, Inc.*, No. CIV.A. 09-929-JJB, 2012 WL 733846, at *4 (M.D.La. Mar. 6, 2012); *Couick v. Wyeth, Inc.*, No. 3:09-CV-210-RJC-DSC, 2012 WL 79670, at *5 (W.D.N.C. Jan. 11, 2012) ("[I]f Defendants' PIs did not match the brand, there are at least some changes to their PIs that federal law would allow, or even require, Defendants to make. A state law claim for failure to include such warnings would not be preempted by federal where the FDA would have permitted, or even required, such changes."); *Del Valle v. PLIVA, Inc.*, No. CIV.A. B:11-113, 2011 WL 7168620, at *5 (S.D. Tex. Dec. 21, 2011), *report and recommendation adopted sub nom. Del Valle v. Qualitest Pharm. Inc.*, No. CIV. B-11-113, 2012 WL 2899406 (S.D. Tex. June 22, 2012), *aff'd sub nom. Lashley v. Pfizer, Inc.*, 750 F.3d 470 (5th Cir. 2014) (finding "Teva['s] . . . failure to use the CBE process, after the brand name manufacturers enhanced their warning labels in 2004, might preclude the application of conflict pre-emption, but only as to the labeling information added by the brand name manufacturers in 2004").

III. ANALYSIS

Teva moves to dismiss all of Plaintiff's claims based on federal impossibility preemption. Defendant argues that "[w]hile framed in various causes of action, including design defect and negligence, the gravamen of *all* of Plaintiff's claims is that Teva is liable to Plaintiffs [sic] for

having allegedly failed to adequately warn healthcare professionals of the risk of osteonecrosis of the jaw . . . associated with the use of alendronate sodium, and that Teva should have redesigned alendronate sodium." ECF No. [11] at 1–2; *see also* ECF No. [18] at 4. Accordingly, Defendant argues that each of Plaintiff's claims is preempted by federal law under *Mensing* and *Bartlett* and must be dismissed with prejudice.

In its Opposition, Plaintiff does not separately rebut each of Defendant's arguments but rather sets forth a single argument that Defendant had a duty to change its warning labels because, under *Mensing*, a generic manufacturer is required to propose stronger labels if it believes such warnings are needed. *See* ECF No. [16] at 2–3. Plaintiff further bolsters its argument by citing to *In re Fosamax (Alendronate Sodium) Product Liability Litigation*, 852 F.3d 268 (3d Cir. 2017), in which the Third Circuit reversed a grant of summary judgment in favor of the brand name manufacturer of Fosamax because genuine issues of material fact existed as to whether the FDA would have approved the label changes sought by Plaintiffs. *Id.* at 271. However, Plaintiff misreads both cases. First, the Third Circuit's decision in *In re Fosamax* is inapplicable here because it analyzes failure to warn claims against a *brand name* manufacturer, which, as described above, has duties distinguishable from a generic manufacture under the FDCA. Second, Plaintiff's reliance on certain passages from *Mensing* in its Opposition is misplaced. The quoted passages analyze the *Mensing* parties' arguments regarding a potential duty of the generic manufacturer to notify the FDA when it believes labeling changes are required. ECF No. [16] at 2–3. However, while the Supreme Court reviewed the conflicting arguments presented by the parties and the FDA as to this duty, it declined to decide whether any duty existed at all, stating: "Because we ultimately find pre-emption even assuming such a duty existed, we do not resolve the matter." *Id.* at 617. Accordingly, the Court declines to apply

these authorities as urged by Plaintiff. Within this framework of the parties' arguments, the Court will analyze each of Plaintiff's claims in turn.

A. Count I: Strict Liability – Defective Design

Plaintiff's first cause of action alleges that alendronate is "defective in its design or formation" because it is "unreasonably dangerous" and "its foreseeable risks exceed[its] benefits . . . . " ECF No. [5-1] ¶ 84. Plaintiff further alleges that Teva knew or should have known that alendronate was defective, was aware of the foreseeable harm that alendronate could cause Plaintiff, and that Plaintiff was harmed as a proximate cause of the defective design. *Id.* ¶¶ 86, 88. Defendant moves to dismiss this claim under *Bartlett* and its progeny, arguing that the claims are preempted under federal law. ECF No. [11] at 10–11. In its Opposition to the Motion, Plaintiff does not appear to respond to Defendant's arguments based on design defect, and to the extent that her arguments regarding failure to warn can be construed as related to a design defect, as noted above, that authority is inapplicable here. *See generally* ECF No. [16].

