UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

AMY TRAHAN and SHANNON TRAHAN, individually and as parents, guardians, and next friends of S.C.T. and A.M.T., and Amanda Trahan,

Plaintiffs,

vs. Case No. 3:13-cv-350-J-34MCR

SANDOZ, INC.,

Defendant,

O R D E R

THIS CAUSE is before the Court on Defendant Sandoz Inc.'s Dispositive Motion to Dismiss Plaintiffs' Amended Complaint With Prejudice for Failure to State a Claim and Incorporated Memorandum of Law (Doc. 52; Motion), filed on March 11, 2014. In the Motion, Defendant Sandoz, Inc. (Sandoz) requests the entry of an order dismissing the Amended Complaint (Doc. 50) pursuant to Rule 12(b)(6), Federal Rules of Civil Procedure (Rule(s)), for failure to state a claim upon which relief can be granted. See Motion at 1. Plaintiffs Amy Trahan and Shannon Trahan, individually and as parents, guardians, and next friends of S.C.T. and A.M.T., and Amanda Trahan filed a response in opposition to the Motion on March 25, 2014. See Plaintiffs' Memorandum in Opposition to Defendant's Motion to Dismiss Plaintiffs' Amended Complaint with Prejudice (Doc. 54; Response). Accordingly, this matter is ripe for review.

I. Standard of Review

When considering a motion to dismiss under Rule 12(b)(6), the Court must accept all factual allegations in the complaint as true, construing the allegations and drawing all reasonable inferences in the light most favorable to the plaintiff. Castro v. Sec'y of Homeland Sec., 472 F.3d 1334, 1336 (11th Cir. 2006); Hill v. White, 321 F.3d 1334, 1335 (11th Cir. 2003). Rule "8(a)(2) requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief.'" Erickson v. Pardus, 551 U.S. 89, 93 (2007). Normally, "[s]pecific facts are not necessary; the statement need only 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" Id. (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007)). However, a complaint's "[f]actual allegations must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." Twombly, 550 U.S. at 555 (internal citations and quotations omitted). As a result, a plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." Id. at 570. Of course, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). In considering a motion to dismiss, a court should "1) eliminate any allegations in the complaint that are merely legal conclusions; and 2) where there are well-pleaded factual allegations, 'assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.'" Amer. Dental Ass'n v. Cigna Corp., 605 F.3d 1283, 1290 (11th Cir. 2010) (quoting Igbal, 556 U.S. at 679)).

II. Background[1] & Summary of the Arguments

This products liability lawsuit pertains to a drug known as methotrexate. See Amended Complaint ¶¶ 12-13. Sandoz manufactures a generic version of methotrexate and packages its product in glass vials (the Methotrexate Product). Id. ¶¶ 13, 16. Among other things, methotrexate is used to treat choriocarincoma. Id. ¶ 12. Plaintiff Amy Trahan (Trahan)[2] was diagnosed with this condition on July 21, 2010, and was treated with Sandoz's Methotrexate Product on July 31, 2010. See id. ¶¶ 11-12, 17. Tragically, due to glass delamination, the methotrexate administered to Trahan contained small pieces of glass that had separated from the vials and mixed with the drug. Id. ¶¶ 17-18. Trahan alleges that as a result of the small pieces of glass in her intravenous injections of the Methotrexate Product, she suffered "serious injuries, including multiple lung collapses and several strokes." Id. ¶ 19. Notably, on October 27, 2010, Sandoz announced a voluntary recall of its Methotrexate Product "following the finding of small glass flakes" in some of the vials that "are the result of delamination of the glass used to manufacture the vials . . . ." See Response, Ex. A.[3]

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[1] In considering the Motion, the Court must accept all factual allegations in the Amended Complaint as true, consider the allegations in the light most favorable to the plaintiff, and accept all reasonable inferences that can be drawn from such allegations. Hill, 321 F.3d at 1335; Jackson v. Okaloosa Cnty., Fla., 21 F.3d 1531, 1534 (11th Cir. 1994). As such, the facts recited here are drawn from the Amended Complaint, and may well differ from those that ultimately can be proved.

[2] Because Amy Trahan is the only plaintiff alleged to have taken the Methotrexate Product, and her family members' claims for loss of consortium are therefore derivative of her own alleged injuries, all subsequent references to Trahan will refer to Amy, unless otherwise noted.

