NOT FOR PUBLICATION

IN RE: FOSAMAX (ALENDRONATE SODIUM) PRODUCTS LIABILITY LITIGATION (NO. II)	:	MDL No. 2243 Civ. No. 08-008 (GEB-LHG)
RELATES TO ALL ACTIONS	:	**MEMORANDUM OPINION**

BROWN, Chief Judge

This matter comes before the Court upon Defendants' Teva Pharmaceuticals USA, Inc., Barr Pharmaceuticals, LLC, Barr Laboratories, Inc., Mylan, Inc., Mylan Pharmaceuticals, Inc., and Apotex Corporation (collectively the "Generic Defendants"), and Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Watson Pharmaceuticals Inc. on behalf of and formally known as Cobalt Pharmaceuticals Company and Sun Pharmaceuticals (collectively "Watson Defendants") Motion for Judgment on the Pleadings. (Doc. No. 251.) Plaintiffs oppose the motion. (Doc. No. 296.) The Court has considered the parties' submissions and decided the matter without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons set forth on the record during the Court's November 14, 2011 conference and as set forth below, the Court grants in part and denies in part the motion.

I. BACKGROUND

The following facts are taken as true for purposes of deciding the instant motion. Plaintiffs in this case were prescribed Fosamax and its generic equivalent alendronate sodium, an oral medication for the treatment of osteoporosis and Paget's disease. The United States Food and Drug Administration ("FDA") approved Merck & Co. Inc.'s ("Merck") new drug application ("NDA") for Fosamax in September 1995. (Murphy Compl. ¶ 32.) Teva Pharmaceuticals

developed the generic form alendronate sodium, and FDA approved its abbreviated new drug application ("ANDA") on February 6, 2008. (*Id.* at ¶ 33.) In the following years, each of the Generic Defendants received approval for and/or marketed alendronate sodium.[1]

Alendronate sodium is in a class of drugs known as bisphosphonates, which are indicated for several conditions including the treatment and prevention of osteoporosis in post-menopausal woman, treatment of increased bone mass in men, treatment of glucocorticoid-induced osteoporosis in men and women, and treatment of Paget's disease in men and women. (*Id.* at ¶¶ 35-36.) In patients with osteoporosis, the loss of live bone tissue causes the bones to become brittle, fragile, and therefore susceptible to fracture. (*Id.* at ¶ 37.) Osteoporosis can occur due to a decrease in vitamin D and estrogen, a reason why post-menopausal women are at an increased risk to develop the condition. (*Id.*)

With respect to estrogen-deprived patients specifically, there may be an increase in the number of osteoclasts, which are a type of bone cell that remove the mineralized matrix of the bone. (*Id.* at ¶ 38.) In healthy patients, another type of bone cell called an osteoblast balances osteoclast activity by building up bone tissue. (*Id.*) Alendronate sodium binds tightly to bone tissue, working to decrease the number of osteoclasts and thereby lessen bone breakdown. Consequently, the drug also increases bone mineralization. (*Id.* at ¶ 41.)

Plaintiffs claim that the result of decreased osteoclast activity is a compromised blood supply to the affected area, causing bone death or "osteonecrosis." (*Id.* at ¶ 45.) There are two frequent locations in which Plaintiffs maintain that osteonecrosis may develop. (*Id.* at ¶ 47.)

[1] Plaintiffs allege that Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. are not generic manufacturers. Watson counters that it has only sold generic Fosamax and asks the Court to take judicial notice of the "Approved Drug Products with Therapeutic Equivalence Evaluations," listing Watson as a generic manufacturer. However, as the Court stated during its November 14, 2011 ruling, the Court must take Plaintiffs' allegations as true. It would be inappropriate under the standard of Fed. R. Civ. P. 12(c) to make a factual determination otherwise. Consequently, the Court's reasoning and conclusions in this opinion as to the Generic Defendants are exclusive of the Watson Defendants.

