UNITED STATES DISTRICT COURT
FOR THE
WESTERN DISTRICT OF NEW YORK

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| JOANNE MACSWAN, | ) | |
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| Plaintiff, | ) | |
| | ) | |
| v. | ) | Case No. 1:20-cv-1661 |
| | ) | |
| MERCK & CO., INC., | ) | |
| | ) | |
| Defendant. | ) | |

**OPINION AND ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION FOR JUDGMENT ON THE PLEADINGS**
(Doc. 17)

Plaintiff Joanne MacSwan brings this action against Defendant Merck & Co., Inc. alleging that, as a result of taking FOSAMAX® ("Fosamax"), a medication for the prevention and treatment of osteoporosis, she suffered serious and debilitating injuries. On October 6, 2020, Plaintiff filed a complaint in New York Supreme Court alleging six causes of action against Defendant: negligence (Count I); strict liability (Count II), breach of express warranty (Count III), breach of implied warranty (Count IV), fraudulent misrepresentation (Count V), and fraudulent concealment (Count VI) (the "Complaint"). Plaintiff seeks compensatory damages and punitive damages. On November 12, 2020, Defendant removed the case to this court and, on November 19, 2020, filed an answer.

Pending before the court is Defendant's September 10, 2021 motion for judgment on the pleadings seeking dismissal of Counts I and II, to the extent they are based on design defect theories, and Counts III, IV, V, and VI in their entirety. (Doc. 17.) Plaintiff opposed the motion on September 24, 2021 and Defendant replied on October 1, 2021, at which time the court took the motion for judgment on the pleadings under advisement.

Plaintiff is represented by Alexandria N. Rowen, Esq. and Hugh M. Russ, III, Esq. Defendant is represented by Michael L. Hecht, Esq., Robert G. Scumaci, Esq., and Stephen E. Marshall, Esq.

## I. Allegations in the Complaint.

Plaintiff is a New York resident. Defendant is a New Jersey corporation with its principal place of business in West Trenton, New Jersey. This action "arises out of Defendant's designing, manufacturing, marketing, distributing, and selling" of Fosamax, which is Defendant's brand name for the compound alendronate, a nitrogenous bisphosphonate drug used "primarily to mitigate or reverse the effects of osteoporosis." (Doc. 1-1 at 4-7, ¶¶ 1, 9, 20.) Bisphosphonates are a class of drugs "used for treating bone conditions" and some, though not Fosamax, "are also used for chemotherapy and for adjunct chemotherapy[.]" *Id.* at 7, ¶ 17.

In September 1995, the United States Food and Drug Administration ("FDA") approved Fosamax for the treatment of osteoporosis. At all relevant times, Defendant was the "designer, manufacturer, marketer, distributor, and seller" of Fosamax, which was a top selling drug for Defendant, averaging over $3 billion in annual sales. *Id.* at 5-6, ¶ 9. From the 1990s to the present, "medical articles and studies" reported "the frequent and common occurrence" of "osteonecrosis of the jaw as a result of nitrogenous bisphosphonates used for chemotherapy" and "atrial fibrillation as result of bisphosphonates use." (Doc. 1-1 at 7, ¶¶ 18-19.)

Defendant allegedly knew or should have known that Fosamax, like all bisphosphonates, "increase[s] the release of inflammatory cytokines which are associated with, and cause, atrial fibrillation[,]" which "is a risk factor and/or predisposition for stroke(s)." *Id.* at 8, ¶¶ 23-24. In addition, because Fosamax is a nitrogenous bisphosphonate, Defendant allegedly knew or should have known that it "shared a similar adverse event profile to other drugs within this specific subclass[,]" *id.* at 7, ¶ 20, including that these drugs "inhibit endothelial cell function[,]" "inhibit vascularization[,]" and "induce ischemic changes specific to patients' mandibles (lower jaws) and maxillae (upper jaws)[.]" *Id.* at 7-8, ¶ 21. Defendant allegedly further knew or should have known

that "these factors combine to create a compromised vascular supply in the affected area" and "a minor injury or disease . . . can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow)—together, osteonecrosis." *Id.* at 8, ¶ 22.

Defendant allegedly "concealed its knowledge" of Fosamax's "unreasonably dangerous risks[,]" and "failed to conduct adequate and sufficient post-marketing surveillance." *Id.* at 4-5, ¶¶ 2-3. "As a result of the defective nature" of Fosamax, Plaintiff "suffered and may continue to suffer severe and permanent personal injuries, including osteonecrosis of the jaw and other irreversible damage to the jaw, and atrial fibrillation, stroke, and other irreversible damage to the brain." *Id.* at 5, ¶ 4.