[3] The Court notes that the parties submitted several exhibits in support of, and in opposition to, the Motion to Dismiss. Motion, Exs. A-E; Response, Ex. A. These documents appear to be Federal Drug Administration (FDA) records available to the public on the FDA or National Institute of Health websites. Under appropriate circumstances, a court may take judicial notice of and consider documents attached to a motion to dismiss or response, which are public records that are "central" to a plaintiff's claims, without converting the motion to dismiss into a motion for summary judgment. See SFM Holdings, Ltd. v. Banc of Am. Sec., LLC, 600 F.3d 1334, 1337 (11th Cir. 2010). This is so, as long as such documents are "public records that [are] 'not subject to reasonable dispute' because they [are] 'capable of accurate and ready determination by resort to

Based on the foregoing, Trahan asserts claims against Sandoz for strict liability defective design and/or manufacture and negligence. See id. ¶¶ 20-38. In addition, her husband, Shannon, and three children, S.C.T., A.M.T., and Amanda, bring causes of action for loss of consortium against Sandoz. Id. ¶¶ 39-56. Sandoz argues that these claims are due to be dismissed because Trahan's strict liability design defect and negligence actions are preempted under federal law. See Motion at 2-4, 10-13. Specifically, Sandoz contends that the design and packaging of the Methotrexate Product must remain identical to the brand-name equivalent. Id. at 6, 18-19. In addition, Sandoz maintains that it could not change the packaging of the Product from glass vials without FDA approval. Id. at 19-20. Because of these restrictions, Sandoz argues that it was impossible for Sandoz to comply with both its obligations under federal law, and any purported state law duty to design a safer product. Id. at 10-12, 20. Thus, Sandoz asserts that Trahan's design defect claims are barred by impossibility preemption. Id. at 20. With respect to Trahan's contention that Sandoz breached its duty to adequately test, inspect or conduct post-distribution testing on its Methotrexate Product, Sandoz asserts that such claims are also preempted because they are actually components of an improper failure to warn claim, id. at 14-15, and further, they "would infringe upon the federal government's exclusive enforcement authority." Id. at 15-16. Sandoz next argues that, to the extent Trahan's claims are premised on a purported manufacturing defect, Trahan fails to sufficiently allege any manufacturing defects separate

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sources whose accuracy [can] not reasonably be questioned.'" Horne v. Potter, 392 F. App'x 800, 802 (11th Cir. 2010) (quoting Fed. R. Evid. 201(b)). Upon review, the Court determines that the parties' exhibits satisfy the foregoing requirements and therefore, the Court will take judicial notice of the documents. Stanifer v. Corin USA Ltd., Inc., No. 6:14-cv-1192-Orl-37DAB, 2014 WL 5823319, at *3 (M.D. Fla. Nov. 10, 2014) ("Courts in this District and elsewhere regularly take judicial notice of public records available on the FDA's website because such document[s] satisfy the requirements of Rule 201.") (collecting cases).

from the preempted design defect claims. Id. at 20-22. Last, Sandoz asserts that the loss of consortium claims are derivative of Trahan's strict liability and negligence claims, and therefore, these claims must fail as well. Id. at 22.

In her Response, Trahan contends that, unlike the requirements for warning labels and drug composition, the law does not mandate that the container for a generic drug be exactly the same as that for the brand-name drug. See Response at 2-4. In addition, Trahan maintains that federal regulations do not require Sandoz to obtain FDA approval before changing the type of container used to package generic methotrexate. Id. at 6-13. As such, Trahan argues that it was not impossible for Sandoz to make a safer Methotrexate Product, the cases on which Sandoz relies are distinguishable, and her claims are not preempted. Trahan also asserts that her claims are not an attempt to enforce federal law, but rather, the violations of federal law are simply evidence of Sandoz's liability. Id. at 13. Last, Trahan responds that her defective manufacturing claim is sufficiently pled because Florida law does not require a plaintiff to choose between a manufacturing or a design defect in a complaint, nor does it require her "to identify and allege the precise defect in the manufacturing process." Id. at 15-17.

III. Discussion

A. Impossibility Preemption

The Supremacy Clause of the United States Constitution provides 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. "In accordance with that principle, when state law conflicts with federal law, state law must give

way." Guarino v. Wyeth, LLC, 719 F.3d 1245, 1248 (11th Cir. 2013). This type of preemption, known as "conflict preemption," applies where "'(1) compliance with both federal and state regulations is a physical impossibility, or (2) the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" Id. (quoting Fresenius Med. Care Holdings, Inc. v. Tucker, 704 F.3d 935, 939 (11th Cir. 2013)). In recent years, the Supreme Court has issued several decisions discussing conflict preemption and the intersection of state law products liability cases against drug manufacturers and the requirements of the federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq. See Mut. Pharm. Co., Inc. v. Bartlett, 133 S. Ct. 2466, 2470 (2013) (finding that state-law design-defect claims "that turn on the adequacy of a drug's warnings," brought against manufacturer of generic prescription drug, are preempted by federal law); PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2572 (2011) (holding that "federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus pre-empt," state tort-law claims based on failure to provide adequate warning labels); Wyeth v. Levine, 129 S. Ct. 1187 (2009) (ruling that the FDA's approval of brand-name drug's warning label do not provide manufacturer with complete defense to state-law tort claim); Buckman Co. v. Plaintiffs' Legal Comm., 121 S. Ct. 1012, 1015 (2001) (finding conflict preemption where state law claim was premised on a fraudulent statements made to the FDA). Here, the Court is asked to determine whether federal law preempts state-law tort claims against the manufacturer of a generic prescription drug based on a purported design and/or manufacturing defect in the packaging for the drug.

