

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

LORISA PINEDA, individually and on behalf of all others similarly situated,	:	CIVIL ACTION
	:	
	:	
v.	:	NO. 24-1074
	:	
LAKE CONSUMER PRODUCTS, INC.	:	

MEMORANDUM OPINION

Henry, J.

September 22, 2025

This is a proposed class action suit brought by Plaintiff, Lorisa Pineda (“Pineda”), on behalf of herself and other similarly situated individuals, against Defendant, Lake Consumer Products, Inc. (“Lake”). Pineda claims that a certain Coal Tar Shampoo manufactured by Lake is not properly manufactured and tested, which resulted in the products containing “undisclosed, dangerously high levels of benzene,” a known carcinogen. Docket No. 40, Pl’s Memo in Opposition to Def’s Mtn to Dismiss (“Pl’s Memo”), p. 1. Pineda alleges that Lake’s failure to properly manufacture and test its Coal Tar Shampoo products, and failure to disclose the products’ alleged safety risks, resulted in the shampoo being adulterated or misbranded. These alleged failures led to Pineda’s Amended Complaint, which contains allegations of breach of express and implied warranty, fraud by misrepresentation, omission and concealment, negligent misrepresentation and omission, violations of consumer protection laws, negligence and unjust enrichment. Lake moved to dismiss the amended complaint for lack of standing, preemption and for allegedly presenting numerous claims that do not state legal theories on which Pineda can recover. For the reasons that follow, I find that the majority of Pineda’s Amended Complaint states plausible claims for relief; accordingly, Lake’s motion will be granted in part and denied in part.

I. FACTUAL BACKGROUND

Lake manufactures and sells over-the-counter shampoo products used to treat various scalp conditions. Docket No. 33, Am. Compl. ¶ 3. Among these products are MG217 Psoriasis Extra Strength, MG217 Psoriasis Medicated Conditioning 3% Coal Tar Shampoo, and MG217 Dandruff Therapeutic Shampoo. *Id.* ¶ 1. These products contain coal tar, which is a complex combination of hydrocarbons, phenols, and heterocyclic oxygen, sulfur and nitrogen compounds. *Id.* ¶ 35.

Pineda is a resident of Pennsylvania. She claims that she purchased “at least one or more” of these products and specifically alleges that she purchased MG217 Medicated Conditioning 3% Shampoo in July 2022 and February 2023. *Id.* ¶ 10. Pineda alleges that Lake’s Coal Tar Shampoo Products contain benzene, with test results indicating the presence of benzene in amounts between 5.64ppm and 10.30ppm. *Id.* ¶¶ 2, 43, 44. Benzene is allegedly hazardous to humans, and is primarily used as a solvent in the chemical and pharmaceutical industries and in gasoline. *Id.* ¶¶ 2, 17-20.

Pineda claims that there should not be any benzene present in Lake’s products at all and that the contamination was avoidable. *Id.* ¶¶ 27-28. Pineda further claims that the amount of benzene present is “dangerously high,” and that “she would not have paid money” for Lake’s products had she known about the presence of benzene. *Id.* ¶¶ 6, 11.

Pineda filed a Complaint, to which Lake filed a motion to dismiss. The Honorable John M. Gallagher granted Lake’s motion but allowed Pineda to amend her complaint in an opinion and order dated December 5, 2024. On December 20, 2024, Pineda filed her Amended Complaint, and on January 9, 2025, this matter was reassigned to me. On January 17, 2025, Lake

filed a motion to dismiss Pineda’s Amended Complaint, raising claims for dismissal based upon lack of standing, federal preemption and failure to state a claim. On March 31, 2025, oral argument was held on Lake’s motion, and it is now ready for decision.

II. LEGAL STANDARD

Under Fed.R.Civ.P. 12(b)(1), a court must grant a motion to dismiss if it lacks subject-matter jurisdiction to hear a claim. “A motion to dismiss for want of standing is ... properly brought pursuant to Rule 12(b)(1), because standing is a jurisdictional matter.” *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 243 (3d Cir. 2012), quoting *Ballentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007). In evaluating a Rule 12(b)(1) motion, a court must first determine whether the movant presents a facial or factual attack. *Mortensen v. First Fed. Sav. & Loan Ass’n*, 549 F.2d 884, 891 (3d Cir. 1977). In reviewing a facial challenge, which contests the sufficiency of the pleadings, “the court must only consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff.” *Gould Elec. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000).

In the instant matter, Lake’s Rule 12(b)(1) motion sets forth a facial attack because it contends that the Amended Complaint lacks sufficient factual allegations to establish standing. A facial attack on standing under Rule 12(b)(1) is evaluated under the same standard as a Rule 12(b)(6) motion. See *Constitution Party of Pa. v. Aichele*, 757 F.3d 347, 358 (3d Cir. 2014).