Despite FDA reports of osteonecrosis and atrial fibrillation among users of Fosamax after its release, Defendant "failed to implement further studies" of these issues and instead "sought to extend the exclusivity period with the FDA through 2018." *Id.* at 8-9, ¶¶ 25-27. On August 25, 2004, the FDA issued a review of bisphosphonates that concluded the risk of osteonecrosis to the jaw were not limited to those used for chemotherapy and required Defendant to update Fosamax's label to warn of the risks of osteonecrosis of the jaw. Notwithstanding this directive, Defendant allegedly "continued to . . . minimize . . . unfavorable findings" and did not update Fosamax's warning label until 2005. (Doc. 1-1 at 10, ¶ 34.) Because Defendant "did not adequately and sufficiently warn consumers, including [Plaintiff], or the medical community" about the "significant" risks of "dental and oral complications" and "atrial fibrillation and resulting stroke" associated with Fosamax, Plaintiff and other consumers continued to use Fosamax despite "several alternative safer products available to treat their conditions." *Id.* at 10 ¶ 36-38.

Plaintiff "was prescribed and began taking" Fosamax in January 2009. *Id.* at 11, ¶ 40. Through "affirmative misrepresentations and omissions," Defendant allegedly "actively concealed" from Plaintiff and her doctors "the verified and significant risks" of Fosamax. *Id.* at 11, ¶ 45. Had the associated risks been properly disclosed, Plaintiff would have ceased using Fosamax. As a result of Defendant's "actions and omissions," Plaintiff asserts she was "permanently and severely injured, having suffered serious

consequences from the ingestion of F[osamax]" and "has required and will continue to require ongoing medical care and treatment." *Id.* at 10-11, ¶ 39.

For each of the six counts in the Complaint, Plaintiff alleges she suffered "significant and permanent injuries[,]" "diminished quality of life," and "other losses and damages" as a result of Defendant's "actions, omissions, and misrepresentations[.]" *Id.* at 12-14, 16, 18-19, 21 ¶¶ 53, 66, 74, 85, 95, 107. She seeks punitive damages on all counts because Defendant allegedly acted knowingly and "with conscious, wanton, willful, and deliberate disregard for the value of [her] life[.]" (Doc. 1-1 at 13, 15-16, 18, 20, 21-22 ¶¶ 55, 68, 76, 87, 97, 109.)

## II. Judicial Notice.

In deciding a motion for judgment on the pleadings, the court may consider documents and information incorporated by reference or integral to a complaint, as well as facts subject to judicial notice. *See Glob. Network Commc'ns, Inc. v. City of New York*, 458 F.3d 150, 156 (2d Cir. 2006). Defendant asks the court to consider the warnings regarding osteonecrosis in Fosamax's FDA-approved label and in Defendant's Patient Information Sheet. Because the Complaint "relies heavily upon [the] terms and effect" of Fosamax's label and warnings distributed to patients, they are integral to the Complaint. *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002) (quoting *Int'l Audiotext Network, Inc. v. Am. Tel. & Tel. Co.*, 62 F.3d 69, 72 (2d Cir.1995) (per curiam)).

Defendant also requests the court take judicial notice of the dates Fosamax's patent rights expired, the market effects of the expiration of those rights, and FDA safety studies on bisphosphonates. Plaintiff criticizes Defendant's allegedly "liberal use of carefully chosen quasi-public documents" but does not oppose Defendant's requests for judicial notice. (Doc. 18-2 at 6.) "The court may judicially notice a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). The court "must take

judicial notice if a party requests it and the court is supplied with the necessary information." *Id.* at (c)(2).

The court takes judicial notice of patent expiration dates and the safety studies cited by Defendant because they can be "accurately and readily" determined from FDA sources "whose accuracy cannot reasonably be questioned." *Id.* at (b)(2); *see also In re Zyprexa Prod. Liab. Litig.*, 549 F. Supp. 2d 496, 501 (E.D.N.Y. 2008) ("Public documents issued by government agencies such as the Food and Drug Administration ("FDA") may also be [judicially noticed]."). The court declines to take judicial notice of the effect of generic competition on Defendant's market share as Defendant has not supplied the court with the court "with the necessary information[,]" Fed. R. Evid. 201(c)(2), and the impact of generic competition is subject to reasonable dispute.

## III. Conclusions of Law and Analysis.

### A. Standard of Review.

"The standard for granting a Rule 12(c) motion for judgment on the pleadings is identical to that for granting a Rule 12(b)(6) motion for failure to state a claim." *Lively v. WAFRA Inv. Advisory Grp., Inc.*, 6 F.4th 293, 301 (2d Cir. 2021) (internal quotation marks omitted) (quoting *Lynch v. City of New York*, 952 F.3d 67, 75 (2d Cir. 2020)). To survive a motion to dismiss filed pursuant to Fed. R. Civ. P. 12(b)(6), "a complaint 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)). Plaintiff must allege sufficient facts to "nudge[] their claims across the line from conceivable to plausible[.]" *Twombly*, 550 U.S. at 570. "A claim has facial plausibility when the plaintiff pleads 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.