Sandoz relies on the Supreme Court's decisions in Bartlett and Mensing to argue that Trahan's design defect claims are barred due to impossibility preemption. In Mensing, the Supreme Court considered a failure-to-warn claim against a manufacturer of generic metoclopramide. See Mensing, 131 S. Ct. at 2572. The Court explained that, pursuant to the FDCA, a "brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label," whereas a manufacturer seeking approval for a generic drug "is responsible for ensuring that its warning label is the same as the brand name's." Id. at 2574 (citing 21 U.S.C. §§ 355(b), (j)). As such, federal law imposes on generic drug manufacturers "an ongoing federal duty of 'sameness.'" Id. at 2575. In Mensing, if plaintiffs' failure to warn allegations were true, then state law imposed a duty to attach a safer label to the product, and federal law demanded that the label remain the same as the corresponding brand-name drug label. Id. at 2577. Because of these conflicting requirements, the Supreme Court held that "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 2578. The Mensing Court acknowledged that while it was "possible" that the manufacturer could have asked the FDA for help, and "possible" the FDA might have eventually let the manufacturer change the label, for preemption purposes, "[t]he question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." Id. at 2579. "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy

those state duties for pre-emption purposes." Id. at 2580-81. As such, the Supreme Court found that the failure-to-warn claim was preempted. Id. at 2581.

The Supreme Court revisited this issue in Bartlett. The Bartlett case concerned failure-to-warn and design defect claims against the manufacturer of a generic drug called sulindac. Bartlett, 133 S. Ct. at 2470. As in Mensing, the Supreme Court held that these claims were barred by impossibility preemption. Id. The Bartlett Court explained that, to obtain FDA approval, the manufacturer of a new brand-name drug must go through the "onerous and lengthy" process of submitting a new-drug application (NDA) establishing that the new drug is safe for use. Id. at 2470-71. In contrast, "a generic drug may be approved without the same level of clinical testing required for approval of a new brand-name drug, provided the generic drug is identical to the already-approved brand-name drug in several key respects." Id. at 2471. The Court explained that a proposed generic drug must be "chemically equivalent" to the approved brand-name drug, meaning it has the same active ingredient(s), route of administration, dosage form, and strength as the brand-name drug. Id. The generic drug must also be "bioequivalent" to an approved brand-name drug, meaning it has the same "rate and extent of absorption," and it must utilize the same labeling approved for the brand-name drug. Id. Once a brand-name or generic drug is approved, "the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" Id. (quoting 21 C.F.R. § 314.70(b)(2)(i)).

The Bartlett Court explained that, under the facts of that case, for the manufacturer of generic sulindac to comply with its state law duty not to sell an "unreasonably dangerous"

product, it would have to change either the drug's design, or its labeling. Id. at 2474. Redesign was not possible, however, because "the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based," such that the manufacturer could not legally make sulindac in another composition. Id. at 2475. Moreover, due to its simple composition, sulindac "is chemically incapable of being redesigned." Id. As such, the only way the manufacturer could have complied with its state law duty to make the product safer was to strengthen the warning label of the drug. Id. As discussed in Mensing, this option was foreclosed to the generic drug manufacturer because of its federal duty to keep the label the same as the brand-name manufacturer. Id. at 2476-77. Although the circuit court reasoned that the manufacturer could "escape the impossibility of complying with both its federal- and state-law duties" by simply removing the drug from the market, the Supreme Court rejected this "stop selling rationale." Id. at 2477. In doing so, the Court explained that "if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.'" Id. at 2477.

Sandoz argues that, for the reasons discussed in Bartlett and Mensing, it is prohibited under federal law from altering the design of its Methotrexate Product. Trahan concedes that Sandoz cannot legally alter the chemical composition of methotrexate, but maintains that her claims are premised not on the design of the drug itself, but on Sandoz's decision to use "substandard glass vials" to package the methotrexate. See Response at 4. Critically, the parties disagree on whether generic drug manufacturers are required to use exactly the same container for their generic drugs as is used to package the brand-name drug. Id. at

4; Motion at 6. Sandoz argues that it was required to match its packaging to the brand-name product, and presents evidence that the brand-name version of methotrexate was also packaged in glass vials. See Motion at 6, Ex. D. Notably, the information Sandoz provides does not indicate whether the glass vials used by the brand-name manufacturer were of the same composition and quality as the vials used for Sandoz's Methotrexate Product. Moreover, Sandoz does not cite to any statute or regulation that requires identical packaging between generic and brand-name drugs. See Motion at 6; see also Bartlett, 133 S. Ct. at 2471 (summarizing requirements for the approval of a generic drug). Instead, Sandoz submits the FDA's response to an unrelated citizen petition, see Motion, Ex. A (Petition Response), as evidence that the FDA interprets its regulations to require a generic drug applicant "to match its proposed packaging for a parenteral medication to glass vials if that is what the [brand-name manufacturer] utilizes, even if glass ampules were previously utilized." Id. at 6.