If a complaint fails to state a claim upon which relief can be granted, the court may dismiss the action pursuant to Fed. R. Civ. P. 12(b)(6). “To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim of 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)). “Only a complaint that states a plausible claim for relief survives a motion to dismiss . . . Threadbare recitals of the elements of a cause of action supported by mere conclusory statements, do not suffice.” *Iqbal*, 556 U.S. at 678-79. A claim satisfies the plausibility standard when the facts alleged “allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Burtch v. Millberg Factors, Inc.*, 662 F.3d 212, 220-21 (3d Cir. 2011) (citing *Iqbal*, 556 U.S. at 678).

In *Connelly v. Lane Construction Corp.*, 809 F.3d 780, 787 (3d Cir. 2016), the Third Circuit instructed district courts to apply a three-step analysis to 12(b)(6) motions: (1) “it must ‘tak[e] note of the elements [the] plaintiff must plead to state a claim;’” (2) “it should identify allegations that, ‘because they are no more than conclusions, are not entitled to the assumption of truth;’” and, (3) “[w]hen there are well-pleaded factual allegations, [the] court should assume their veracity and then determine whether they plausibly give rise to an entitlement of relief.” (quoting *Iqbal*, 556 U.S. at 675, 679). See *Burtch*, 662 F.3d at 221; *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011); *Santiago v. Warminster Township*, 629 F.3d 121, 130 (3d Cir. 2010).

III. ANALYSIS

In its Motion to Dismiss, Lake first argues that Pineda lacks standing to pursue injunctive relief or to assert multi-state claims. Docket No. 37, Def’s Memo in Support of Mtn to Dismiss (“Def’s Memo”), pp. 6-10. Next, it argues that the FDCA preempts Pineda’s state law claims, and that her fraud claims lack the requisite specificity. *Id.*, pp. 11-18. Lastly, Lake argues that its products are not improperly manufactured, that Pineda failed to allege either a plausible breach of express warranty or breach of implied warranty claim, and that Pineda’s claims for negligence and unjust enrichment must be dismissed. *Id.*, pp. 19-25.

A. STANDING

In its motion, Lake argues that Pineda lacks standing to pursue both injunctive relief and multi-state claims. Standing is a threshold jurisdictional requirement arising from Article III of the United States Constitution. U.S. Const. art. III, §2, cl. 1. To have standing, a “plaintiff must have suffered an injury in fact – a concrete and imminent harm to a legally protected interest, like property or money – that is fairly traceable to the challenged conduct and likely to be redressed by the lawsuit.” *Biden v. Nebraska*, 600 U.S. 477, 489 (2023). As will be discussed more fully below, I find that Pineda lacks standing to seek injunctive relief but does have proper standing to pursue multi-state claims.

1. Injunctive Relief

Lake argues that to be entitled to injunctive relief, a plaintiff is required to show a “sufficient likelihood that [they] will again be wronged in a similar way,” (quoting *City of Los Angeles v. Lyons*, 461 U.S. 95, 111 (1983)), and that the threat of suffering a concrete injury is actual and imminent. Def’s Memo, p. 6. According to Lake, because Pineda does not allege that she intends to purchase Coal Tar Shampoo again in the future, she “fails to allege any imminent threat.” Def’s Memo, p. 7. Lake argues that because Pineda now knows about the benzene in coal tar products, she “need only look at a product’s label to avoid being misled in the future.” *Id.*

Pineda contends that her claims go beyond allegations that she now knows about the benzene and cannot be misled again, as the Amended Complaint also alleges manufacturing and testing failures on the part of Lake, and that Lake should price its products differently because of said manufacturing and testing failures. Pineda does not, however, allege that she plans to purchase Lake’s Coal Tar Shampoo again.

A plaintiff pursuing standing for injunctive relief must demonstrate a future injury that is “realistic, sufficiently real and immediate – not speculative, conjectural or hypothetical.” *Pierre v. Healthy Beverage, LLC*, 2022 WL 596097, *5 (E.D. Pa. Feb. 28, 2022) (quoting *McNair v. Synapse Grp. Inc.*, 672 F.3d 213, 223 (3d Cir. 2012) (internal quotation marks omitted)). The Supreme Court has “repeatedly reiterated that ‘threatened injury must be *certainly impending* to constitute injury in fact,’ and that ‘[a]llegations of *possible* future injury’ are not sufficient.” *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 409 (2013) (emphasis in original) (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)).

In the instant matter, because of her failure to allege that she intends a future purchase of Coal Tar Shampoo, Pineda cannot establish an imminent threat sufficient to provide standing for the purposes of injunctive relief. As Pineda now knows that Coal Tar Shampoos contain benzene, she only needs to check the label on a product to avoid future harm. Further, through this lawsuit, she is also clearly aware of the allegedly deceptive labeling and improper manufacturing, testing and pricing practices from which she seeks future protection. “The law accords people the dignity of assuming that they act rationally, in light of the information they possess.” *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Liab. Litig.*, 903 F.3d 278, 293 (3d Cir. 2018) (citing *McNair*, 672 F.3d at 225). That same rationale applies here, as the law affords Pineda the dignity of assuming that she acts rationally, and that she will not act in such a way that she will again suffer the same alleged “injury.” Therefore, I conclude that Pineda does not have standing to seek injunctive relief.