The sufficiency of a complaint under Rule 12(b)(6) is evaluated using a "two-pronged approach[.]" *Hayden v. Paterson*, 594 F.3d 150, 161 (2d Cir. 2010) (internal quotation marks omitted) (quoting *Iqbal*, 556 U.S. at 679). First, the court discounts legal conclusions and "[t]hreadbare recitals of the elements of a cause of action, supported by

mere conclusory statements[.]" *Iqbal*, 556 U.S. at 678. The court is also "'not bound to accept as true a legal conclusion couched as a factual allegation[.]'" *Id.* (citation omitted). Second, the court considers whether the factual allegations, taken as true, "plausibly give rise to an entitlement to relief." *Id.* at 679. This second step is fact-bound and context-specific, requiring the court "to draw on its judicial experience and common sense." *Id.* The court does not "weigh the evidence" or "evaluate the likelihood" that a plaintiff's claims will prevail. *Christiansen v. Omnicom Grp., Inc.*, 852 F.3d 195, 201 (2d Cir. 2017).[1]

**B. Whether Plaintiff's Design Defect Claims Must Be Dismissed.**

In Count I, Plaintiff alleges that Defendant was negligent because it breached its duty of reasonable care "by failing to properly and effectively test F[osamax], to analyze the resulting data, and to implement any necessary precautions" and by "failing to warn [Plaintiff] of the extreme risks associated with F[osamax] and of the possibility of resulting harm which could foreseeably occur." (Doc. 1-1 at 12, ¶¶ 51-52.) Plaintiff characterizes Count I as a negligent design claim based on the allegation that Defendant failed "to implement any necessary precautions." *Id.*[2]

In Count II (strict liability), Plaintiff asserts that Defendant knowingly "manufactured, marketed, distributed, supplied, and/or sold F[osamax] in a defective and unreasonably dangerous condition[.]" *Id.* at 13, ¶ 57. Fosamax was allegedly "defective in its design and/or formulation, as the foreseeable risks exceeded the benefits associated

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[1] Contrary to Plaintiff's assertion, *see* Doc. 18-2 at 10, the "no set of facts" pleading standard derived from *Conley v. Gibson*, 355 U.S. 41 (1957), is no longer good law. "[T]his famous passage has earned its retirement. The phrase is best forgotten as an incomplete, negative gloss on an accepted pleading standard: once a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 563 (2007); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 670 (2009) ("*Twombly* retired the *Conley* no-set-of-facts test[.]").

[2] Defendant contends that Plaintiff only "arguably attempts to assert a negligent design defect claim[,]" (Doc. 17 at 8), but does not assert Plaintiff's negligent design defect claim is insufficiently pled and Defendant does not seek a more definite statement pursuant to Fed. R. Civ. P. 12(e).

with its design and/or formulation" and "posed a greater risk than other similar medications. *Id.* at 14, ¶ 61. Defendant allegedly "knew, or should have known," of its "defective nature[.]" *Id.* at 14, ¶ 63. In addition, "Defendant failed to indicate anywhere on related packaging of the risks posed by the use of F[osamax]." *Id.* at 14, ¶ 62. Plaintiff alleges she used Fosamax as prescribed and as intended by Defendant and could not have foreseen its risks.

Defendant moves to dismiss Plaintiff's design defect claims, but not her failure to warn claims, in Counts I and II. Under New York law, "claims for negligent design and design-based strict products liability should be analyzed under the same standard in products liability cases." *Kennedy v. Covidien, LP*, 2019 WL 1429979, at *5 (S.D.N.Y. Mar. 29, 2019) (citing *Denny v. Ford Motor Co.*, 662 N.E.2d 730, 735-36 (N.Y. 1995)). To state a claim for negligent or strict products liability defective design under New York law, a plaintiff must allege that: "(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury." *Lewis v. Abbott Labs.*, 2009 WL 2231701, at *4 (S.D.N.Y. July 24, 2009) (citing *Voss v. Black & Decker Mfg. Co.*, 450 N.E.2d 204, 207 (N.Y. 1983)). Defendant argues that because Plaintiff has failed to allege a feasible safer alternative design, her defective design claims must be dismissed. Plaintiff responds that her allegations are sufficient to put Defendant on notice "of the basis of her design defect claim" because "[f]or example, [she] alleges that F[osamax] could have been designed without nitrogen." (Doc. 18-2 at 11.)

The Complaint contains no allegations of a feasible alternative design and is silent on the issue of designing Fosamax without nitrogen. Although Plaintiff asserts that there were "several alternative safer products available," (Doc. 1-1 at 10, ¶ 36), this will not suffice. *See Kennedy*, 2019 WL 1429979, at *4 ("Plaintiff's conclusory allegation alluding to a safer alternative is not pleaded in sufficient detail to support a reasonable inference that there are indeed feasible alternative products."); *Oden v. Bos. Sci. Corp.*, 330 F. Supp. 3d 877, 889 (E.D.N.Y. 2018) (holding that allegations that "safer, reasonable alternative designs existed and could have been utilized," failed to adequately

"plead the existence of a feasible alternative design"); *Hilaire v. DeWalt Indus. Tool Co.*, 54 F. Supp. 3d 223, 248 (E.D.N.Y. 2014) (finding that plaintiff "cannot satisfy his burden to propose a feasible alternative design by proposing that an entirely different product could have been used"); *Simon v. Smith & Nephew, Inc.*, 990 F.Supp.2d 395, 405 (S.D.N.Y. 2013) (holding that "an allegation that [defendant] could have manufactured a different product altogether, or that others have done so, does not itself make out a plausible claim of design defect").