The first is the jaw. (*Id.* at ¶ 45.) A minor injury or disease in the jaw may turn into a non-healing wound because the bones making up the jaw are unable to mend properly. (*Id.* ¶ at 51.) FDA has received numerous reports of osteonecrosis of the jaw among users of alendronate sodium and recommended in January 2005 that Merck amend the labeling for Fosamax to warn of this risk. (*Id.* at ¶¶ 56, 58-60.) In July of 2005, Merck changed the Fosamax "precautions" section of the label to include reference to the reports of osteonecrosis of the jaw associated with a number of activities, including taking Fosamax. (*Id.* at ¶¶ 60, 62.) Plaintiffs point out that the "warning" section of the Fosamax label was not changed and they charge Merck with failing to affirmatively warn patients of the increased risk of osteonecrosis of the jaw associated with Fosamax use.[2] (*Id.* at ¶ 61.)

The second location for osteonecrosis is in the femur. (*Id.* at ¶ 69.) Three studies published in 2005, 2009, and early 2010 found and expressed concern regarding non-spinal fractures, including in the subtrochanteric area of the femur (just below the hip), in patients on long-term alendronate therapy. (*Id.* at ¶¶ 70,-72.) FDA issued a Safety Announcement on March 10, 2010 concerning potential adverse side effects associated with Fosamax. (*Id.* at ¶ 73.) But FDA concluded in this announcement that it did not believe there was enough data to support a clear causal link between bisphosphonates use and femur fractures. (*Id.* at ¶ 75.) It did, however, state that it was working with the American Society of Bone and Mineral Research Subtrochanteric Femoral Fracture Task Force to gather information on the issue. (*Id.* at ¶ 76.) The Task Force issued its report in September 2010, finding evidence of a relationship between long-term bisphosphonate use and femoral fractures. (*Id.* at ¶ 77.) But the report stopped short of concluding that there was a causal association. (*Id.*)

[2] The harm associated with osteonecrosis of the jaw in patients who were prescribed Fosamax is currently the subject of another MDL in U.S. District Court for the Southern District of New York—*Boles v. Merck & Co.*, Case No. 06-9455.

Nonetheless, FDA issued another Safety Announcement on October 13, 2010 with regard to bisphosphonates, including Fosamax. (*Id.* at ¶ 78.) FDA announced that information about the risk of fractures in patients who take bisphosphonates for osteoporosis would be included in the "indications and usage" section of the labeling and in Medication Guides. (*Id.* at ¶ 79.) The most-recent Fosamax label "warning" section, amended on January 25, 2011, contains no information about the risk, but the "precautions" section reports that "[a]typical, low-energy, or low trauma factures of the femoral shaft have been reported in bisphosphonates-treated patients," but that "[c]ausality has not been established." (*Id.* at ¶¶ 80-83.)

On February 23, 2011, less than two months after Merck updated the Fosomax label, the Journal of the American Medical Association published a study, finding that, among older women, bisphosphonate treatment for longer than 5 years was associated with an increased risk of subtrochanteric or femoral shaft factures. (*Id.* at ¶ 85.)

Plaintiffs allege injuries caused from the use of alendronate sodium.[3] Plaintiffs claim that as a result of Generic Defendants' claims regarding the safety and efficacy of alendronate sodium, they were prescribed and used the drug long-term. Each alleges that as a direct and proximate cause of using alendronate sodium, they suffered fractures of the femur (sometimes both femurs), requiring hospitalization, surgery, and/or rehabilitation. As a result, the Plaintiffs claim significant harm; physical injury; enduring pain and suffering; bodily impairment; an increased risk of future osteonecrosis of the jaw and femur; risk of future hospitalizations, surgeries, and rehabilitation; mental anguish; emotional distress; and economic losses. Had Plaintiffs or their health-care-providers been made aware of unreasonable risks that Generic

[3] Claims against Merck, Sharp & Dohme, Corp. arising out of the ingestion of branded-drug, Fosomax, are not at issue in this motion and not affected by the Court's conclusions.

Defendants knew or should have known about, they would have not used or have been prescribed alendronate sodium.