2. Multi-State Claims

Lake also contends that Pineda neither resided in nor purchased shampoo in any state other than Pennsylvania, has therefore alleged no injury-in-fact in states other than Pennsylvania

and has no standing for claims in any state other than Pennsylvania. In response, Pineda argues that as a proposed class representative, she may represent people from Pennsylvania as well as people in any states whose law does not conflict with Pennsylvania.

It is true that Pineda has not alleged that she resided or purchased the Coal Tar Shampoo product in question anywhere other than Pennsylvania. However, Pineda is not pursuing claims personally in states other than Pennsylvania. Rather, as a proposed class representative, Pineda is seeking to represent people from Pennsylvania and from other states whose laws do not conflict with Pennsylvania.

There is a split in authority within the Third Circuit as to whether, at the motion to dismiss stage, a named plaintiff (such as Pineda) in a putative class action who herself has proper standing can bring claims on behalf of a putative class she seeks to represent under the laws of states the named plaintiff did not reside in nor suffer an injury in. Many courts find this question is more appropriate for class certification and deny motions to dismiss based upon the alleged lack of multi-state standing of the named plaintiff. See, *e.g.*, *Mayor and City Council of Baltimore v. Merck Sharp & Dohme Corp.*, 2023 WL 8018980 (E.D. Nov. 20, 2023) (finding that to dismiss multi-state claims on standing grounds at the motion to dismiss stage prior to understanding the breadth of the class would be premature); *Pierre v. Healthy Beverage, LLC*, 2022 WL 596097, at *8 (E.D. Pa. Feb. 28, 2022) (finding named plaintiffs had sufficient standing for nationwide claims and deferring decision on multi-state claims to class certification stage); *Garner v. Global Plasma Solutions, Inc.*, 590 F.Supp.3d 738, 743 (D. Del. 2022) (allowing plaintiff to bring claims on behalf of a multistate class and stating that “[a]ny problem with raising claims under several states’ laws goes to the propriety of class certification, not standing.”); *In re Generic Pharm. Pricing Antitrust Litig*, 368 F.Supp.3d 814, 831 (E.D. Pa.

2019) (declining to dismiss because state law claims of named plaintiffs “largely parallel those of the putative class members”); *Gress v. Freedom Mortg. Corp.*, 386 F.Supp.3d 455, 462 (M.D. Pa. June 2, 2019) (“Plaintiffs’ capacity to state claims under the laws of other states on behalf of putative class members ... is a matter to be decided under the rubric of Rule 23” and is not an issue of standing); *In re Liquid Aluminum Sulfate Antitrust Litig.*, 2017 WL 3131977, at *19 (D.N.J. July 20, 2017) (rejecting the defendants’ argument that named plaintiffs lack standing to bring state law claims under the laws of a state in which they do not reside). However, some courts find that such multi-state claims must be dismissed for lack of standing. See, e.g., *Ponzio v. Mercedes-Benz, USA, LLC*, 447 F.Supp.3d 194, 223 (D.N.J. 2020); *Semeran v. Blackberry Corp.*, 2016 WL 3647966, at *6 (D.N.J. July 6, 2016); *In re Niaspan Antitrust Litig.*, 42 F.Supp.3d 735, 758 (E.D. Pa. Sept. 5, 2014); *In re Magnesium Oxide Antitrust Litig.*, 2011 WL 5008090, at *10 (D.N.J. Oct. 20, 2011).

I am persuaded by the former approach and find that Pineda has standing to maintain multi-state claims in this matter. Lake does not argue that Pineda lacks standing to bring her own claims under Pennsylvania law. Furthermore, the claims under the laws of other states are based on Lake’s product and alleged general conduct that is identical to Pineda’s individual claims. Therefore, I find that Pineda’s ability to bring claims under the laws of other states on behalf of putative class members is an issue to be decided when addressing class certification. Therefore, Lake’s motion to dismiss as to Pineda’s standing will be denied.

B. PREEMPTION

Next, Lake argues that Pineda’s state law claims are preempted by the Food, Drug, and Cosmetic Act (“FDCA”), which prohibits states from establishing any requirement for over-the-counter (“OTC”) drugs “that is different from or in addition to, . . . a requirement under” the

FDCA. 21 U.S.C. § 379(r)(a). “Preemption is an affirmative defense that the defendant has the burden to prove.” *Lupian v. Joseph Cory Holdings LLC*, 905 F.3d 127, 130 (3d Cir. 2018) (citing *In re Asbestos Prods. Liab. Litig. (No. VI)*, 822 F.3d 125, 133 n.6 (3d Cir. 2016)). Accordingly, Lake has the burden of demonstrating that Pineda’s state-law claims are preempted by the FDCA.