On the present record, the Court is not persuaded that it was impossible for Sandoz to use a safer container. First, Sandoz's reliance on the Petition Response is misplaced. Upon careful review, it appears that the FDA denied the generic drug application due to differences in the formulation of the drug, not differences in the container. See Petition Response at 2-3. The FDA wrote that the brand-name drug was originally "aseptically formulated in ampules," but that Genzyme, the manufacturer, had since obtained FDA approval for "a new formulation which is a terminally sterilized drug product in amber glass, stoppered vials." See Petition Response at 2. It explains that this "new formulation was developed to produce a formulation that could be terminally sterilized rather than aseptically

processed . . . ." Id. at 2 n.3. In contrast, the generic drug manufacturer sought approval of a generic version of the drug with a "formulation aseptically processed in ampules . . . ." Id. at 2. The FDA found that the application could not be approved because "the ampule formulation was not qualitatively and quantitatively (Q1/Q2) the same as Genzyme's reformulated [brand-name drug] in vials, and recommends that [the manufacturer] reformulate its test product to be Q1/Q2 the same as Genzyme's reformulated [brand-name] product . . . ." Id. (emphasis added). The FDA then cites to a regulation that requires the generic drug product to "contain the same inactive ingredients and in the same concentration as the [brand-name drug] . . . ." Id., Ex. A at 3 n.6. Although the FDA refers to the two different formulations as the vial formulation and the ampule formulation, it appears that the difference of concern to the FDA was not the packaging used but the reformulated product. The FDA does not instruct the manufacturer to package its generic product in an identical vial, but instead advises that it "reformulate" the product to be quantitatively and qualitatively the same as the brand-name drug, with a citation to the regulation requiring generic drugs to have the same inactive ingredients in the same concentration. Although it is possible that the container variation was problematic, the FDA did not explicitly identify that difference as an issue and its explanation suggests that the problem was the variation in the drug formulas.

However, even if the FDA does require Sandoz to use the same type of container as the brand-name product, the Court has no evidence to suggest that Sandoz used glass vials that were identical or equivalent to the glass vials of the brand-name drug. Indeed, as there is no suggestion that the brand-name version of methotrexate also suffered from glass

delamination, it is at least plausible that the two manufacturers used different types of glass vials. Accepting the allegations in the Amended Complaint as true, to the extent Sandoz used low quality or defective glass vials which were more susceptible to delamination, Sandoz has not shown as a matter of law that it was impossible for it to use a different, non-defective glass vial. Significantly, "[i]mpossibility pre-emption is a demanding defense," see Wyeth, 555 U.S. at 573, and in the absence of "clear evidence" that it was impossible for Sandoz to implement a safer packaging option for its Methotrexate Product, the Court is not convinced that impossibility preemption applies here. See Mensing, 131 S. Ct. at 2581 n.8.

Sandoz also cites to an FDA regulation, 21 C.F.R. § 314.70(b)(2)(vi), arguing that, after obtaining FDA approval to market its Methotrexate Product, it could not change the drug container without FDA approval. See Motion at 19-20. Section 314.70 governs changes to an approved drug application and divides such requests into major changes, which require prior approval, moderate changes, which require prior notice, and minor changes, which need only be described in an annual report. See 21 C.F.R. § 314.70(b)-(d). A major change, requiring FDA approval prior to distribution, includes:

> any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug products as these factors may relate to the safety or effectiveness of the drug product.

21 C.F.R. § 314.70(b)(1). Trahan argues that an improved glass vial would not have "an adverse effect" on the "safety or effectiveness of the drug product," and therefore, does not

require prior approval. However, the regulation specifically defines "major changes" to include:

> [c]hanges in a drug product container closure system that controls the drug product delivered to a patient or changes in the type (e.g., glass to high density polyethylene (HDPE), HDPE to polyvinyl chloride, vial to syringe) or composition (e.g., one HDPE resin to another HPDE resin) of a packaging component that may affect the impurity profile of the drug product.