Accordingly, Plaintiffs brought suit in a variety of courts and venues. Merck moved for centralization of the actions, and on May 25, 2011, the United States Judicial Panel on Multidistrict Litigation ordered that outside actions and actions in the District of New Jersey be transferred here for coordinated and consolidated pretrial proceedings. (*See* Doc. No. 30.) Plaintiffs brought numerous causes of action arising under state law, which the Court categorizes into the following legal claims against the Generic Defendants:

- Defective Manufacturing;
- Defective Design;
- Failure to Warn;
- Negligence;
- Fraud, Misrepresentation, Failure to Conform to Representation;
- Negligent Misrepresentation;
- Breach of Express Warranty;
- Breach of Implied Warranty;
- Violation of Consumer Protection Laws;
- Restitution; and
- Loss of Consortium.

Generic Defendants now move for Judgment on the Pleadings under Federal Rule of Civil Procedure 12(c) on the basis that all of Plaintiffs' claims against them are preempted by federal law.

II. DISCUSSION

A. Standard of Review

A motion for judgment on the pleadings under Federal Rule of Civil Procedure 12(c) is governed by the same standard as a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). *Turbe v. Virgin Islands*, 938 F.2d 427, 428 (3d. Cir. 1991). A motion to dismiss under

12(b)(6) may be granted only if, accepting all well-pleaded allegations in the complaint as true and viewing them in the light most favorable to the plaintiff, a court finds that the plaintiff has failed to set forth fair notice of what the claim is and the grounds upon which it rests. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citing *Conley v. Gibson*, 355 U.S. 41, 47 (1957)).

A complaint must contain sufficient factual matter to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (citing *Twombly*, 550 U.S. at 570). The plausibility standard requires that "the plaintiff plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged" and demands "more than a sheer possibility that a defendant has acted unlawfully." *Id*. (citing *Twombly*, 550 U.S. at 556). Although a court must accept as true all factual allegations in a complaint, that tenet is "inapplicable to legal conclusions," and "[a] pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Id*. (citing *Twombly*, 550 U.S. at 555); see also *Phillips v. County of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008). In evaluating a motion to dismiss, a court may consider only the complaint, exhibits attached to the complaint, matters of public record, and undisputedly authentic documents if the complainant's claims are based upon those documents. See *Pension Benefit Guar. Corp. v. White Consol. Indus*., 998 F.2d 1192, 1196 (3d Cir. 1993).

B. Law of Preemption

The Supremacy Clause states that federal law "shall be the supreme Law of the Land . . . and any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Implied preemption, the type of preemption at issue in this motion, occurs when it is "impossible for a private party to comply with both state and federal requirements."

Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995). In other words, when state law requires what federal law forbids, state law must give way. *See Wyeth v. Levine*, 555 U.S. 555, 583 (2009).

In *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011) ("*Mensing*"), plaintiffs brought state failure-to-warn claims against several generic manufacturers of the drug metoclopramide. *Mensing*, 131 S. Ct. at 2573. Plaintiffs contended that the generic manufacturers failed to change metoclopramide labeling to adequately warn of the risk of a severe neurological disorder called tardive diskinesia, in violation of state tort law. *Id.* The state tort laws applicable in the case required manufacturers that are "or should be aware of [their] product's danger to label that product in a way that renders it reasonably safe." *Id.* at 2573. Consequently, the parties in *Mensing* agreed that manufacturers may be under a duty to change labeling to warn of dangers in order to comply with state law. *Id.*

On the other hand, under the Federal Food, Drug, and Cosmetic Act ("FDCA)[4], the Court found that generic manufacturers have a federal duty of "sameness" to, at all times, insure that the label for the generic drug is identical to the label adorning the corresponding reference-listed drug. *Id.* at 2575. The plaintiffs insisted that there were several ways the generic manufacturers could have provided metoclopramide warnings to patients and prescribing physicians. First, plaintiffs argued that FDA's "changes-being-effected" (CBE) process allowed generics manufacturers to add or strengthen warnings or precautions. *Id.* The Court, however, disagreed, concluding that the generic manufacturers may use the CBE process only to update their label to match the reference-listed drug's labeling. *Id.* In fact, had a generic manufacturer unilaterally