To prevail on a Rule 12(b)(6) motion to dismiss based on an affirmative defense, as Lake seeks to do here, a defendant must show that “the defense is ‘apparent on the face of the complaint’ and documents relied on in the complaint.” *Lupian*, 905 F.3d at 130 (quoting *Bohus v. Restaurant.com, Inc.*, 784 F.3d 918, 923 n.2 (3d Cir. 2015)). To survive preemption, a plaintiff’s claim “must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA.” *McGee v. Johnson & Johnson*, 684 F.Supp.3d 371, 378-79 (W.D. Pa. July 26, 2023) (quoting *Scanlon v. Medtronic Sofamor Danek USA Inc.*, 61 F.Supp.3d 403, 411 (D. Del. 2014)). As applicable to Lake’s preemption argument, Pineda has asserted claims for both labeling and manufacturing issues. As will be discussed below, I find Pineda’s claims are preempted to the extent she argues Lake should have mentioned benzene on the Coal Tar Shampoo’s label but are not preempted based on Lake’s alleged failure to comply with current good manufacturing practices (“cGMPs”).

1. Express Preemption

Pursuant to the United States Constitution, “state laws that conflict with federal law are without effect.” *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008) (internal quotation marks omitted). However, federal preemption of state law “will not lie unless it is the clear and manifest purpose of Congress.” *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993) (internal quotation marks omitted).

To ensure uniformity in the regulation of over-the-counter (“OTC”) drugs, the FDCA contains a broad express preemption provision. That provision prohibits states from establishing “any requirement . . . (1) that relates to the regulation of a [nonprescription drug]; and (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under [the FDCA].” 21 U.S.C. §379r(a). Simply put, federal law expressly preempts any state law that applies to OTC drugs and purports to impose “labeling requirements that are not exactly the same as those set forth in the FDCA and its regulations.” *Critcher v. L’Oreal USA, Inc.*, 959 F.3d 31, 35-36 (2d Cir. 2020). But preemption only extends to manufacturers that comply with federal law; state-law claims that are premised on a “parallel” violation of federal law may proceed. *Medtronic v. Lohr*, 518 U.S. 470, 495 (1996) (claims based on state law are permissible where the statute's duties “parallel federal requirements”).

The FDA regulates OTC drugs such as the Coal Tar Shampoo products in question by issuing a comprehensive set of regulations called a monograph. 21 C.F.R. §§ 330.1, 358.701. The FDA issued the monograph for coal tar as to certain scalp conditions in 1991, and it specified, in relevant part, the permissible active ingredients and their concentrations, indications for use, warnings, directions and other mandatory labeling requirements. 21 C.F.R. § 358.50. The monograph expressly permitted coal tar as an active ingredient in Coal Tar Shampoo products. *Id.*, §§ 358.703, 357.710(a)(1).

The FDA’s regulations state that OTC Coal Tar drug products are “generally recognized as safe” and “not misbranded” if they comply with the monograph and “each general condition” set forth in 21 C.F.R. § 330.1. 21 C.F.R. § 358.701(a). Section 330.1 specifies that OTC drugs must meet the conditions described therein concerning manufacture, labeling, dosage, containers, and language permitted and prohibited. *Id.*, § 330.1(c)(1). Any product that fails to comply with

these requirements is considered “adulterated” or “misbranded” and cannot be sold. 21 U.S.C. §§ 331, 351, 352. An OTC drug that complies with all monograph requirements is not misbranded.

In the instant matter, Lake argues that because the FDA monograph lists coal tar as a permitted active ingredient in its Coal Tar Shampoo products and does not require manufacturers to mention the presence of benzene on the label, its Coal Tar Shampoo complies with the monograph. Lake argues that Pineda seeks to require Lake to “make disclosures not required under the FDCA that would conflict with the FDA’s conclusion that coal tar is safe.” Def’s Memo, p. 13. As Pineda’s claim would allegedly impose requirements that differ from and are in addition to those required by the FDCA, Lake argues that Pineda’s claims are preempted by federal law. *Id.*

In response, Pineda argues that she is not seeking to impose any labeling or marketing requirement on Lake that is non-parallel to federal requirements, but rather that Lake has failed to meet already-established federal requirements. Pl’s Memo, pp. 15-16. Pineda points out that more recently than the monograph, the FDA produced guidance stating that “[m]anufacturers should not use benzene in the manufacture of drugs.” Am. Compl. ¶ 49. Therefore, Pineda argues that Lake is already required by federal law to manufacture its products without benzene, and she is not seeking to add any “different” or “additional” labeling requirement that would be preempted by the FDCA.

The relevant monograph for OTC Coal Tar Shampoo products lists coal tar as an active ingredient and does not require manufacturers to warn consumers of benzene or mention benzene in any capacity on the label.¹ 21 C.F.R. §§ 358.50, 358.703, 357.710(a)(1). Accordingly, Pineda’s allegation that Lake should have warned about the presence of benzene on the product

¹ I may take judicial notice of regulatory materials such as monographs. Fed. R. Evid. 201; *Williams v. Galderma Lab’ys, L.P.*, 2024 WL 4213220, at *3 n. 2 (N.D. Ill. Sept. 17, 2024).

label is preempted because it would be an “addition” to the label not required by federal law. 21 U.S.C. § 379r(a). Pineda’s claims are expressly preempted by the FDCA labeling requirement for Coal Tar Shampoo products to the extent they are based on Lake’s failure to disclose the presence of benzene on the product label. No matter how Pineda attempts to frame her claims, her Amended Complaint seeks to impose liability on Lake through a finding that it should have labeled the Products differently – not as required by the FDCA – to warn consumers of the presence of benzene. That is precisely the type of claim that is expressly preempted by the FDCA, and therefore, Pineda’s labeling claims are stricken from her Amended Complaint.