See 21 C.F.R. § 314.70(b)(2)(vi). As such, Sandoz is correct that, at this time, it can only change the glass vial to a different type or quality if the FDA gives Sandoz prior approval to make the change.[4]

However, because there is no basis to find that Sandoz was required under federal law to choose the purportedly substandard glass vial in the first place, the fact that Sandoz could not later change the vial without FDA approval does not establish impossibility preemption. Sandoz is likely correct that, after the initial approval of the Methotrexate Product, changing the packaging container would have been a "major change" that it could not undertake unilaterally. Moreover, the Court acknowledges that the need to obtain "the Federal Government's special permission and assistance, which is dependent on the

[4] Trahan argues that the improved packaging she proposes is not encompassed by this provision because it would not have an "adverse effect" on the safety or effectiveness of the drug product. See Response at 6-8. Presumably, most changes that a manufacturer seeks to make are ones that it believes will not have an adverse effect on the safety or effectiveness of the drug product. The question is not whether the change will have that effect, but whether it has "a substantial potential" to do so. See 21 C.F.R. § 314.70(b)(1). The FDA specifically enumerates a change to the type or composition of the drug product packaging as precisely the type of alteration that has a "substantial potential" to have an "adverse effect" on drug safety. Id. § 314.70(b)(2)(vi). If a manufacturer's belief that its change to the type or composition of its packaging will not have an adverse effect could relieve it of the requirement for obtaining preapproval, the regulation would be meaningless. Indeed, subsection (c) describes moderate changes, which do not require preapproval, to include "[a] change in the container closure system that does not affect the quality of the drug product, except those described in paragraphs (b) and (d) of this section . . . ." See 21 C.F.R. § 314.70(c)(2)(I) (emphasis added). As such, even changes that do not affect the quality of the drug product, but are nonetheless changes to the type or composition of the packaging, require preapproval.

exercise of judgment by a federal agency," demonstrates that changing the container was impossible for preemption purposes. See Mensing, 131 S. Ct. at 2579, 2580-81. However, this argument would mandate preemption only if Sandoz's alleged breach of duty was solely in failing to redesign its Methotrexate Product after FDA approval. See Estate of Cassel v. Alza Corp., No. 12-cv-771-WMC, 2014 WL 856023, at *5 (W.D. Wis. Mar. 5, 2014); see also Frazier v. Mylan Inc., 911 F. Supp. 2d 1285, 1294-95 (N.D. Ga. 2012). Indeed, the Bartlett case on which Sandoz relies addresses whether the generic manufacturer could redesign sulindac to comply with its state law duties, having explained that to obtain FDA approval for generic sulindac in the first place, the law required the manufacturer to utilize an identical drug composition. See Bartlett, 133 S. Ct. at 2471, 2474-75.[5] Here, in her Amended

[5] It appears that some courts have relied on Bartlett to find preemption in design defect cases against brand-name manufacturers because the manufacturer could not redesign the drug without FDA approval. Those cases do not address whether the brand-name manufacturer was required to use the allegedly defective design in the first place. See Yates v. Ortho-McNeil Pharm., Inc., No. 3:09 oe 40023, 2015 WL 66423, at *5-6 (N.D. Ohio Jan. 5, 2015) (citing Amos v. Biogen Idec Inc., 28 F. Supp. 3d 164, 169 (W.D.N.Y. 2014)); Booker v. Johnson & Johnson, No. 3:12 oe 40000, 2014 WL 5113305, at *4-5 (N.D. Ohio Oct. 10, 2014); see also Thompson v. Allergan USA, Inc., 993 F. Supp. 2d 1007 (E.D. Mo. Jan. 28, 2014). It follows from the reasoning in these cases that once a drug has received FDA approval, it is shielded from any future liability because the drug cannot later be altered without FDA permission. If this is the correct interpretation of Bartlett, then it appears virtually all design defect cases against generic and brand-name prescription drug manufacturers alike would be preempted. See Estate of Cassel, 2014 WL 856023, at *5; see also Hunt v. McNeil Consumer Healthcare, 6 F. Supp. 3d 694, 703 & n.8 (E.D. La. 2014) (acknowledging the debate on the scope of Bartlett and noting that if the broader interpretation is correct "it would effectively foreclose all design-defect claims, since manufacturers are prohibited from unilaterally altering a drug's composition"). In support of this broader interpretation, courts cite the statement in Bartlett that "[o]nce a drug–whether a generic or brand-name–is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" See Bartlett, 133 S. Ct. at 2476-77. The Bartlett Court went on to hold that "state-law design-defect claims . . . that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling." Id. at 2479. However, in the next sentence, the Bartlett Court reaffirms that "federal law establishes no safe-harbor for drug companies– but it does prevent them from taking certain remedial measures." Id. (emphasis added). Indeed, the Supreme Court previously recognized that Congress's failure to enact an express preemption provision in the 70-year history of the FDCA, "coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." See Wyeth, 555 U.S. at 574-75. The Wyeth Court further explained that "[s]tate tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that