Plaintiff's allegation that Fosamax, "as a nitrogenous bisphosphonate, shared a similar adverse event profile to other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen)[,]" (Doc. 1-1 at 7, ¶ 20), also does not adequately plead a feasible design alternative; it merely describes a drug subclass to which Fosamax belongs. In any event, Plaintiff may not amend her pleading through her brief to transform this statement into a proposed alternative design. *See Wright v. Ernst & Young LLP*, 152 F.3d 169, 178 (2d Cir. 1998) (holding a "party may not amend [a] pleading through statements in briefs") (citation omitted). Assuming *arguendo* that it is feasible to design Fosamax without nitrogen, Plaintiff fails to allege that such a design would be "safer[,]" *Lewis*, 2009 WL 2231701, at *4, because the Complaint alleges that all bisphosphonates—not just those containing nitrogen—cause atrial fibrillation.

*DiBartolo v. Abbott Laboratoris*, 914 F. Supp. 2d 601 (S.D.N.Y. 2012), is instructive. There, the plaintiff alleged that "Humira was defectively designed because all TNF-blockers, including Humira, have an 'inherent defect,': their 'causal association' with cancer." *Id.* at 622. The district court found that the plaintiff's argument, "that it was unnecessary for her to include specific allegations that [defendant] could have implemented an alternative design, and that it was sufficient simply to assert a claim for design defect[,]" had been "squarely rejected by New York courts." *Id.* (footnote omitted).

"'It is well settled that to establish a claim predicated upon a design defect, plaintiffs must present evidence that the product, as designed, was not reasonably safe because there was a substantial likelihood of harm and that it was feasible to design the

product in a safer manner'" and thus a plaintiff must "adequately allege[] a safer alternative design." *Id.* at 622-23 (quoting *Sabater v. Lead Industries Association, Inc.*, 704 N.Y.S.2d 800, 804 (Sup. Ct. 2000)). Where a plaintiff has "fail[ed] to allege that defendant could have designed its drug more safely," his or her design defect claims must be dismissed. *Id.* at 623; *see also Lewis*, 2009 WL 2231701, at *4 (S.D.N.Y. July 24, 2009) (dismissing design defect claims in part because "plaintiff has not alleged that it was feasible for Abbott Laboratories to design Depakote in a safer manner"); *Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 578 (E.D.N.Y. 2012) (granting drug manufacturer's motion to dismiss plaintiffs' design defect claim under New York and West Virginia law because "[p]laintiffs do not plead facts alleging the existence of a feasible alternative design that would make the product safer").

Although Plaintiff argues that, at the pleading stage, she is not required to specify how Fosamax should be altered, the cases on which she relies, *Ohuche v. Merck & Co.*, 2011 WL 2682133 (S.D.N.Y. July 7, 2011) and *Sullivan v. Aventis, Inc.*, 2015 WL 4879112 (S.D.N.Y. Aug. 13, 2015), do not support her contention. In *Ohuche v. Merck & Co.*, the district court rejected the defendant's argument that a plaintiff "must *establish* that it was feasible to design the product in a safer manner in order to allege a plausible design defect claim[,]" finding this "would require a plaintiff to possess technical, scientific knowledge of the inner workings" of medications that "[m]ost doctors do not possess this sort of specialized knowledge." 2011 WL 2682133, at *2 (emphasis in original) (internal quotation marks omitted and alterations adopted). The *Ohuche* court held it would "be unfair" to "penalize" the plaintiff, who was proceeding pro se, "for not being more specific about the possible design defects[.]" *Id.* at *3; *see also Graham v. Henderson*, 89 F.3d 75, 79 (2d Cir. 1996) ("[T]he pleadings of a *pro se* plaintiff must be read liberally and should be interpreted 'to raise the strongest arguments that they suggest.'") (quoting *Burgos v. Hopkins*, 14 F.3d 787, 790 (2d Cir. 1994)).

The *Ohuche* court correctly determined that there is no requirement that a plaintiff *establish* the elements of her claim at the pleading stage, but a plaintiff must still plausibly plead them. It therefore effectively dismissed the claim by requiring the

plaintiff "to specifically state the particular product liability claim(s) she is asserting (design defect, manufacturing defect, failure to warn) and provide whatever supporting detail she may have available to her." *Ohuche*, 2011 WL 2682133, at *3. This limited ruling offers Plaintiff no relief in this case from the requirement that she plausibly allege a safer alternative design. *See Kennedy*, 2019 WL 1429979, at *3 ("The particular circumstances in *Ohuche* cannot be read to undermine the general requirement that an alternative design must be pleaded, even if it is not fully developed at the pleading stage."); *Koublani v. Cochlear Ltd.*, 2021 WL 2577068, at *11 (E.D.N.Y. June 23, 2021) (same).