The Court agrees that under *Mensing* and *Bartlett*, Plaintiff's claims based on design defect are preempted. To comply with its design obligations under the FDCA, Teva must manufacture alendronate such that it is identical in all material respects to the brand name drug, Fosamax. *See* 21 U.S.C. § 355(j)(2)(A). Teva may not change the design of alendronate since the basis of its FDA approval under the expedited process for generics relies on alendronate's "sameness" in design as the bioequivalent of the brand name. Under state law, however, Teva may have had a conflicting duty to change the design of alendronate given information about its risks. Because it would be impossible for Teva to both change the design and fulfill its "duty of sameness," Plaintiff's state law claims based on design defect are preempted. Accordingly, Count I is dismissed.

B. Counts II & III: Strict Liability – Failure to Warn and Negligence Based on Allegations that Defendant Failed to Deviate Alendronate's Label from the FDA Approved Brand Name Label

Count II alleges that Teva knew or should have known about the risks of alendronate, failed to warn Plaintiff of these risks associated with alendronate, and downplayed the "serious and dangerous side effects of alendronate." ECF No. [5-1] ¶¶ 92–94. In particular, Allbright alleges that Teva should have changed its warning label or notified the FDA that it should change the approved warning label based on the risks of alendronate. *See, e.g., id.* ¶¶ 12–13, 26, 35, 51–52. Plaintiff further alleges that as a proximate result of Defendant's failure to warn, Allbright developed severe and permanent injuries, including osteonecrosis of the jaw. *Id.* at ¶¶ 101–02. Teva argues that federal law expressly prohibits generic manufacturers—like Teva—from unilaterally deviating from the label approved for brand name drugs, and that its duties under federal law preempt any state law duties. ECF No. [11] at 9; *see also* ECF No. [18] at 4–5.

The Court agrees that Plaintiff's failure to warn claim based on an obligation of Defendant to deviate its alendronate label from the approved brand name label is preempted. *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1249 (11th Cir. 2013). To comply with its label obligations under the FDCA, Teva must label alendronate with the same warnings as the brand name, Fosamax. Under state law, however, Teva may have a conflicting duty to change the label based on information about the risks of alendronate. *See id.*; *see also Mensing*, 564 U.S. 604 at 618. Given that it would be impossible for Teva to both change the label and fulfill its "duty of sameness," Plaintiff's state law claims based on failure to deviate alendronate's label from the approved FDA label are preempted.

In Count III, Plaintiff alleges that Teva did not exercise due care when it failed to test alendronate before release; failed to analyze pre-market and post- market data; designed, manufactured, labeled, marketed, advertised, promoted, distributed, and sold alendronate without adequate warnings; and continued manufacturing alendronate without appropriate warning and instruction labels. ECF No. [5-1] ¶¶ 105–06. As with Count II, in support of her negligence cause of action Allbright alleges that Teva should have changed its warning label or notified the FDA that it should change the approved warning label based on the risks of alendronate. *See, e.g.*, *id.* ¶¶ 12–13, 26, 35, 51–52. Plaintiff further alleges that as a proximate result of Defendant's negligence, Allbright developed severe and permanent injuries, including osteonecrosis of the jaw. *Id.* ¶ 107. In its Motion, Defendant argues that this claim is also preempted by federal law. ECF No. [11] at 11–13. Additionally, Defendant argues that to the extent Plaintiff's negligence claim asserts that Defendant had a state law duty to test, investigate, and conduct market surveillance which may have produced evidence that could have been presented to the FDA resulting in a label change, these claims are further precluded by *Mensing*. *Id.* at 12–13.