Complaint Trahan arguably states a claim that Sandoz breached its duty to design a reasonably safe product when it initially selected the defective glass, prior to FDA approval. Complying with its state law duty of care at that time was not "impossible" in the absence of any federal law requiring Sandoz to utilize the allegedly defective glass container. See Estate of Cassel, 2014 WL 856023, at *5; see also Wimbush v. Wyeth, 619 F.3d 632, 643-46 (6th Cir. 2010) ("[W]e can discern no physical impossibility between complying with a state law duty to exercise reasonable care in the process leading up to placing a drug on the market and complying with the federal government's process for approving drugs."). For the reasons discussed above, on this record, it appears Sandoz could have used a non-defective container for its Methotrexate Product. Accordingly, "in the absence of clear evidence that [Sandoz] could not have accomplished what state law required of it," the Court will deny Sandoz's request for dismissal of Trahan's design and manufacturing defect claims based on impossibility preemption. Mensing, 131 Ct. at 2581 n. 8.

B. Failure to Test

Trahan also alleges that Sandoz negligently failed to conduct adequate inspections, tests, and/or post-distribution tests for the possibility of delamination in its Methotrexate Product. See Amended Complaint at 7. Sandoz argues that these failure to test claims are merely components of a failure-to-warn claim and are therefore preempted under Mensing and Bartlett. See Motion at 14. Indeed, in some instances failure to test and inspect

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may motivate injured persons to come forward with information." Id. at 579. As such, this Court does not interpret the Bartlett decision to change course and foreclose all design defect claims against prescription drug manufacturers in the absence of an express statement that it was doing so. To the contrary, because the Bartlett Court stated its express understanding that it was not providing a safe-harbor for drug companies, the Court declines to interpret Bartlett in such a way as to preempt Trahan's claims on the current limited record.

allegations are used to support a larger failure to warn cause of action, and therefore, in cases against generic drug manufacturers, claims premised on those allegations are preempted. See, e.g., Drager v. PLIVA USA, 741 F.3d 470, 476-77 (4th Cir. 2014); Phelps v. Wyeth, Inc., 857 F. Supp. 2d 1114, 1126 (D. Or. 2012) ("[P]laintiffs' failure to conduct post-marketing activities and failure-to-test claims cannot be stand-alone causes of action. Rather, they are a part of the failure to warn claim."); Metz v. Wyeth, LLC, No. 8:10-CV-2658-T-27AEP, 2011 WL 5024448, at *1 n.1 (M.D. Fla. Oct. 20, 2011) ("[T]he conduct complained of is [the manufacturer's] failure to warn-including the cause of such failure (e.g., lack of testing) and the manner by which [the manufacturer] failed to warn consumers and physicians.")). Trahan responds that "none of [her] claims are based on inadequate warnings." See Response at 4. Rather, Trahan argues that Sandoz breached its duty to Trahan because its "post-distribution testing and inspections were insufficient to detect glass delamination when it occurred and then to get the defective Methotrexate Product off the market immediately." Id. at 5-6.

Under Florida negligence law, "a manufacturer has a duty to exercise reasonable care so that its products will be reasonably safe for use in a foreseeable manner . . . ." Pulte Home Corp., Inc. v. Ply Gem Indus., Inc., 804 F. Supp. 1471, 1486 (M.D. Fla. 1992). "[A] manufacturer's duty to use reasonable care includes making reasonable tests to discover latent hazards," although "the law does not require him to make tests that are not practical or economically feasible in relation to the risk." See Barfield v. Atl. Coast Line R.R. Co., 197 So. 2d 545, 547 (Fla. 2d Dist. Ct. App. 1967). However, "[t]he duty to test . . . is a subpart of a manufacturer's duty to design a product with reasonable care, and thus is subsumed in

[a plaintiff's] claims for defective design and failure to warn." See Adams v. G.D. Searle & Co., Inc., 576 So. 2d 728, 730-31 (Fla. 2d Dist. Ct. App. 1991) (citing Kociemba v. G.D. Searle & Co., 707 F. Supp. 1517, 1528 (D. Minn. 1989) ("The duty to test is subpart of duties to design a product non-negligently, manufacture a product non-negligently, and provide adequate warnings of dangers associated with its use.")); see also Hall v. Sunjoy Indus. Grp., Inc., 764 F. Supp. 2d 1297, 1302 (M.D. Fla. 2011).