2. Implied preemption

I have already found that Plaintiff’s claims are expressly preempted to the extent they allege labeling issues, such as a failure to disclose the presence of benzene on the label of the Coal Tar Shampoos. However, a state-law claim not expressly preempted by the FDCA may still be impliedly preempted. See *Buckman Co. v. Pls.’ Legal Comm.*, 531 U.S. 341, 352-53 (2001). Section 337(a) of the FDCA provides that “proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.” See 21 U.S.C. § 337(a). That language shows “that Congress intended that the [FDCA] be enforced exclusively by the Federal Government.” See *Buckman Co.*, 531 U.S. at 352. Therefore, § 337(a) preempts any state-law claim that exists “solely by virtue” of an FDCA infraction, although a state-law claim based on “traditional state tort law” that happens to “parallel” the FDCA is outside of § 337(a)’s preemptive scope. See *id.*

As stated above, FDA regulations require a product to be “manufactured in compliance with current good manufacturing practices, as established by parts 210 and 211,” see 21 C.F.R. § 330.1(a), and that a product “contains suitable active ingredients which are safe in amounts administered,” 21 C.F.R. § 330.1(e). “[A]llegations based upon specific cGMPs, as incorporated

by parallel state regulatory frameworks, may ‘survive preemption at the motion to dismiss stage.’” *In re Chantix*, 735 F.Supp.3d 352, 388-89 (S.D.N.Y. May 28, 2024) (quoting *McGee v. Johnson & Johnson*, 684 F.Supp.3d 371, 381-82 (W.D. Pa. 2023)).

To survive preemption, Pineda must identify “what regulations under the cGMPs . . . parallel [her] state law claim, *Mendez v. Shah*, 94 F.Supp.3d 633, 639 (D.N.J. 2015), and should not “simply provide a laundry list of alleged cGMP violations,” which is “too general to be capable of enforcement.” *Silver v. Medtronic, Inc.*, 236 F.Supp.3d 889, 897 (M.D. Pa. 2017) (internal quotations omitted). Here, Pineda has identified several cGMPs that were allegedly violated in connection with the manufacture of the Coal Tar Shampoo products. Specifically, Pineda cites to the cGMP that requires a manufacturer to have “written procedures for production and process control designed to assure that the drug products have the identity, strength, quality and purity they purport . . . to possess,” Am. Compl. ¶ 24 (citing to 21 C.F.R. § 211.100), “laboratory controls” must include “establishment of scientifically sound and appropriate specifications. . . to assure that . . . drug products conform to appropriate standards of identity, strength, quality, and purity,” Am. Compl. ¶ 25 (citing to 21 C.F.R. § 211.160), and laboratory records that include “data derived from all tests necessary to assure compliance with established specifications and standards,” and a “statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the . . . drug product tested. Am. Compl. ¶ 26 (citing to 21 C.F.R. § 211.194(a)(6)). I find these allegations to be sufficient “given the information to which Plaintiff has access at this early stage of litigation, . . . to survive preemption at the motion to dismiss stage.” *McGee*, 684 F.Supp.3d at 381. Accordingly, I find that Pineda’s claims are not preempted to the extent they are based upon Lake’s alleged failure to comply with cGMPs.

C. BREACH OF WARRANTIES

Next, Lake argues that Pineda's claims for breach of express warranty (Count 1) and breach of implied warranty (Count 2) should be dismissed.

Under Pennsylvania law, "[a]ny 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 creates an express warranty that the goods shall conform to the affirmation or promise." *Drumheller v. Johnson & Johnson*, 2021 WL 1853407, at*14 (E.D. Pa. May 10, 2021) (quoting 13 Pa.C.S. § 2313(a)(1)). A promise becomes the basis of the bargain if the plaintiff can prove "that she read, heard, saw or knew of the advertisement containing the affirmation of facts or promise." *Starks v. Coloplast Corp.*, 2014 WL 617130, at *6 (E.D. Pa. Feb. 18, 2014) (quoting *Parkinson v. Guidant Corp.*, 315 F.Supp.2d 741, 752 (W.D. Pa. 2004)). Absent a demonstration that a promise or affirmative statement was made, how or by whom the promise was made, or what was in fact promised, a claim for breach of express warranty is not sufficiently plead. *Gross v. Stryker Corp.*, 858 F.Supp.2d 466, 501-02 (W.D. Pa. Mar. 14, 2012).