[4] Because "all relevant events" in *Mensing* predated the Food and Drug Administration Amendments Act (FDAAA), the Court stated that "it expressed no view on the impact of the 2007 Act." *Mensing*, 131 S. Ct. at 2574. Because events giving rise to the alleged injuries in this case occurred before and after 2007, this opinion will determine whether the FDAAA has any effect on the preemption analysis.

changed its label through the CBE process, it would have been in violation of its duty of sameness. *Id.*

Second, the plaintiffs argued that the generic metoclopramide manufacturers should have sent "dear health care professional" (also known as "dear doctor") letters to inform prescribing physicians of new or additional warnings. But again, the Court found this avenue unavailable to generics manufacturers because dear doctor letters are considered by the FDA to be "labeling" and must be "consistent with and not contrary to [the drug's] labeling." *Id.* at 2576; *see also* 21 C.F.R. 201.100(d)(1). Therefore, if a generics manufacturer were to send a dear doctor letter containing new or additional warning information, it would violate the duty of sameness and misleadingly suggest a difference between the generic and corresponding branded drug. *Mensing*, 131 S. Ct. at 2576.

Third, the plaintiffs maintained that the generic manufacturers could have proposed stronger labels to the FDA. If FDA agreed, the agency "would have worked with the brand-name manufacturer to create a new label for both the brand-name and the generic drug." *Id.* The Court, however, concluded that even if a generic manufacturer has a duty to ask the FDA for assistance in changing the label, the request would not satisfy the state law duty. *Id.* at 2578. While the generic manufacturer "might eventually have been able to accomplish under federal law what state law requires," it could not independently do so. *Id.*

Accordingly, the Court held "that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 2581. As a result, the *Mensing* plaintiffs' state failure-to-warn claims were

preempted "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 2587.

In this case, the Generic Defendants move for judgment on the pleadings arguing that federal drug regulations preempt all of Plaintiffs' state law claims. Specifically, they contend that the Supreme Court's decision in *Mensing* requires that all state law claims arising from allegedly defective alendronate sodium labeling be dismissed because it is impossible to comply with both federal drug regulations and state tort and statutory duties. Defendants insist that failure to adequately warn is at the heart of each of Plaintiffs' claims, and thus, Defendants conclude that all must be dismissed. The Court will analyze each of Plaintiffs' claims in turn.

C. Application

1. Defective Manufacturing

The defective manufacturing claims must be dismissed. Plaintiffs merely recite the elements for this claim stating that the alendronate sodium "placed in the stream of commerce by Defendants was defective in its manufacture and construction . . . in that it deviated from product specification such that it was unreasonably dangerous to an ordinary user or consumer. . . ." (Brown Compl. at ¶ 115; Murphy Compl. at ¶ 111.) But Plaintiffs provide no sort of factual allegations supporting this 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. Therefore, Plaintiffs have provided no "more than a sheer possibility" that Generic Defendants defectively manufactured alendronate sodium. *Iqbal*, 129 S. Ct. at 1949. And this "formulaic recitation of the elements of a cause of action will not do." *Id.* (citing *Twombly*, 550 U.S. at 555). Consequently, the Court need not even reach the question of preemption to conclude that Plaintiffs' defective manufacturing claims must be dismissed.

2. Defective Design

Plaintiffs' claims alleging defective design are preempted. The Supreme Court found that that a generic drug is "designed to be a copy of a reference listed drug" and must be "identical in active ingredients, safety, and efficacy." *Mensing*, 131 S. Ct. at 2574 n. 2; *see also* 21 U.S.C. § 355(j)(2)(A) (requirements for an ANDA). To gain admittance to the market, a generic must demonstrate pharmaceutical equivalence and bioequivalence. *Id.* at § 355(j)(2)(A)(i)-(iii). Important here, an ANDA must also demonstrate that the "active ingredient of the new drug is the same as that of the listed drug." *Id.* § 355(j)(2)(A)(ii)(I). Hence, the "duty of sameness" also applies in the context of generic drug design. *Mensing* stands for the principle that a federal duty of sameness arising out of FDA's regulatory requirements preempts any conflicting tort duty arising under state law. *Mensing*, 131 S. Ct. at 2577-78.

