NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JUAN HUERTAS, EVA MISTRETTA, JOSE VILLARREAL, DON PENALES, JR., MIKE POOVEY, JEREMY WYANT, CHRISTOPHER CADORETTE, JONATHAN MARTIN, SEAN STEINWEDEL, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

BAYER U.S., LLC,

Defendant.

Civil Action No: 21-20021 (SDW)(CLW)

OPINION

May 23, 2023

WIGENTON, District Judge.

Before this Court is Defendant Bayer, LLC's ("Bayer" or "Defendant") Motion to Dismiss, (D.E. 39), Plaintiffs Juan Huertas, Eva Mistretta, Jose Villarreal, Don Penales, Jr., Mike Poovey, Jeremy Wyant, Christopher Cadorette, Jonathan Martin, and Sean Steinwedel's (collectively, "Plaintiffs") First Amended Class Action Complaint ("FAC"), (D.E. 29), pursuant to Federal Rules of Civil Procedure ("Rule") 12(b)(1) and 12(b)(6). Jurisdiction is proper pursuant to 28 U.S.C. § 1332. Venue is proper pursuant to 28 U.S.C. § 1391. This opinion is issued without oral argument pursuant to Rule 78. For the reasons stated herein, the Motion to Dismiss is **GRANTED**.

I. BACKGROUND AND PROCEDURAL HISTORY

A. Facts Underlying the Allegations

Defendant Bayer U.S., LLC is a Delaware corporation, headquartered in Whippany, New Jersey. (D.E. 29 ¶ 18.) Defendant manufactures Lotrimin and Tinactin sprays, which are "anti-fungal drug products regulated by the United States Food & Drug Administration ("FDA")[,] pursuant to the federal Food, Drug[,] and Cosmetics Act ("FDCA")," and sells them throughout the United States. (*Id.* ¶¶ 1–2.) "Lotrimin is the brand name for Clotrimazole," an antifungal spray or cream that treats various skin infections. (*Id.* ¶ 23.) "Tinactin is the brand name for Tolnaftate," an antifungal spray or cream that treats athlete's foot or ringworm. (*Id.* ¶ 24.)

In October 2021, Bayer announced a voluntary recall of certain Lotrimin and Tinactin products, specifically recalling unexpired "spray products with lot numbers beginning with TN, CV, or NAA, distributed between September 2018 to September 2021," because of "the presence of benzene in some samples of the products" (the "Products"). (*Id.* ¶ 33; *see also id.* n.9.) Bayer required consumers seeking a refund to "visit one of . . . two websites" and complete forms on the websites, and then "provide a photograph of each product for which consumers seek a refund . . . ." (*Id.* ¶ 65.) Bayer also advised consumers not to use the Products and confirmed that "[b]enzene is *not* an ingredient in any of Bayer Consumer Health products." (*Id.* ¶¶ 33, 35 (alteration in original).)

Also in October 2021, "pharmaceutical testing laboratory Valisure, LLC ("Valisure") tested a sampling of Lotrimin and Tinactin Products," and "found detectable levels of benzene in 12 of the 13 Products tested [(the "Tested Products")], with benzene levels that significantly exceeded the guidelines established by the FDA of 2 parts ppm for drug product[s] with a

significant therapeutic advance in 11 of the 13 Products Valisure tested."[1] (*Id.* ¶¶ 37–38 (internal quotations omitted).) Several samples exceeded FDA limits for benzene, and in one of the samples, the level of benzene was "105 times the 2ppm strict limit set by the FDA for drug products). (*Id.* ¶ 40.)