In the instant matter, Lake argues that Pineda has not alleged any affirmation of fact or promise made by Lake, has not pled the content of any express warranty, how or when the warranty was made, that it became a basis of the bargain, or that it was directed at Pineda. Def's Memo, p. 21. However, a review of the Amended Complaint shows that Pineda has pled sufficient detail at this stage of the case to survive Lake's motion to dismiss. The Amended Complaint alleges that Lake represented that the Products were properly manufactured and tested and complied with the cGMPs. Am. Compl. ¶¶ 72-73. The Amended Complaint also states that Lake made statements in the product labeling and packaging that described the product as safe and effective and made no mention of the presence of benzene. *Id.* ¶ 73. The Amended

Complaint also states that these affirmative representations became part of the “basis of the bargain” in every purchase made by Pineda. *Id.* ¶ 76. Lake directed consumers to use the product at least twice a week for “best results,” when using the products in such a manner allegedly increased the risk of exposure to undisclosed benzene. *Id.* ¶ 74. I find that these allegations regarding the product deviating from the quality expected of them and not being safe as intended are sufficient to plead a breach of express warranty claim, as they demonstrate that an affirmative statement was made by Lake in its packaging, marketing and advertising materials that the products were safe and of the quality expected of them. Accordingly, Lake’s motion to dismiss Count 2 for breach of express warranty will be denied.

Next, as to breach of implied warranty, Plaintiff must show: 1) the existence of the implied warranty; 2) breach of the implied warranty; 3) a causal connection between the defendant's breach and the plaintiff's injury or damage; and 4) the extent of loss proximately caused by the defendant's breach. *Byrd v. Essex Silverline Corp.*, 2008 WL 81887, at *3 (E.D. Pa. Jan. 8, 2008). To sufficiently allege breach of the implied warranty, the product purchased must be unfit for its ordinary purpose. See 13 Pa. C.S.A. § 2314(b)(3); *Weinberg v. Legion Athletics, Inc.*, 683 F.Supp.3d 438, 451 (July 21, 2023.) The Pennsylvania Supreme Court has noted that, “[t]he concept of merchantability does not require that the goods be the best quality, or the best obtainable, but it does require that they have an inherent soundness which makes them suitable for the purpose for which they are designed, that they may be free from significant defects, that they perform in the way that goods of that kind should perform, and that they be of reasonable quality within expected variations and for the ordinary purpose for which they are used.” *Bruno v. Roundhouse Cycles Inc.*, 750 F. Supp. 3d 501, 511 (W.D. Pa. 2024) (quoting *Gall by Gall v. Allegheny County Health Dep’t*, 555 A.2d 786, 789-90 (Pa. 1989)); see also

Phillips, 883 A.2d at 444. In other words, what is required is evidence “only that the goods upon delivery were not of a merchantable quality or fit for their particular purpose.” *Bruno*, 750 F.Supp.3d at 511 (quoting *Vlases v. Montgomery Ward & Co.*, 377 F.2d 846, 850 (3d Cir. 1967)).

In support of its argument that Pineda’s breach of implied warranty claim should be dismissed, Lake argues that Pineda did not “plausibly allege that the specific bottles of Coal Tar Shampoo that she purchased were manufactured incorrectly,” but rather that “bottles of Coal Tar Shampoo, bearing the same expiration date and partial lot number as the bottles she purchased contained benzene.” Def’s Memo, p. 22. As Lake sees it, Pineda has pled that the entire product formula is defective, which it argues is an attempt to plead a defective design theory through a breach of implied warranty claim, which is impermissible in Pennsylvania. See *Tatum v. Takeda Pharms. N. Am., Inc.*, 2012 WL 5182895, at *3 (E.D. Pa. Oct. 19, 2012) (claims for breach of implied warranty or merchantability or fitness are not cognizable under Pennsylvania law to the extent they are based on a design defect or failure to warn).

First, I do not read the Amended Complaint to allege that the entire product formula is defective, thereby pleading a defective design theory. Rather, the Amended Complaint sets forth that at a minimum, at least one Product purchased by Pineda bore the same lot number prefix and expiration date as a sample that was shown to contain high levels of benzene. At the current stage of the case, I find that Pineda has sufficiently pled the necessary elements to support a breach of implied warranty claim. Pineda pled that the presence of benzene made the Coal Tar Shampoo Products that she purchased unfit for their ordinary purpose. Accordingly, Lake’s motion will be denied as to the breach of implied warranty.

D. FRAUD

Next, Lake alleges that Pineda's claim of fraud in Count 3 based upon affirmative misrepresentation, omission and concealment must fail because Pineda failed to plead the elements with requisite specificity. Def's Memo, pp. 17-18. To prevail on a fraud claim, Pineda must establish: "(1) a representation; (2) which is material to the transaction at hand; (3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; (4) with the intent of misleading another into relying on it; (5) justifiable reliance on the misrepresentation; and, (6) the resulting injury was proximately caused by the reliance." *Cohen v. Johnson & Johnson*, 634 F. Supp. 3d 216, 234 (W.D. Pa. 2022) (citing *Bortz v. Noon*, 556 Pa. 489, 499 (1999)).