*Sullivan v. Aventis, Inc.*, in which the district court found sufficient the plaintiff's allegations that "'safer alternative designs' existed that were 'economically and technologically feasible' that would have 'prevented and/or significantly reduced the risk of the [p]laintiff's injuries without impairing the reasonably anticipated or intended function of the product,'" does not mandate a different result. 2015 WL 4879112, at *7. The *Sullivan* court held that requiring "more detail concerning how the design should have been altered and why it was feasible" would "require the plaintiff to possess technical or scientific knowledge about the inner workings of the product, which would contravene the notice pleading requirement of Federal Rule of Civil Procedure 8, even under the *Iqbal–Twombly* standard." *Id.* (citation omitted). However, the district court distinguished *Dibartolo*, 914 F. Supp. 2d 601, and *Reed*, 839 F. Supp. 2d 571, "because [p]laintiff here has pleaded greater detail than the plaintiffs in those cases." *Id.* In this case, Plaintiff's Complaint does not contain even the minimal detail found to be sufficient in *Sullivan*.

As alternative grounds for dismissal of Plaintiff's design defect claims, Defendant argues the claims are pre-empted by federal law. In *Mut. Pharm. Co., Inc. v. Bartlett*, the Supreme Court held that a state law design defect claim was pre-empted because the manufacturer could not "redesign" a drug to comply with state law tort duties without first obtaining FDA approval as "the altered chemical would be a new drug that would require its own [New Drug Application] to be marketed in interstate commerce." 570

U.S. 472, 483-84 (2013) (citation omitted). *Bartlett* involved a generic drug, which must have "the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based." *Id.* at 483-84. However, the distinction between brand-name and generic drugs is not necessarily dispositive because brand-name drugs like Fosamax must also seek approval from the FDA for changes in formulation. *Id.* at 477 ("Once a drug—whether 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.") (citing 21 C.F.R. § 314.70(b)(2)(i)). For this reason, some courts have found *Bartlett* pre-emption applies to design defect claims involving brand-name drugs as well. *See Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 298 (6th Cir. 2015) (applying New York law and finding "to the extent [plaintiff] argues that defendants should have altered the formulation of [the name brand drug] after the FDA had approved [it], we find this claim clearly preempted"); *see also Amos v. Biogen Idec Inc.*, 28 F. Supp. 3d 164, 169 (W.D.N.Y. 2014) (holding "such claims are preempted as a matter of law[,]" although plaintiff had voluntarily withdrawn those claims).

Other courts have not followed the Sixth Circuit and have instead held that design defect claims involving brand-name drugs are not pre-empted because manufacturers can comply with state law duties by choosing an alternative design pre-approval or strengthening warning labels. *See Sullivan*, 2015 WL 4879112, at *5-*6 (holding design defect claim not pre-empted under New York law because "drug manufacturers can . . . avoid liability . . . by choosing a safer design for a drug [pre-approval]" or "even if redesign is not feasible, there is no federal law that prevents a manufacturer from complying with its state-law duty by strengthening a brand-name drug's warning label (pre- or post-approval"); *Holley v. Gilead Scis., Inc.*, 379 F. Supp. 3d 809, 823 (N.D. Cal. 2019) ("District courts that have considered the question have ruled both ways. Of those courts that are not bound by the Sixth Circuit's ruling in *Yates*, a majority has found no preemption under these circumstances.") (collecting cases).

Defendant concedes that, unlike generic drug manufacturers, brand name manufacturers can update warning labels but contends this is only relevant to failure to warn claims and not design defect claims. Warning labels may be relevant in design defect cases because the risk-utility analysis required under New York law "is directly impacted by the strength of the drug's warnings." *Sullivan*, 2015 WL 4879112, at *5.[3] The *Sullivan* court thus found "a New York design defect claim concerning a brand-name drug imposes on manufacturers a duty to render a drug safer either by redesigning the drug *or by strengthening the drug's warning* to ameliorate its risk-utility profile[.]" *Id.* (emphasis supplied); *see also Brazil v. Janssen Rsch. & Dev. LLC*, 249 F. Supp. 3d 1321, 1346 (N.D. Ga. 2016) ("As the [Supreme] Court explained in *Levine* and *Mensing*, a brand name drug manufacturer may use the FDA's ["changes being effected"] regulation to unilaterally change its labeling without prior FDA approval. In doing so, a brand name drug manufacturer may comply with both state and federal law. . . . State law claims, including a design defect claim, requiring a brand name drug manufacturer to provide a more robust warning are therefore not preempted.") (citing *Wyeth v. Levine*, 555 U.S. 555 (2009); *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011)). Because "[h]ow far to extend *Bartlett* is a difficult legal issue and one that has divided the courts that have confronted the issue," *Brazil*, 249 F. Supp. 3d at 1346, including district courts within the Second Circuit,[4] and because Plaintiff's claims must be dismissed on other grounds, the court