B. Facts Pertinent to Individual Plaintiffs

1. Juan Huertas

In or about August 2021, Plaintiff Juan Huertas ("Huertas"), a resident of New York, "purchased a canister of Defendant's Lotrimin Anti-Fungal (AF) Athlete's Foot Deodorant Powder Spray" with lot number TN009K7,[2] from a CVS in New York. (*Id.* ¶ 80.) Huertas reviewed the Product's label and disclosures and "used the Product as directed on the label." (*Id.*) Huertas did not learn of the recall before using the product.[3] (*Id.*) At some point after his purchase, Huertas learned of benzene contamination in Defendant's products "and was unable to use the remaining portion of his Lotrimin product . . . ."[4] (*Id.* ¶ 81.) Huertas subsequently purchased boric acid to treat an athlete's foot condition. (*Id.*)

2. Eva Mistretta

In or about July 2021, Plaintiff Eva Mistretta ("Mistretta"), a resident of New York,

[1] According to the Complaint, Valisure's testing detected Benzene in the following Tested Products lot numbers: TN005K8, TN006MX, TN0047R, TN006TD, TN004BX, TN008CY, TN008CZ, TN007TJ, TN008CT, TN006AT, TN0067A, and TN008CU. (*Id.* ¶ 41.)

[2] This lot number corresponds to a product included in Defendant's recall notice, (*id.* ¶ 33), but not to a lot number in the Tested Products, (*id.* ¶ 41).

[3] The recall issued approximately three months after Huertas's purchase. The Complaint does not specify when, how often, or for how long Huertas used the Product. (*Id.* ¶ 33; *see also id.* n.9.)

[4] The Complaint does not specify how or when Huertas learned of the issue, whether he discarded the remnant of the product specifically because he learned of the recall, whether he pursued a remedy under the recall, or whether the product had worked during use. (*Id.* ¶ 81.)

"purchased a canister of Defendant's Tinactin Athlete's Foot Liquid Spray" with lot number CV01E2X,[5] from a Walgreens in New York. (*Id.* ¶ 82.) Mistretta reviewed the Product's labels and disclosures, and "used the Product as directed on the label." (*Id.*) Mistretta did not learn of the recall prior to using the product.[6] (*Id.*) At some point after her purchase, Mistretta learned of benzene contamination in Defendant's products "and was unable to use the remaining portion of her Tinactin product . . . ."[7] (*Id.* ¶ 83.)

3. Jose Villarreal

Sometime "[b]etween September 2018 and September 2021, Plaintiff Jose Villarreal ("Villarreal"), a resident of Missouri, came into possession[8] of Defendant's "Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray"[9] in Missouri. (*Id.* ¶ 84.) Villarreal reviewed the Product's label and disclosures, and "used the Product as directed on the label." (*Id.*) At some point after obtaining the product, Villarreal learned of benzene contamination in Defendant's products "and was unable to use the remaining portion of his Product . . . ."[10] (*Id.* ¶ 85.)

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[5] This lot number corresponds to a product included in Defendant's recall notice, (*id.* ¶ 33), but not to a lot number in the Tested Products, (*id.* ¶ 41).

[6] The recall issued approximately four months after Mistretta's purchase. The Complaint does not specify when, how often, or for how long Mistretta used the Product. (*Id.* ¶ 33; *see also id.* n.9.)

[7] The Complaint does not specify how or when Mistretta learned of the issue, whether she discarded the remnant of the product specifically because she learned of potential benzene contamination, whether she pursued a remedy under the recall, or whether the product had worked during use. (*Id.* ¶ 83.)

[8] This paragraph of the Complaint fails to present clear facts as it first does not specify that Villarreal purchased the product, then discusses "each product he purchased," despite only naming one product and not specifying that it had been purchased, and then later discusses a purchase of Lotrimin, despite having not established that the product had actually been purchased. (*Id.* ¶ 84.)

[9] The Complaint does not specify a lot number for the product purchased. (*Id.*)

[10] The Complaint does not specify how or when Villarreal learned of the issue, whether he discarded the remnant of the product specifically because he learned of potential benzene contamination, whether he learned of the recall and if so when, whether he pursued a remedy under the recall, or whether the products had worked during use. (*Id.* ¶ 85.)