Here, plaintiffs allege that Generic Defendants' alendronate sodium should have been designed differently to comply with state tort law. Plaintiffs allege that bisphosphonates are a class of drug, of which alendronate sodium is a member, that have a demonstrated link to bone fractures. (Murphy Compl. at ¶ 85.) Thus, generic Fosamax was defectively designed because its active ingredient was "unreasonably dangerous," "defective," and that there "was both technical and economic feasibility . . . of using an alternative design or formulation." (*Id.* at ¶¶ 116, 124.) But "[i]t was not lawful under federal law for the Manufacturers to do what state law required of them," *Mensing* 131 S. Ct. at 2577, because FDA requires generic Fosomax to have the same active ingredient as Fosomax (alendronate sodium). Therefore, Plaintiffs' design claims are preempted.

3. Failure to Warn

Plaintiffs' claims of failure to warn are squarely preempted by *Mensing*. The essence of Plaintiffs' claim is that the alendronate sodium labeling was insufficient and that Generic Defendants failed to satisfy their state law duty to provide accurate warning of the risks of osteonecrosis associated with long-term use. (*See, e.g.*, Murphy Compl. ¶¶ 81, 87, 101, 132; Brown Compl. ¶¶ 129, 130). Necessarily, under Plaintiffs' theory, the Generic Defendants should have altered the alendronate sodium label to provide new, different, and stronger warnings. According to Plaintiffs, the Generic Defendants had knowledge of the dangerous side effects that could result from long-term alendronate sodium use but gave no warning of these side effects, all while concealing their knowledge of them. (Brown Compl. at ¶ 89, 93.)

But if the Generic Defendants "had independently changed their labels to satisfy their state-law duty, they would have violated federal law." *Mensing*, 131 S. Ct. at 2578. Federal drug regulations "demand that generic drug labels be the same at all times as the corresponding brand-name drug labels." *Id.* The Generic Defendants could not alter the labeling without action by the FDA or manufacturer of the corresponding reference-listed drug.[5] *See id*. at 2575-76. Plaintiffs' insistence that Generic Defendants could have brought safety information to Merck misses the point. (*See* Pl.'s Opp Br. At 16; Doc. No. 296.) Even if Generic Defendants had bypassed the FDA and taken their safety information to Merck directly, they would still be unable to change alendronate sodium labeling themselves. Alteration of the generic label ultimately depends on the actions of a third party, something the Generic Defendants have no control over. *See Mensing*, 131 S. Ct. at 2579 ("We can often imagine that a third party or the

[5] Plaintiffs insist that Generic Defendants could have simply removed alendronate sodium from the market. Whatever the merit of that contention, it is essentially a re-argument of *Mensing*. The Supreme Court unequivocally held that failure-to-warn claims against generic drug manufacturers are preempted by federal law. To accept Plaintiffs' argument that Generic Defendants could have simply stopped marketing alendronate sodium, this Court would have to directly contravene binding law.

Federal Government *might* do something that makes it lawful for a private party to accomplish under federal law what state law requires of it."). But if "conjectures suffice to prevent" impossibility preemption, "it is unclear when . . . the *Supremacy Clause* would have any force." *Id.* (emphasis in original).

Contrary to Plaintiffs' assertions, the Food and Drug Administration Amendments Act ("FDAAA") does not change this analysis. First, nothing in FDAAA alters *Mensing's* analysis of the viability of sending Dear Doctor Letters. Specifically, FDA regulations still require that letters be "consistent with and not contrary to such approved or permitted labeling." 21 C.F.R. 201.100(d)(1). Thus, Generic Defendants could not, without violating federal law, advise prescribing physicians of warning information different from that provided in the FDA-approved label. Second, FDAAA did not change the fact that the Generic Defendants still cannot unilaterally change their alendronate sodium labels. Under the amendments, once FDA "becomes aware of new safety information" that it "believes should be included in the labeling" of a drug, FDA must notify the reference-listed drug manufacturer. 21 U.S.C. § 355(o)(4)(A). Then the manufacturer must propose a change to the label reflecting the new safety information and the FDA must act upon this proposal. *Id*. § 355(a)(4)(B)–(C). Importantly, under this section, if the manufacturer of the branded drug is still marketing the drug, as is the case here, FDA must first approach that manufacturer. *Id.* § 355(a)(4)(A). Only if the branded drug is no longer being marketed can the FDA require a generic manufacturer to propose a change. *Id.* And even if the Generic Defendants were to notify FDA of "new safety information," there is no guarantee that the branded drug's labeling would ultimately be changed. *See id.* § 355(o)(4)(C). Accordingly, the *Mensing* analysis is not affected by FDAAA because the Generic Manufacturers are still unable to unilaterally change drug labeling "without special permission