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[3] New York's "risk-utility" approach to determining whether a product is defective requires consideration of the following factors:

> (1) the utility of the product to the public as a whole and to the individual user; (2) the nature of the product-that is, the likelihood that it will cause injury; (3) the availability of a safer design; (4) the potential for designing and manufacturing the product so that it is safer but remains functional and reasonably priced; (5) the ability of the plaintiff to have avoided injury by careful use of the product; (6) *the degree of awareness of the potential danger of the product which reasonably can be attributed to the plaintiff*; and (7) the manufacturer's ability to spread any cost related to improving the safety of the design.

*Voss v Black & Decker Mfg. Co.*, 59 N.Y.2d 102, 109 (1983) (emphasis supplied).

[4] *Compare Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 178 (S.D.N.Y. 2016) ("[T]his case law, read holistically, indicates that federal law preempts all pre-FDA approval failure to

declines to decide at this juncture whether Plaintiff's design defect claims are pre-empted.

Because Plaintiff fails to plausibly allege a feasible alternative design, Defendant's motion to dismiss the design defect claims in Counts I and II is GRANTED.

**C. Whether Plaintiff's Express Warranty Claim Must Be Dismissed.**

In Count III of the Complaint, Plaintiff asserts that Defendant breached an express warranty because, upon information and belief, Defendant "expressly represented" to her "through its advertising and otherwise" that Fosamax "had been adequately tested, was to be prescribed in accordance with its intended uses, was of merchantable quality, and was not dangerous." (Doc. 1-1 at 15, ¶ 70.) She claims Fosamax "does not conform with Defendant's express warranties" because it is "inherently dangerous, has numerous adverse side effects, and has been known to cause sever and permanent injuries including, but not limited to, osteonecrosis of the jaw." *Id.* at 15-16, ¶ 71. Plaintiff and her doctors "reasonably relied" on the express warranties and Fosamax "failed to perform in accordance with how [they] reasonably assumed it would." *Id.* at 16, ¶¶ 72-73.

Under New York law, "[a]n express warranty is an 'affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain.'" *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 286 (E.D.N.Y. 2009) (quoting N.Y. U.C.C. § 2–313(1)(a)). To assert a breach of express warranty claim, Plaintiff must plausibly allege: "(1) the existence of a material statement amounting to a warranty, (2) the buyer's reliance on this warranty as a basis for the contract with the immediate seller, (3) breach of the warranty, and (4) injury to the buyer caused by the breach." *Goldemberg v. Johnson & Johnson Consumer Cos.*, 8 F. Supp. 3d 467, 482 (S.D.N.Y. 2014). The first element "requires a showing of a specific affirmation of fact or promise that is false and misleading." *Kennedy*, 2019 WL 1429979, at *6 (citing *DiBartolo*, 914 F. Supp. 2d at 626).

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warn and design defect claims for branded prescription medication."), *with Sullivan*, 2015 WL 4879112, at *5 (holding that federal law does not preempt design defect claims regarding a brand name drug).

Defendant argues that Plaintiff fails to identify to any specific affirmation or promise by Defendant with regard to Fosamax's safety. The court agrees. For this reason, her generic allegations fail to state a claim for breach of express warranty. *See Kennedy*, 2019 WL 1429979, at *6 ("[Plaintiff's] characterization of Defendant's marketing material as generally implying that PCOx Mesh was 'safe and effective' does not identify any specific actionable conduct or statement on behalf of Defendant."); *Horowitz*, 613 F. Supp. 2d at 286 ("Plaintiff does not even describe how this representation [that the product was safe] was made. Without sufficient allegations identifying the conduct at issue, plaintiff has failed to give the defendants notice of the grounds of her claim. Her claim for breach of express warranty must, therefore, be dismissed."); *Morrison v. Hoffmann-La Roche, Inc.*, 2016 WL 5678546, at *10 (E.D.N.Y. Sept. 29, 2016) ("Plaintiff does not even describe how these alleged representations were made beyond the all-encompassing bald assertion that . . . defendants expressly and implicitly warranted product safety. This lack of specificity renders [p]laintiff's allegations insufficient to support an express warranty claim[.]") (citations omitted).

For the reasons stated above, Defendant's motion to dismiss Count III is GRANTED.

**D. Whether Plaintiff's Implied Warranty Claim Must Be Dismissed.**

Plaintiff alleges in Count IV that Defendant breached an implied warranty of merchantability, which Defendant and her doctors reasonably relied on, (1) "by manufacturing, marketing, distributing, supplying, selling, and/or promoting [Fosamax], which was not reasonably fit for its intended purpose[,]" (2) "with an unreasonably fit product[,]" and (3) "by its egregious behavior and utter disregard for human life." (Doc. 1-1 at 17-18, ¶¶ 82-84.) Defendant contends that, because Plaintiff's design defect claims must be dismissed, her implied warranty of merchantability claim must also be dismissed.