4. Jeremy Wyant

Sometime "[b]etween September 2018 and September 2021, Plaintiff Jeremy Wyant ("Wyant"), a resident of Indiana purchased Defendant's "Lotrimin Anti-Fungal Jock Itch (AFJI) Athlete's Foot Powder Spray,"[11] "Tinactin Jock Itch (JI) Powder Spray," with lot number TN00273,[12] "Tinactin Athlete's Foot Powder Spray,"[13] and "Tinactin Athlete's Foot Liquid Spray"[14] in Indiana. (*Id.* ¶ 86.) Wyant reviewed the Products' labels and disclosures, and "used the Products as directed on the labels." (*Id.*) At some point after his purchase, Wyant learned of benzene contamination in Defendant's products "and was unable to use the remaining portion[s] of his Products . . . ."[15] (*Id.* ¶ 87.)

5. Mike Poovey

Sometime "[b]etween September 2018 and September 2021, Plaintiff Mike Poovey ("Poovey"), a resident of South Carolina, purchased Defendant's "Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray," with lot number TN001NK,[16] in South Carolina. (*Id.* ¶ 88.) Poovey reviewed the product's label and disclosures, and "used the Product as directed on the label." (*Id.*)

[11] The Complaint does not specify a lot number for the product purchased. (*Id.*)

[12] This lot number corresponds to a product included in Defendant's recall notice, (*id.* ¶ 33), but not to a lot number in the Tested Products, (*id.* ¶ 41).

[13] The Complaint does not specify a lot number for the product purchased. (*Id.*)

[14] The Complaint does not specify a lot number for the product purchased. (*Id.*)

[15] The Complaint does not specify how or when Wyant learned of the issue, whether he discarded the remnants of the products specifically because he learned of potential benzene contamination, whether he learned of the recall and if so when, whether he pursued a remedy under the recall, or whether the products had worked during use. (*Id.* ¶ 87.)

[16] This lot number corresponds to a product included in Defendant's recall notice, (*id.* ¶ 33), but not to a lot number in the Tested Products, (*id.* ¶ 41).

At some point after his purchase, Poovey learned of benzene contamination in Defendant's products "and was unable to use the remaining portion of his Lotrimin product . . . ."[17] (*Id.* ¶ 89.)

6. Christopher Cadorette

Sometime "[b]etween September 2018 and September 2021, Plaintiff Christopher Cadorette ("Cadorette"), a resident of Massachusetts, "purchased canisters of Defendant's Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray"[18] and "Lotrimin Anti-Fungal Jock Itch (AFJI) Athlete's Foot Powder Spray"[19] in Massachusetts. (*Id.* ¶ 90.) Cadorette reviewed the products' labels and disclosures, and "used the Products as directed on the label[s]." (*Id.*) At some point after his purchase, Cadorette learned of benzene contamination in Defendant's products "and was unable to use the remaining portion of his Lotrimin product . . . ."[20] (*Id.* ¶ 91.)

7. Sean Steinwedel

Sometime "[b]etween September 2018 and September 2021, Plaintiff Sean Steinwedel ("Steinwedel"), a resident of Delaware, purchased canisters of Defendant's "Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray,"[21] "Lotrimin Anti-Fungal Jock Itch (AFJI) Athlete's Foot

[17] The Complaint does not specify how or when Poovey learned of the issue, whether he discarded the remnant of the product specifically because he learned of potential benzene contamination, whether he learned of the recall and if so when, whether he pursued a remedy under the recall, or whether the product had worked during use. (*Id.* ¶ 89.)

[18] The Complaint does not specify a lot number for the product purchased. (*Id.*)

[19] The Complaint does not specify a lot number for the product purchased. (*Id.*)

[20] The Complaint does not specify how or when Cadorette learned of the issue, which portion or portions of which product or products he was unable to use (the Complaint specifies that he was unable to use "the remaining portion" of his "Lotrimin product," not "portions" of "products"), whether he discarded the remnant or remnants of the product or products specifically because he learned of potential benzene contamination, whether he learned of the recall and if so when, whether he pursued a remedy under the recall, or whether the product or products had worked during use. (*Id.* ¶ 91.)