and assistance, which is dependent on the exercise of judgment by a federal agency." *Mensing*, 131 S. Ct. at 2581.

Plaintiffs advance several other theories as to why the failure-to-warn claims are not preempted. In their opposition brief, Plaintiffs argue that failure to update generic labeling to reflect labeling changes made to Fosamax are not preempted. Plaintiffs cite FDA Guidance that urges generic manufacturers to promptly implement labeling changes made by the corresponding branded drug. (Pl.'s Ex. F, "FDA, Guidance for Industry: Revising ANDA Labeling Following Revision of RLD Labeling" (2000)). Failure timely update generic labeling, one district court found, affects the *Mensing* preemption analysis. *See Fisher v. Pelstring*, No. 09-cv-00252, 2011 U.S. Dist. LEXIS 116162 (D.S.C. Sept. 30, 2011). But in this case, Plaintiffs offer only pure conjecture to support the theory that Generic Defendants failed to promptly update alendronate sodium labeling. In their brief, Plaintiffs point out that defendants in the metoclopramide litigation admitted to lagging behind in label updates and that, in this case, the "failure of some or all Defendants to timely strengthen their warnings . . . could have directly resulted in the prescription of Defendants' alendronate sodium to Plaintiffs." (Pl.'s Opp. Br. at 11-12; Doc. No. 296.) While there have been several updates to the Fosamax labeling, neither Plaintiffs' briefing nor pleadings provide any facts to plausibly support the theory that Generic Defendants failed to update their labeling. That a failure to timely update alendronate sodium labeling "could have occurred" is nothing "more than a sheer possibility" and is not "sufficient to state a claim for relief." *See Iqbal*, 129 S. Ct. at 1949.

Finally, Plaintiffs' brief advances the theory that Generic Defendants failed to effectively communicate warnings because they did not send Dear Doctor letters "highlighting" or "explaining" warning information. But Plaintiffs did not plead this claim, and instead raise it

now only in their briefing. Plaintiffs plead only that the warnings were deficient for failing to disclose of risks not already in alendronate sodium labeling. In other words, Plaintiffs' pleadings only claim that the drug's labeling was insufficient in substance; they do not "give fair notice" of any claim that what was in the labeling was sufficient but needed to be more effectively communicated. (Brown Compl. at ¶¶ 71-89.) Indeed, Plaintiffs' complaints are entirely devoted to asserting that the Generic Defendants knew of the risk of osteonecrosis and bone damage but failed to include such information in alendronate sodium labeling. Thus, the gravamen of the failure-to-warn claims is that the alendronate sodium labeling should have been changed to include stronger warnings—a claim that is plainly preempted by federal law under *Mensing*.

4. Negligence

Plaintiffs' negligence claims are also preempted. Plaintiffs allege that the Generic Defendants "failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotion and distribution" of alendronate sodium. (Brown Compl. at ¶ 136.) First, an allegation that the labeling, marketing, and promotion failed to live up to a standard of ordinary care is preempted by *Mensing* for the reasons explained in the Court's analysis of the failure-to-warn claims. This aspect of the negligence claim necessarily supposes that state law required Generic Defendants to have altered alendronate sodium labeling in order to conform to a standard of ordinary care, but *Mensing* held that because federal law imposes a "duty to keep the label the same," it is impossible for manufacturers "to comply with both their state-law duty" and federal law. *Mensing*, 131 S. Ct. at 2587.