Here, Trahan does not set forth a separate cause of action for failure to test or inspect the Methotrexate Product. Rather, she includes these allegations in her negligence claim to support her contention that Sandoz failed to exercise reasonable care in the design, manufacture, sale, supply and/or distribution of its Methotrexate Product.[6] See Amended Complaint at 7. Significantly, in this case, Trahan does not assert a failure-to-warn claim, and thus, the alleged inadequate testing and inspection allegations are not pled as the basis of a negligent failure-to-warn claim. Unlike the cases cited by Sandoz, Trahan does not rely on the inadequate testing or inspection of the Methotrexate Product to argue or imply that Sandoz should have used that information to provide different or additional information to consumers, the medical community, or the FDA. See Metz v. Wyeth, LLC, 872 F. Supp. 2d 1335, 1340 (M.D. Fla. 2012). Rather, Trahan contends that the inadequate testing demonstrates negligence because Sandoz should have detected the defective condition of the glass vials, removed the defective product from the marketplace, and used a different

[6] Trahan also alleged a duty to exercise reasonable care in the marketing and promotion of the Methotrexate Product. See Amended Complaint ¶ 32. However, in her Response, Trahan disavows any attempt to assert a failure to warn claim and states in her response that "to the extent that these words are construed as warnings, [Trahan] agree[s] to strike those words from the Amended Complaint." See Response at 6. Accordingly, the Court disregards any references to marketing, promotion, or a failure to warn in the Amended Complaint.

container. As such, her contention that Sandoz failed to adequately test or inspect the Methotrexate Product is a subset of her negligent design and manufacturing claims, not a "disguised" failure to warn claim. Because the Court has determined that Trahan's defective design and manufacturing claims are not otherwise preempted, Trahan may rely on a failure to test or inspect in support of those claims.

Sandoz also argues that the claims premised on a failure to test or inspect are "impliedly preempted to the extent [Trahan] intended to allege [that] Sandoz failed to comply with federal regulations or statutes in the testing or inspection of methotrexate, or failed to recall methotrexate earlier." See Motion at 15. Sandoz contends that such allegations are "attempts to privately enforce the FDCA or regulations promulgated thereunder" and are preempted because they "interfere with FDA's exclusive authority to enforce the FDCA pursuant to 21 U.S.C. § 337(a)." Id. Trahan responds that she is not attempting to privately enforce FDA rules and regulations, and maintains that she "will use [Sandoz's] potential violation of federal law (e.g., 21 C.F.R. § 211.94) as evidence of [Sandoz's] liability." See Response at 13. In Buckman, the Supreme Court held that a claim premised on "fraud on the FDA" was preempted because it conflicted with "the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." See Buckman, 531 U.S. at 350. The plaintiffs in Buckman were injured from the use of a medical device and sought damages from a regulatory consultant who purportedly made misrepresentations to the FDA in gaining approval of the device. Id. at 343. Plaintiffs' theory was that if the misrepresentations had not been made, the FDA would not have approved the device, and they would not have been injured. Id. Because this "fraud on the FDA" claim did not rely on

traditional tort law, and existed "solely by virtue of the FDCA disclosure requirements," the Court found preemption. Id. at 353. Notably, the Buckman Court distinguished the claims before it from those asserted in Medtronic because "it is clear that the Medtronic claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements." Id. at 352. Here, none of Trahan's claims rely solely on a violation of a federal statute or regulation. See generally Amended Complaint. As set forth above, Trahan alleges that Sandoz breached its duty of care under Florida law when it failed to conduct reasonable tests or inspections of the Methotrexate Product to ensure that the product was reasonably safe to use. The possibility that this alleged failure to exercise due care may also violate provisions of federal law, a possibility raised by Sandoz but not alleged in the Amended Complaint, does not preclude Trahan's claim. See Lefaivre v. KV Pharm. Co., 636 F.3d 935, 944 (8th Cir. 2011) (finding state law claims were not preempted by Buckman and explaining that "simply because conduct violates the FDCA does not mean a state-law claim based on that same conduct depends on the FDCA's existence." (internal quotation omitted)); Cooper v. Wyeth, No. 09-929-JJB, 2012 WL 733846, at *5 (M.D. La. Mar. 6, 2012); see also Wimbush, 619 F.3d at 644 ("Simply because tort liability 'parallel[s] federal safety requirements' does not mean that liability is preempted."). Accordingly, Sandoz's conflict preemption argument is unavailing.[7]

[7] Whether Trahan may use evidence that Sandoz violated federal standards in failing to test, inspect or recall the Methotrexate Product to support her negligence claims is not a question currently before the Court at this motion to dismiss stage in the proceedings. See In re Mentor Obtape Transobturator Sling Prods. Liab. Litig., No. MDL Docket No. 2004, 2010 WL 1734638, at *1 (M.D. Ga. Apr. 23, 2010) (collecting cases where courts have "found regulatory compliance evidence probative of state law product liability claims").