[21] The Complaint does not specify a lot number for the product purchased. (*Id.*)

Powder Spray,"[22] "Lotrimin Anti-Fungal (AF) Athlete's Foot Deodorant Powder Spray,"[23] "Tinactin Jock Itch (JI) Powder Spray,"[24] and "Tinactin Athlete's Foot Deodorant Powder Spray"[25] in Delaware. (*Id.* ¶ 92.) Steinwedel reviewed the products' labels and disclosures, and "used the Products as directed on the labels." (*Id.*) At some point after his purchase, Steinwedel learned of benzene contamination in Defendant's products "and was unable to use the remaining portion[s] of his Products . . . ."[26] (*Id.* ¶ 93.)

8. Don Penales, Jr.

Sometime "[b]etween September 2018 and September 2021, Plaintiff Don Penales, Jr. ("Penales"), a resident of California purchased canisters of Defendant's "Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray,"[27] "Lotrimin AF Athlete's Foot Liquid Spray,"[28] "Tinactin Athlete's Foot Deodorant Powder Spray,"[29] and "Tinactin Athlete's Foot Liquid Spray"[30] in California. (*Id.* ¶ 94.) Penales reviewed the products' label and disclosures, and "used the Products as directed on the labels." (*Id.*) At some point after his purchase, Penales learned of benzene

[22] The Complaint does not specify a lot number for the product purchased. (*Id.*)

[23] The Complaint does not specify a lot number for the product purchased. (*Id.*)

[24] The Complaint does not specify a lot number for the product purchased. (*Id.*)

[25] The Complaint does not specify a lot number for the product purchased. (*Id.*)

[26] The Complaint does not specify how or when Steinwedel learned of the issue, whether he discarded the remnants of the products specifically because he learned of potential benzene contamination, whether he learned of the recall and if so when, whether he pursued a remedy under the recall, or whether the products had worked during use. (*Id.* ¶ 93.)

[27] The Complaint does not specify a lot number for the product purchased. (*Id.*)

[28] The Complaint does not specify a lot number for the product purchased. (*Id.*)

[29] The Complaint does not specify a lot number for the product purchased. (*Id.*)

[30] The Complaint does not specify a lot number for the product purchased. (*Id.*)

contamination in Defendant's products "and was unable to use the remaining portion[s] of his Products . . . ."[31] (*Id.* ¶ 95.)

9. Jonathan Martin

Sometime "[b]etween September 2018 and September 2021, Plaintiff Jonathan Martin ("Martin"), a resident of California purchased Defendant's "Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray"[32] in California. (*Id.* ¶ 96.) Martin reviewed the product's label and disclosures.[33] (*Id.*) At some point after his purchase, Martin learned of benzene contamination in Defendant's products "and was unable to use the remaining portion of his Lotrimin Product . . . ."[34] (*Id.* ¶ 97.)

C. Plaintiffs' Allegations

Plaintiffs assert that benzene is "a carcinogenic impurity that has been linked to leukemia and other cancers," (*id.* ¶¶ 1, 27, 29),[35] and that "[t]here is probably no safe level of exposure to

[31] The Complaint does not specify how or when Penales learned of the issue, whether he discarded the remnants of the products specifically because he learned of potential benzene contamination, whether he learned of the recall and if so when, whether he pursued a remedy under the recall, or whether the products had worked during use. (*Id.* ¶ 95.)