"The implied warranty of merchantability is a guarantee by the seller that its goods are fit for the intended purpose for which they are used and that they will pass in the trade without objection." *Caronia v. Philip Morris USA, Inc.*, 715 F.3d 417, 433 (2d Cir. 2013) (quoting *Saratoga Spa & Bath, Inc. v. Beeche Systems Corp.*, 656 N.Y.S.2d 787, 789 (3d

Dep't 1997)). "To establish a breach of the implied warranty of merchantability, a plaintiff must show that 'a defect in the product was a substantial factor in causing the injury and . . . the defect complained of existed at the time the product left the manufacturer or entity in the line of distribution being sued.'" *Nemes v. Dick's Sporting Goods, Inc.*, 521 F. Supp. 3d 328, 341-42 (S.D.N.Y. 2021) (ellipsis in original) (quoting *DiBartolo*, 914 F. Supp. 2d at 627). "The alleged defect may arise from 'a manufacturing flaw, improper design, or a failure to provide adequate warnings regarding use of the product.'" *Id.* at 342 (quoting *Adesina v. Aladan Corp.*, 438 F. Supp. 2d 329, 345 (S.D.N.Y. 2006)).

Because Defendant does not challenge "Plaintiff's possible failure to warn claims at this time[,]" (Doc. 17 at 7 n.1), her implied warranty claim may proceed on a failure to warn basis notwithstanding the dismissal of her design defect claims. "[T]he New York Court of Appeals has taken care to distinguish this merchantability-related strict liability from the liability that is more typically associated with claims for defective products." *Caronia*, 715 F.3d at 434. While "[a]s a practical matter, the distinction between the defect concepts in tort law and in implied warranty theory may have little or no effect in most cases[,]" in this case the distinction is dispositive. *Denny v. Ford Motor Co.*, 662 N.E.2d 730, 738 (N.Y. 1995). In contrast to a tort claim, for an implied warranty claim "recovery may be had upon a showing that the product was not minimally safe for its expected purpose—without regard to the feasibility of alternative designs or the manufacturer's 'reasonableness' in marketing it in that unsafe condition." *Id.* at 736; *see also Porrazzo v. Bumble Bee Foods, LLC*, 822 F. Supp. 2d 406, 422 (S.D.N.Y. 2011) ("Plaintiff's ability to recover under his breach of implied warranty claim is not affected by the feasibility of making the product safer[.]").

Plaintiff's failure to allege a feasible alternative design is therefore not fatal to her implied warranty claim and, as this is Defendant's sole basis for dismissal of the claim, Defendant's motion to dismiss Count IV must be DENIED.

**E. Whether Plaintiff's Fraud Claims Must Be Dismissed.**

In Count V, Plaintiff claims that Defendant "made fraudulent representations with

respect to F[osamax] and its associated risks" with "the purpose of deceiving" Plaintiff and her doctors "into relying upon" them, which they "justifiably" did. (Doc. 1-1 at 19, ¶¶ 89-94.) Plaintiff alleges in Count VI that Defendant knew the risks associated with Fosamax and a duty to disclose material information about Fosamax but "fraudulently concealed true and accurate information" about those risks and "instead fraudulently represented" Fosamax as "fit and safe to use as part of [Plaintiff's] required treatment." *Id.* at 20, ¶ 100. The alleged purpose of the fraudulent concealment was to induce reliance upon Defendant's misrepresentations, and Plaintiff and her doctors did in fact "justifiably" rely on those misrepresentations. *Id.* at 21, ¶¶ 105-06.

The parties agree that Count V and VI sound in fraud and therefore "must be pled with particularity, Fed. R. Civ. P. 9(b), which requires that the plaintiff (1) detail the statements (or omissions) that the plaintiff contends are fraudulent, (2) identify the speaker, (3) state where and when the statements (or omissions) were made, and (4) explain why the statements (or omissions) are fraudulent." *Eternity Glob. Master Fund Ltd. v. Morgan Guar. Tr. Co. of N.Y.*, 375 F.3d 168, 187 (2d Cir. 2004) (internal quotation marks and citations omitted). "The 9(b) requirement serves to: (1) give defendants fair notice of plaintiffs' claims; (2) assist drafting of responsive pleadings; (3) protect defendants' reputations and good will from frivolous or baseless claims; and (4) minimize the number of strike suits." *Kuczynski v. Ragen Corp.*, 732 F. Supp. 378, 383 (S.D.N.Y. 1989) (citations omitted).