Under Federal Rule of Civil Procedure 9(b), "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). This pleadings standard also applies to Pineda's negligent misrepresentation claim. See *Petruska v. Gannon Univ.*, 462 F.3d 294, 310 (3d Cir.2006) (explaining that a state law fraudulent misrepresentation claim must be pled with particularity under Rule 9(b)). To satisfy Rule 9(b)'s pleading requirements, a plaintiff must "plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation." *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir.2007). "The purpose of Rule 9(b) is to provide a defendant with notice of the precise misconduct with which he or she is charged and to prevent false or unsubstantiated charges." *Schmidt v. Ford Motor Co.*, 972 F.Supp.2d 712, 720 (E.D.Pa.2013) (quoting *Cooper v. Broadspire Servs., Inc.*, 2005 WL 1712390, at *5 (E.D.Pa. July 20, 2005)). Here, Pineda sufficiently identifies the product and alleged misrepresentations, thereby putting Lake on notice of its alleged wrongdoing. As correctly stated by Pineda, the

Amended Complaint sets forth the following relevant information: (i) Defendant Lake (the “who”); (ii) wrongly manufactured and sold Coal Tar Shampoo Products that did not comply to cGMPs because they improperly contained benzene, a substance associated with serious risks (the “what”); (iii) but nevertheless Lake sold its Coal Tar Shampoo Products to Plaintiff and other class members in Pennsylvania and throughout the United States (the “where”); (iv) since at least July 2022 in Plaintiff’s case, and likely earlier, through the present (the “when”); (v) for the purpose of duping customers into paying for contaminated, non-cGMP compliant Coal Tar Shampoo Products to deceptively boost Lake’s own profits (the “how” and “why”). See Pl’s Memo, p. 23n (citing Am. Compl. ¶¶ 1-6, 8, 10-12, 58-59.) These allegations are sufficient to meet Rule 9(b)’s particularity standard.

In further objection to Pineda’s fraud claim, Lake also argues that Pineda’s allegation regarding reliance (an element of a fraud claim) is “patently implausible or unrealistic,” as the products’ warning label warned that it contained coal tar, which is known to cause cancer. Def’s Memo, pp. 17-18. Lake argues that it is unrealistic for Pineda to assert that she reasonably relied on the coal tar cancer warning and still used the product but would not have used the product had she known of the risk of cancer from benzene. However, this argument overlooks the fact that benzene exposure has a plethora of other alleged side effects in addition to cancer. Am. Compl. ¶ 19. The fact that the label may have put Pineda on notice regarding the risk of cancer from exposure to coal tar does not address Pineda’s argument that she should have been put on notice of benzene and all its other many alleged serious health effects. Accordingly, I find this argument unavailing, and Lake’s motion will be denied as to Pineda’s fraud claim.²

² Lake’s argument regarding Pineda’s fraud claim contains a brief paragraph stating that for the same reasons Pineda’s fraud claim must be dismissed, Pineda’s claims for negligent misrepresentation are subject to dismissal. Def’s Memo, p. 18. Under Pennsylvania law, to prove negligent misrepresentation, a plaintiff must prove: “(1) a misrepresentation of a material fact; (2) made under circumstances in which the misrepresenter ought to have known

E. NEGLIGENCE

Lake also argues that Pineda's claim for negligence must be dismissed because in order to recover in tort, she must plead physical injury or property damage, not just economic losses, which Pineda has failed to do. Def's Memo, p. 23. It is true that "[t]he general rule of law is that economic losses may not be recovered in tort absent physical injury or property damage." *Spivack v. Berks Ridge Corp., Inc.*, 586 A.2d 402, 405 (Pa. Super. 1990). This is known as Pennsylvania's economic loss doctrine. However, this doctrine only applies to situations in which "a party in privity of contract with another suffers an injury to a product itself, resulting in a purely economic loss." *Roamingwood Sewer & Water Ass'n v. Nat'l Diversified Sales, Inc.*, 720 F. Supp. 3d 353, 363–64 (M.D. Pa. 2024) (citing *Duquesne Light Co. v. Westinghouse Elec. Corp.*, 66 F.3d 604, 620 (3d Cir. 1995)).

There is nothing contained in the Amended Complaint that leads me to conclude that Pineda and Lake were in privity of contract with each other so as to require application of the economic loss doctrine to bar Pineda's negligence claim. I find that whether privity of contract existed between the parties is a fact question not appropriate for resolution in a motion to dismiss. Accordingly, Lake's motion will be denied as to Pineda's negligence claim.

F. UNJUST ENRICHMENT

Lastly, Lake argues that Pineda's claim for unjust enrichment must be dismissed because "a claim for unjust enrichment does not lie where the plaintiff admits they received and used the service or goods at issue." Def's Memo, p. 24 (citing *Mazur v Milo's Kitchen, LLC*, 2013 WL

of its falsity; (3) with an intent to induce another to act on it; and (4) which results in injury to a party acting in justifiable reliance on the misrepresentation." *Bortz v. Noon*, 729 A.2d 555, 561 (Pa. 1999) (citing *Gibbs v. Ernst*, 647 A.2d 882, 890 (Pa. 1994)). I find that the negligent misrepresentation claim contained in Pineda's Amended Complaint is sufficiently factually specific to properly plead the above elements. Accordingly, Lake's motion to dismiss will be denied as to Pineda's negligent misrepresentation claim.