[32] The Complaint does not specify a lot number for the product purchased. (*Id.*)

[33] The Complaint indicates that "*Mr. Villarreal* used the Products as directed on the labels," and notes that Martin reviewed the labels and disclosures "for each Product he purchased," despite the Complaint indicating he purchased only one Product. (*Id.* (emphasis added).) This Court presumes that these are scrivener's errors resulting from copying and pasting allegations from Plaintiff to Plaintiff, as this section pertains to Martin and otherwise indicates the use of one Product. (*Id.*)

[34] The Complaint does not specify how or when Martin learned of the issue, whether he discarded the remnant of the product specifically because he learned of potential benzene contamination, whether he learned of the recall and if so when, whether he pursued a remedy under the recall, or whether the product had worked during use. (*Id.* ¶ 97.)

[35] *Benzene and Cancer Risk*, AM. CANCER SOC'Y (Jan. 5, 2016), https://www.cancer.org/cancer/cancer-causes/benzene.html.

benzene," (*id.* ¶ 27).[36] Plaintiffs further contend that "[t]he presence of benzene in the Products renders them adulterated and misbranded," (*id.* ¶ 2), "the presence of benzene in Defendant's Products appears to be *the result of contamination* or a deficiency [in] the manufacturing process designed, implemented, and used by Bayer to manufacture the Products," (*id.* ¶ 35 (alteration in original)), and "any significant detection of benzene in such products is unacceptable," (*id.* ¶ 36).

Further, because Valisure detected "unacceptable levels of Benzene" in some of the Tested Products, Plaintiffs posit, the Products must have also "contained impermissible levels of benzene," and the Products were, therefore, "worthless" and "dangerous to use . . . ." (*Id.* ¶¶ 43–44, 59.) Plaintiffs assert that they were deprived of the benefit of the bargain for the Products because they wasted portions of the Products when they "were forced to discard the remainder of their Products due to the contamination or to buy replacement products to treat their athlete's foot or other conditions." (*Id.* ¶¶ 59–60, 62–64; *see also id.* ¶¶ 81, 83, 85, 87, 89, 91, 93, 95, 97.) As a result of using the Products, Plaintiffs maintain that they "are at significantly increased risk of contracting [b]enzene-caused [c]ancers," (*id.* ¶ 70), thus "they will be forced to undergo medical monitoring at considerable expense," (*id.* ¶ 63; *see also id.* ¶¶ 64, 71–78.)

Plaintiffs additionally contend that Defendant's recall offered inadequate compensation to consumers because it was not sufficiently publicized, consumers were required to submit photos of the Products, Defendant promised no changes to manufacturing practices, the recall amount did not include statutory damages that are available in certain states, Defendant did not make the criteria for refund known, Defendant described the recall as a "precautionary measure," and Defendant has not compensated consumers for medical monitoring. (*Id.* ¶ 79.)

[36] Smith, Martyn T., *Advances in Understanding Benzene Health Effects and Susceptibility*, 31 ANN. REV. OF PUB. HEALTH 133, 133–48 (2010), https://www.annualreviews.org/doi/full/10.1146/annurev.publhealth.012809.103646.

Finally, Plaintiffs seek to represent multiple potential classes, including (1) a nationwide class of consumers who purchased specific Lotrimin spray products at issue; (2) a nationwide class of consumers who purchased specific Tinactin spray products at issue; (3) a subclass of consumers who purchased the Lotrimin spray products in New York; (4) a subclass of consumers who purchased the Lotrimin products in Missouri; (5) a subclass of consumers who purchased the Lotrimin products in Indiana; (6) a subclass of consumers who purchased Lotrimin products in South Carolina; (7) a subclass of consumers who purchased Lotrimin products in Massachusetts; (8) a subclass of consumers who purchased Lotrimin products in Delaware; (9) a subclass of consumers who purchased Lotrimin products in California; (10) a subclass of consumers who purchased the Tinactin spray products in New York; (11) a subclass of consumers who purchased Tinactin products in Indiana; (12) a subclass of consumers who purchased Tinactin products in Delaware; and (13) a subclass of consumers who purchased Tinactin products in California. (*Id.* ¶¶ 98–110.)