The Court agrees that Plaintiff's negligence claims based on failure to change the labels or design of alendronate in violation of Defendant's obligations under federal law are precluded. *See Tsavaris v. Pfizer, Inc.*, 154 F. Supp. 3d 1327, 1337 (S.D. Fla. 2016), *appeal dismissed* (May 12, 2016). Similarly, Plaintiffs negligence claims based on failure to test, investigate, and conduct market surveillance fail because Plaintiff cannot avoid preemption by hypothesizing a potential scenario in which Defendant may have complied with both its federal and state obligations. *See Mensing*, 564 U.S. at 620–621.

C. Counts II & III: Strict Liability – Failure to Warn and Negligence Based on Allegations that Defendant Failed to Update Alendronate's Labels Consistent with the FDA Approved Brand Name Label

In contrast to claims based on a generic manufacturer's failure to change labels or design in violation of the its federal duties, claims regarding failure to *update* warning labels consistent with brand name labels—that is, violations of a generic manufacturer's "duty of sameness"—are not preempted by federal law. *See, e.g.*, *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 584 (6th Cir. 2013); *In re Fosamax*, 965 F. Supp. 2d 413 (S.D.N.Y 2013); *Phelps v. Wyeth, Inc.*, 938 F. Supp. 2d 1055 (D. Or. 2013); *Johnson v. Teva Pharm. USA, Inc.*, No. 2:10 CV 404, 2012 WL 1866839, at *13 (W.D. La. May 21, 2012), *aff'd*, 758 F.3d 605 (5th Cir. 2014); *Cooper v. Wyeth, Inc*., No. CIV.A. 09-929-JJB, 2012 WL 733846, at *4 (M.D.La. Mar. 6, 2012); *Couick v. Wyeth, Inc.*, No. 3:09-CV-210-RJC-DSC, 2012 WL 79670, at *5 (W.D.N.C. Jan. 11, 2012); *Del Valle v. PLIVA, Inc.*, No. CIV.A. B:11-113, 2011 WL 7168620, at *5 (S.D. Tex. Dec. 21, 2011), *report and recommendation adopted sub nom. Del Valle v. Qualitest Pharm. Inc.*, No. CIV. B-11-113, 2012 WL 2899406 (S.D. Tex. June 22, 2012), *aff'd sub nom. Lashley v. Pfizer, Inc.*, 750 F.3d 470 (5th Cir. 2014).

Plaintiff has alleged that Teva failed to timely update warning labels as required by the FDA's 2004 guidance. ECF No. [5-1] ¶ 41. In both Count II and Count III, Plaintiff alleges that Teva failed to include proper warning labels. *See id.* ¶¶ 92, 94, 105. However, Plaintiff's specific allegations regarding Teva's failure to update alendronate labels consistent with the brand name labels are sparse, at best. *See id.* ¶¶ 40–43. To the extent Plaintiff's negligence and strict liability failure to warn claims can be read as an allegation that Defendant breached its "duty of sameness" by failing to update its labels consistent with directives from the FDA, these claims are not preempted. However, Plaintiff has not provided sufficient factual matter to

withstand Defendant's Motion. Plaintiff thus will be permitted to amend to include that viable claim. Accordingly, Counts II and III are dismissed with leave to replead those counts only under a theory of liability not preempted by federal law.

IV. CONCLUSION

Accordingly, for the foregoing reasons, it is **ORDERED AND ADJUDGED** as follows:

1. Defendant's Motion, **ECF No. [11]**, is **GRANTED.**
2. **COUNT I** is preempted by federal law and **DISMISSED WITH PREJUDICE**.
3. To the extent that the claims in **COUNT II AND COUNT III** are premised on theories of liability preempted by federal law, those claims are **DISMISSED WITH PREJUDICE.**
4. To the extent that the claims in Count II and Count III are premised on theories of liability not preempted by federal law, those claims are **DISMISSED WITHOUT PREJUDICE.** Plaintiff is granted leave to replead her non-preempted claims and shall **FILE** her amended complaint by no later than **December 15, 2017**.

DONE AND ORDERED in Chambers at Miami, Florida, this 30th day of November, 2017.

BETH BLOOM
UNITED STATES DISTRICT JUDGE

Copies to:
Counsel of Record