In this case, Plaintiff makes only vague allegations of misrepresentations and omissions and "woefully misses the 9(b) particularity mark: no statements [or omissions] are specified, no speaker is identified, [and] no time or place of the statements [or omissions] is identified[.]" *Ferrari Club of Am., Inc. v. Bourdage*, 2017 WL 6419061, at *3 (W.D.N.Y. Apr. 25, 2017); *see also Amos*, 28 F. Supp. 3d at 172-73 ("Plaintiff further claims that defendants made misrepresentations in advertisements, website statements, written and oral information provided to patients and doctors and other marketing materials, but fails to identify any such misrepresentation, and fails to explain why such misrepresentations were fraudulent. These general averments of fraud lack the

particularity required by Rule 9(b)[.]").

Because Plaintiff has failed to plead fraud with particularity as required by Rule 9(b), Defendant's motion to dismiss Counts V and VI is GRANTED.

**F. Whether Plaintiff Should Be Granted Leave to Amend.**

Plaintiff requests leave to amend "if the Court determines that any cause of action is subject to dismissal[.]" (Doc. 18-2 at 18.) She seeks to plead additional facts "learned during the course of discovery[,]" in particular that she was first prescribed and began taking Fosamax in 2001, not 2009. *Id.* at 19. Defendant opposes the request for leave to amend because the deadline for amending pleadings in the court's scheduling order was April 30, 2021; Plaintiff "knew at that time, or certainly could have easily confirmed, the date of her first Fosamax use" at the time she filed the Complaint; and any amendments would be futile. (Doc. 19 at 10.)

The court must "freely give leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a)(2). "Mere delay . . . absent a showing of bad faith or undue prejudice, does not provide a basis for a district court to deny the right to amend." *Prompt Nursing Emp. Agency LLC v. Valdez*, 222 F. Supp. 3d 194, 200-01 (E.D.N.Y. 2016) (quoting *State Teachers Ret. Bd. v. Fluor Corp.*, 654 F.2d 843, 856 (2d Cir. 1981)). There is no evidence of bad faith by Plaintiff and, although Defendant "may be prejudiced by additional discovery demands, discovery is part of litigation[.]" *Id.* at 201. Plaintiff requested leave to amend prior to the close of discovery and any prejudice to Defendant would not be undue at this stage. *See State Teachers Ret. Bd. v. Fluor Corp.*, 654 F.2d 843, 856 (2d Cir. 1981) (finding insufficient prejudice where the defendant had not filed for summary judgment, a trial date had not been set, and the amendment would not involve a great deal of additional discovery); *Ruotolo v. City of New York*, 514 F.3d 184, 192 (2d Cir. 2008) ("Undue prejudice arises when an amendment comes on the eve of trial and would result in new problems of proof.").[5]

[5] Defendant does not explain its own decision to postpone seeking judgment on the pleadings until almost a year after the Complaint was filed, which arguably contributed to Plaintiff's delay in seeking leave to amend.

Proposed amendments are futile when they "would fail to cure prior deficiencies or to state a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure." *IBEW Local Union No. 58 Pension Trust Fund & Annuity Fund v. Royal Bank of Scotland Grp., PLC*, 783 F.3d 383, 389 (2d Cir. 2015) (quoting *Panther Partners Inc. v. Ikanos Commc'ns, Inc.*, 681 F.3d 114, 119 (2d Cir. 2012)). The court cannot assess the futility of Plaintiff's proposed amendments because she has failed to attach a copy of the proposed amended pleading to her motion as required by Local Rule 15(a). Identifying a single date change is insufficient. *See* L.R. 15(a) ("The proposed amended pleading must be a complete pleading superseding the original pleading in all respects.").

Because "'outright dismissal for reasons not going to the merits is viewed with disfavor in the federal courts[,]'" and, in turn, "dismissals for insufficient pleadings are ordinarily with leave to replead[,]" the court conditionally GRANTS Plaintiff's request for leave to amend. *Stern v. Gen. Elec. Co.*, 924 F.2d 472, 477 (2d Cir. 1991) (quoting *Nagler v. Admiral Corp.*, 248 F.2d 319, 322 (2d Cir. 1957)). Plaintiff may file an amended complaint within thirty (30) days of this Opinion and Order. Plaintiff is ordered to comply with this court's Local Rules and is advised that failure to do so may result in the denial of leave to amend. *See Walsh v. Caliber Home Loans, Inc.*, 2021 WL 124684, at *1 (S.D.N.Y. Jan. 13, 2021) ("Failure to comply with the Local Rules is a sufficient ground to warrant denial of a motion.") (collecting cases).

## CONCLUSION

For the foregoing reasons, the court GRANTS IN PART and DENIES IN PART Defendant's motion for judgment on the pleadings (Doc. 17) and GRANTS Plaintiff's request for leave to amend (Doc. 18-2). Counts I and II, to the extent they allege design defect theories, and Counts III, V, and VI are DISMISSED WITHOUT PREJUDICE. Plaintiff may file an amended complaint within thirty (30) days of this Opinion and Order.

SO ORDERED.

Dated this 4th day of May, 2022.

Christina Reiss, District Judge
United States District Court