D. Procedural History

On November 16, 2021, Plaintiffs filed a six-count putative class action suit in this Court. (D.E. 1 ¶¶ 52–105.) Defendant filed a Motion to Dismiss on January 24, 2022, which this Court granted on August 19, 2022 and afforded Plaintiffs an opportunity to amend. (D.E. 27; D.E. 28.)

Plaintiffs filed the fifteen-count FAC on September 16, 2022, asserting the following claims: Breach of Express Warranty (Count I); Breach of Implied Warranty (Count II); Violation of New York General Business Law § 349 (Count III); Violation of New York General Business Law § 350 (Count IV); Fraud (Count V); Unjust Enrichment (Count VI); Violation of the NJCFA, N.J. Stat. §§ 56:8-1, *et seq.* (Count VII); Violation of the Missouri Merchandising Practices Act, Mo. Rev. Stat. Ann. §§ 407.010, *et seq.* (Count VIII); Violation of the Indiana Deceptive Consumer

Sales Act, Ind. Code §§ 24-5-0.5-0.1, *et seq.* (Count IX); Violation of South Carolina's Unfair Trade Practices Act, S.C. Code §§ 39-5-10, *et seq.* (Count X); Violation of the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93 §§ 1, *et seq.* (Count XI); Violation of the Delaware Consumer Fraud Act, Del. Code tit. 6 §§ 2511, *et seq.* (Count XII); Violation of the CLRA, Cal. Civ. Code §§ 1750, *et seq.* (Count XIII); Violation of the UCL, Cal. Bus. & Prof. Code §§ 17200, *et seq.* (Count XIV); Violation of the FAL, Cal. Bus. & Prof. Code §§ 17500, *et seq.* (Count XV); and Negligent Misrepresentation (Count XVI). (D.E. 29 ¶¶ 121–304.) Defendant filed the instant Motion to Dismiss on October 28, 2022, and the parties completed timely briefing on January 13, 2023.[37] (D.E. 39; D.E. 42; D.E. 43.)

II. LEGAL STANDARD

A. Rule 12(b)(1) Motion to Dismiss

Subject matter jurisdiction establishes a court's "very power to hear the case." *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977). A district court has subject matter jurisdiction to hear claims "arising under the Constitution, laws, or treaties of the United States" pursuant to 28 U.S.C. § 1331. "A motion to dismiss for want of standing is . . . properly brought pursuant to Rule 12(b)(1), because standing is a jurisdictional matter." *Ballentine v. United States*, No. 1999-130, 2006 WL 3298270, at *1 (D.V.I. Sept. 21, 2001), *aff'd and adopted by* 486 F.3d 806, 808–10, 48 V.I. 1059 (3d Cir. 2007). A defendant may move to dismiss a complaint for lack of subject matter jurisdiction under Rule 12(b)(1) by challenging jurisdiction

[37] After this Motion was fully briefed, Plaintiffs submitted letters containing supplemental authority on April 4, 2023 and May 18, 2023, including three recent out-of-Circuit District Court Opinions. (*See* D.E. 44 (citing *Barnes v. Unilever U.S. Inc.*, 2023 WL 2456385 (N.D. Ill. Mar. 11, 2023); *Clinger v. Edgewell Pers. Care Brands, LLC*, 2023 WL 2477499 (D. Conn. Mar. 13, 2023); D.E. 47 (citing *Henning v. Luxury Brand Partners*, LLC, Case No. 3:22-cv-7011, ECF No. 37 (N.D. Cal. May 11, 2023)). The supplemental authority submitted is unpersuasive in relation to the factual allegations in this matter and Third Circuit precedent.