3245203, at *10 (W.D. Pa. June 25, 2013)). Specifically, Lake argues that to be successful on an unjust enrichment claim, Pineda must allege that Lake “refused to provide a service or goods after [Pineda] provided [Lake] with a benefit,” Def’s Memo, p. 24 (citing *Tatum*, 2012 WL 5182895, at *5). Obviously, Pineda cannot make such an allegation, as she purchased and used the Coal Tar Shampoo product after providing the benefit (payment) to Lake.

In response to this argument, Pineda argues that the allegations in the Amended Complaint are sufficient to plead unjust enrichment, as it alleges that Lake derived financial benefits from Pineda’s purchases, that Lake enticed these purchases through fraudulent pretenses, and that it would be unjust for Lake to retain these payments it received. Pl’s Memo, p. 278 (citing Am. Compl. ¶¶ 155-157.)) Pineda further argues that the cases cited by Lake for the proposition that unjust enrichment cannot be pled if a product was kept or used are “outliers,” as “many other courts permit unjust enrichment claims . . . for myriad products that are kept or used.” Pl’s Memo, p. 27.

To state a claim for unjust enrichment in Pennsylvania, Pineda must show 1) a benefit was conferred on Lake; 2) Lake retained the benefit; and 3) it would be inequitable for Lake to retain the benefit without paying full value for it. See *Lampe v. Lampe*, 665 F.3d 506, 520 (3d Cir. 2011). Although it is true that Pineda has pled the elements of an unjust enrichment claim, numerous courts in Pennsylvania have found that where the purchaser of a consumer product was able to use the product for its intended purpose, the purchaser could not then bring an unjust enrichment claim. See *Mazur*, 2013 WL 3245203, at *10 (finding that despite the fact that plaintiff was dissatisfied with a product, she received and used the product, thus an unjust enrichment claim was not available); *Tatum v. Takeda Pharm. North America, Inc.*, 2012 WL 5182895, at *5 (E.D.Pa. Oct. 19, 2012) (finding that the plaintiff’s claim that the Defendants

were aware of the risks of a drug but chose not to disclose them failed to state a claim for unjust enrichment because there was no allegation that the Defendants failed to provide the drugs once they were purchased by the Plaintiffs); *In re Avandia Mktg., Sales Practices and Prod. Liab. Litig.*, 2011 WL 4007908, at *2 (E.D. Pa. Sept. 7, 2011) (finding that the plaintiff's allegations that the product at issue was not safe failed to state a claim for unjust enrichment where the plaintiff received the product for which he paid). See also, *Drumheller v. Johnson & Johnson*, 2021 WL 1853407, at *17–18 (E.D. Pa. May 10, 2021); *McGrain v. C.R. Bard, Inc.*, 551 F.Supp.3d 529, 546 (E.D. Pa. July 30, 2021); *Brown v. C.R. Bard, Inc.*, 2022 WL 420914 (E.D. Pa. Feb. 11, 2022); *Bostic v. Ethicon, Inc.*, 2022 WL 952129, at *16 (E.D. Pa. Mar. 29, 2022); *Vey v. Amazon.com*, 2024 WL 2396840 (W.D. Pa. May 23, 2024).

Here, the Amended Complaint does not allege that Lake refused to provide Pineda with the Coal Tar Shampoo product in exchange for her payment. Rather, Pineda paid for the Coal Tar Shampoo Product, Lake accepted that payment and provided her with the product, and Pineda kept and/or used the product. The instant set of facts parallels caselaw in this jurisdiction that states a claim for unjust enrichment must be dismissed when the plaintiff received the product for which she paid. Therefore, I will grant Lake's motion to dismiss as to Pineda's unjust enrichment claim with prejudice, as any amendment of said claim would be futile.

III. CONCLUSION

For the reasons discussed more fully above, Defendant's Motion to Dismiss is granted in part and denied in part. An appropriate Order will follow.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

LORISA PINEDA, individually and on	:	
behalf of all others similarly situated,	:	CIVIL ACTION
	:	
	:	
v.	:	NO. 24-1074
	:	
LAKE CONSUMER PRODUCTS, INC.	:	

ORDER

AND NOW, this 22nd day of September 2025, upon consideration of the Motion to Dismiss filed by Defendant, Lake Consumer Products, Inc. (Docket No. 37), as well as Plaintiff's opposition thereto, and all Notices of Supplemental Authority, and after oral argument being held, it is hereby **ORDERED** as follows:

1. The Motion to Dismiss of Defendant, Lake Consumer Products, Inc., (Docket No. 37), is **GRANTED** in part and **DENIED** in part.

2. Defendant's Motion is **GRANTED** to the extent it seeks to dismiss all claims contained in the Amended Complaint flowing from allegations that Defendant was required to warn of the presence of benzene on the product label as expressly preempted by the FDCA. All such labeling claims are **DISMISSED** from Plaintiff's Amended Complaint with prejudice.

3. Defendant's Motion is **GRANTED** as to Plaintiff's claim for unjust enrichment and Count VII is **DISMISSED** from Plaintiff's Amended Complaint with prejudice.

4. Defendant's Motion is **DENIED** in all other respects.

5. Defendant shall file an Answer to the Amended Complaint within twenty days of the date of this Order.

BY THE COURT:

/s/ Catherine Henry

CATHERINE HENRY, J.