C. Manufacturing Defect

Finally, Sandoz attacks Trahan's manufacturing defect claim as insufficiently pled to satisfy the Rule 8 requirements. See Motion at 20. According to Sandoz, "to state a manufacturing defect claim capable of withstanding a motion to dismiss, plaintiffs must plead that the methotrexate Amy Trahan allegedly took deviated from specifications or an identifiable error in the manufacturing process rendered the specific methotrexate allegedly administered to her unsafe." Id. at 21. However, upon review, Sandoz's arguments are without merit.

Here, Trahan specifically alleges that the Methotrexate Product administered to her was defective because it contained glass fragments. Trahan contends that the glass fragments were present in the drug because the glass of the vials used to package the drug had delaminated. In light of these specific factual allegations as to the flaw in the Methotrexate Product, Sandoz's contention that the Amended Complaint is "devoid of factual allegations suggesting a 'flaw where the defect lies in an alleged departure from a correctly designed product'" is not well-taken. See Motion at 21 (citing Husky Indus., Inc. v. Black, 434 S. 2d 988, 991 n.4 (Fla. 4th Dist. Ct. App. 1983)).[8] It is certainly reasonable to infer that

[8] The Court notes that the cases on which Sandoz relies are distinguishable because in those cases there were no allegations to suggest that the plaintiffs' injuries were caused by anything other than the dangerous side effects of the drug administered. As such, the claims were essentially that the manufacturer should have formulated a safer drug or issued stronger warnings, and the courts rejected the merely formulaic references to unidentified manufacturing defects. See In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II), MDL No. 2243.008 (GEB-LHG), 2011 WL 5903623, at *5 (D.N.J. Nov. 21, 2011) ("Plaintiffs provide no sort of factual allegations supporting [the manufacturing defect] cause of action. In fact, the complaints are dedicated to alleging that alendronate sodium labeling and formulation (i.e., the design), not the manufacturing, are defective and dangerous."); In re Accutane Prods. Liab., MDL No. 1626, 2012 WL 3194952, at *1, 3 (M.D. Fla. Aug. 7, 2012) (seeking damages for side effects resulting from the ingestion of isotretinoin); Metz, 872 F. Supp. 2d at 1337-38, 1340 n.4 (alleging injuries from the side effects of metoclopramide); Lyman v. Pfizer, Inc., No. 2:09-cv-262, 2012 WL 368675, at *1, 4 n.4 (D. Vt. Feb. 3, 2012) (same); Cooper, 2012 WL 733846, at *1, (continued...)

the presence of glass flakes in the methotrexate is a departure from the intended design of the product. Moreover, at this stage in the proceedings, Trahan need not specifically allege whether the delamination was the result of a design or manufacturing defect in the vials. See Brandt v. Depuy Orthopaedics, Inc., No. 6:10-cv-306-Orl-19KRS, 2010 WL 2612037, at *3 (M.D. Fla. June 28, 2010) ("Florida law does not require that a plaintiff specifically set out the type of defect (design, manufacturing, or failure to warn) at the pleadings state."); see also McConnell v. Union Carbide Corp., 937 So. 2d 148, 152 (Fla. 4th Dist. Ct. App. 2006). Indeed, "[i]t is difficult for a plaintiff at this stage in the litigation to know the source of the defect that was responsible for the harm caused: whether there was a surprising manufacturing problem, [or] a systemic issue with a product in its design . . . .'" Bailey v. Janssen Pharmaceutica, Inc., 288 F. App'x 597, 605-06 (11th Cir. 2008). Drawing all reasonable inferences in the light most favorable to Trahan, it is plausible that the delamination was an unanticipated result from the design of the glass vials, or the product of a manufacturing anomaly that rendered the glass unusually susceptible to delamination. As such, the Court finds that in the Amended Complaint Trahan adequately states a claim for manufacturing defect and will deny the Motion to Dismiss on this basis as well. Because the Court will not dismiss Trahan's primary claims, Sandoz's request that the Court dismiss the derivative loss of consortium claims brought by her husband and children is also due to be denied. In light of the foregoing, it is

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[8](...continued)
9 (same); In re Pamidronate Prods. Liab. Litig., 842 F. Supp. 2d 479, 482 (E.D.N.Y. Jan. 30, 2012) (alleging the use of pamidronate caused osteonecrosis of the jaw).

ORDERED:

1. Defendant Sandoz Inc.'s Dispositive Motion to Dismiss Plaintiffs' Amended Complaint With Prejudice for Failure to State a Claim and Incorporated Memorandum of Law (Doc. 52) is **DENIED**.

2. The parties are directed to complete a case management conference and file an amended case management report no later than **April 27, 2015**.

DONE AND ORDERED in Jacksonville, Florida, this 26thday of March, 2015.

MARCIA MORALES HOWARD
United States District Judge

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Copies to:

Counsel of Record