facially or factually. *Const. Party of Pa. v. Aichele*, 757 F.3d 347, 357 (3d Cir. 2014) (citing *In re Schering Plough Corp. Intron/Temodar Consumer Class Action (Schering Plough)*, 678 F.3d 235, 243 (3d Cir. 2012)). "A facial attack 'contests the sufficiency of the complaint because of a defect on its face,' whereas a factual attack 'asserts that the factual underpinnings of the basis for jurisdiction fails to comport with the jurisdictional prerequisites.'" *Halabi v. Fed. Nat'l Mortg. Ass'n*, Civ. No. 17-1712, 2018 WL 706483, at *2 (D.N.J. Feb. 5, 2018) (quoting *Elbeco Inc. v. Nat'l Ret. Fund*, 128 F. Supp. 3d 849, 854 (E.D. Pa. 2015)). A motion to dismiss for lack of standing is considered a facial attack. *Schering Plough*, 678 F.3d at 243. "[A] facial attack calls for a district court to apply the same standard of review it would use in considering a motion to dismiss under Rule 12(b)(6), i.e., construing the alleged facts in favor of the nonmoving party." *Const. Party of Pa.*, 757 F.3d at 358 (citing *Schering Plough.*, 678 F.3d at 243)).

Importantly, when a defendant challenges the court's exercise of subject matter jurisdiction, the plaintiff has the burden of proving jurisdiction to survive the motion. *See Dev. Fin. Corp. v. Alpha Hous. & Health Care, Inc.*, 54 F.3d 156, 158 (3d Cir. 1995). Additionally, "[i]n the class action context, the standing inquiry focuses solely on the class representatives." *In re Valsartan, Losartan, and Irbesartan Prods. Liab. Litig.* (*Valsartan II*), No. 2875, 2021 WL 100204, at *5 (D.N.J. Jan. 12, 2021) (citing *Mielo v. Steak'n Shake Operations, Inc.*, 897 F.3d 467, 478 (3d Cir. 2018)).

B. Rule 12(b)(6) Motion to Dismiss

An adequate complaint must be "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). This Rule "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level . . . ." *Bell Atlantic*

Corp. v. Twombly, 550 U.S. 544, 555 (2007) (citing 5 C. WRIGHT & A. MILLER, FEDERAL PRACTICE AND PROCEDURE § 1216, 235–36 (3d ed. 2004)); *see also Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008) (stating that Rule 8 "requires a 'showing,' rather than a blanket assertion, of an entitlement to relief" (quoting *Twombly*, 550 U.S. at 555)).

When considering a Motion to Dismiss under Rule 12(b)(6), a court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Phillips*, 515 F.3d at 231 (quoting *Pinker v. Roche Holdings, Ltd.*, 292 F.3d 361, 374 n.7 (3d Cir. 2002)). However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 555); *see also Fowler v. UPMC Shadyside*, 578 F.3d 203, 209–11 (3d Cir. 2009) (discussing the *Iqbal* standard). Determining whether the allegations in a complaint are "plausible" is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679 (citation omitted). If "the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct," the complaint should be dismissed for failing to "show[] . . . that the pleader is entitled to relief" as required by Rule 8(a)(2). *Id.*

III. DISCUSSION

This Court previously dismissed Plaintiffs' Complaint for lack of standing because Plaintiffs did not meet the burden of proving jurisdiction to survive the motion, *see Dev. Fin. Corp.*, 54 F.3d at 158, by failing to present facts that would demonstrate "that the Products did not work as intended," that Plaintiffs "suffered wasted portions of the Products," or that Plaintiffs

purchased a replacement product and effectively paid for the same treatment twice." (D.E. 27 at 7–12.) This Court also found that Plaintiffs did not adequately plead physical injury because the Complaint contained "a conclusory allegation that [Plaintiffs] have suffered cellular and genetic injuries that increase risk of cancer," yet provided no factual basis for physical injury and relied instead on mere speculation. (*Id.* at 12–13.) With the addition of multiple Plaintiffs and a plethora of conclusory statements, copied and pasted vague assertions, and facts requiring inferential leaps, the abundant additional allegations in the FAC have not remedied the factual deficiencies that existed in the original Complaint, and Plaintiffs do not meet the burden of proving jurisdiction to survive Defendant's Motion.