Second, Plaintiffs' allegation of failure to exercise ordinary care in the design, testing, and manufacture fail for the reasons explain in this opinion's analysis of the design and

manufacturing defect claim sections. There is no factual support for the manufacturing defect claim. Additionally, *Mensing* demonstrates that a state tort duty requiring generic manufacturers to violate a federal duty of sameness is preempted. Here, Plaintiffs' negligence claim necessarily alleges that Generic Defendants should have changed the active ingredient in its generic Fosomax, but such action is barred by FDA's ANDA requirements. Thus, this state law claim is preempted.

5. Breach of Implied Warranty

The breach of implied warranty claims are preempted. Plaintiffs state that Generic Defendants "impliedly warranted [alendronate sodium] to be of merchantable quality, fitness, and safe for such use" but that the drug "was not of merchantable quality" because it was "unreasonably dangerous." (Brown Compl. at ¶¶ 150-52.) Because this cause of action is reliant on the argument that alendronate sodium should have been designed differently, it fails for the reasons explained in the Court's analysis of the design defect claims. Pursuant to FDA's equivalence requirements of generic drugs, the Generic Defendants could not have changed the generic drug's active ingredient to be different from the active ingredient in Fosamax. But the breach of implied warranty claim necessarily alleges that manufacturers should have changed alendronate sodium's design. This would be in violation of the federal duty of sameness, and therefore, this claim is preempted.

6. Breach of Express Warranty, Fraud, Misrepresentation, Failure to Conform to Representation, Negligent Misrepresentation, and Violation of Consumer Protection Statutes

These claims are preempted because the gravamen of these allegations is the insufficiency of alendronate sodium labeling. Each of these claims alleges that the Generic

Defendants made false statements or representations that alendronate sodium was safe and effective for the treatment of osteoporosis. Throughout their complaints, Plaintiffs attack the accuracy of the alendronate sodium labeling. "Defendants' representations regarding the character and quality of [alendronate sodium] were untrue." (Brown Compl. at ¶159.) Further, Plaintiffs state that "Defendants describe and represent that their Product has characteristics that simply do not conform to reality." (*Id.* at ¶ 143.) The claims plead that the Generic Defendants should have changed or omitted the allegedly inaccurate or insufficient labeling information. *See Fisher v. Pelstring*, No. 09-cv-0252, 2011 U.S. Dist. LEXIS 116162, *14 (D. S.C. September 30, 2011) (finding that plaintiff's breach of express warranty claim against generic drug manufacturer was preempted by *Mensing*).

But federal drug regulations forbid a generics manufacturer from unilaterally changing, omitting, or strengthening drug labeling. *See Mensing*, 131 S. Ct. at 2578 ("[S]tate law imposed on the Manufacturers a duty to attach a safer label to their generic [drug]. Federal law however, demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels."). Here, the Generic Defendants under federal law cannot unilaterally change or update their alendronate sodium labels and simultaneously conform to a state law duty that requires them to change those labels. Therefore, the federal duty of sameness conflicts with and consequently preempts the Plaintiffs' claims of breach of express warranty, fraud, misrepresentation, failure to conform to representation, negligent misrepresentation, and violation of consumer protection statutes.

7. Plaintiffs' Remaining Claims

Because judgment on the pleadings is granted in favor of Generic Defendants on Plaintiffs' state tort claims, including fraud and intentional wrongdoing, Plaintiffs' requests for

restitution and claims of loss of consortium must also be dismissed. Both restitution and loss of consortium are dependent on the survival of Plaintiffs' state tort claims. However, *Mensing* preempts the state tort claims against Generic Defendants. Thus, Plaintiffs will not be able to recover restitution from Generic Defendants absent claims of fraud or intentional wrongdoing, nor can loss of consortium survive as a derivative claim.

III. CONCLUSION

For the reasons above, the Court grants the motion for judgment on the pleadings in favor of Generic Defendants as to Plaintiffs' state law claims. The Court denies the motion for judgment on the pleadings by the Watson Defendants. An appropriate order is filed herewith.

Dated: November 21, 2011

_____/s/ Garrett E. Brown_____

HON. GARRETT E. BROWN, U.S.D.J.