Article III of the United States Constitution limits the power of the federal judiciary to the adjudication of actual "cases" or "controversies." *Golden v. Zwickler*, 394 U.S. 103, 108 (1969); *see also Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 471 (1982). To enforce the "case" or "controversy" requirement, Article III requires that a plaintiff "have 'standing' to invoke the power of a federal court . . . ." *Allen v. Wright*, 468 U.S. 737, 750 (1984). Standing, therefore, is a "threshold question in every federal case, determining the power of the court to entertain the suit." *Warth v. Seldin*, 422 U.S. 490, 498 (1975). A plaintiff has standing to sue when:

> First, the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly . . . trace[able] to the challenged action of the defendant, and not . . . the result [of] the independent action of some third party not before the court. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Lujan v. Defs. of Wildlife, 504 U.S. 555, 560–61 (1992) (internal quotations and citations omitted); *see also Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016).

Here, Plaintiffs allege two primary separate injuries: economic harm due to the loss of the purchase price of the Products, and risk of physical injury from exposure to benzene via use of the Products, resulting in the need for a medical monitoring program. (D.E. 29 ¶¶ 67–78; 81, 83, 85, 87, 89, 91, 93, 95, 97.) Defendant's challenge to each injury rests squarely on "the '[f]irst and foremost' of the three standing elements, injury in fact." *Cottrell v. Alcon Labs.*, 874 F.3d 154, 162 (3d Cir. 2017) (quoting *Spokeo, Inc.*, 578 U.S. at 338). After assessing Plaintiffs' allegations of economic harm and physical injury, for the reasons elucidated herein, this Court finds that the FAC does not contain sufficient factual detail and concrete allegations to overcome Defendant's challenge. Plaintiffs neither have standing to pursue claims for economic harm related to the loss of the purchase price of the Products, nor have standing to pursue claims for physical injury related to the use of the Products.

A. Economic Harm

Plaintiffs allege that they each suffered economic harm because the Product or Products were "worth less than [they] bargained for," the Product or Products were worthless because of benzene contamination, they were "unable to use the remaining portion" or portions of the Product or Products, and Huertas purchased another product to replace the Product at issue. (D.E. 29 ¶¶ 81, 81, 83, 85, 87, 89, 91, 93, 95, 97.) Defendant maintains that Plaintiffs cannot establish standing, as it pertains to economic harm, because Plaintiffs do not allege the following: that the Products did not perform; that the Plaintiffs purchased replacement products, and that the one product Huertas bought as a replacement was incomparable to the Product he had purchased; that the Products contained benzene above applicable FDA limits, but even if the benzene were above

the limits such a violation is insufficient to confer standing; that the Products the Plaintiffs purchased were not tested for contamination; and that the unrelated Tested Products only serve as representative testing, which cannot be relied upon to establish injury. (D.E. 39-1 at 18–23.) Further, Defendant contends that Plaintiffs failed to "plausibly allege that they wasted any product." (*Id.* at 23.)

In analyzing Plaintiffs' Complaint, this Court accepts Plaintiffs' facts as true and views the facts in a light favorable to Plaintiff. *Phillips*, 515 F.3d at 231. When doing so, however, the FAC does not sufficiently allege facts to support the conclusion that Plaintiffs suffered economic loss. To establish an economic loss from a product, a plaintiff "must allege facts that would permit a factfinder to value the purported injury at something more than zero dollars without resorting to mere conjecture." *In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Liab. Litig. (Johnson & Johnson)*, 903 F.3d 278, 285 (3d Cir. 2018). A plaintiff may rely on one or more of several different theories of economic loss. *Id.* at 281–83. In this case, Plaintiffs primarily rely on the benefit of the bargain theory. (D.E. 29 ¶¶ 81, 81, 83, 85, 87, 89, 91, 93, 95, 97.) "Under the benefit of the bargain theory, a plaintiff might successfully plead an economic injury by alleging that [he or] she bargained for a product worth a given value but received a product worth less than that value." *Johnson & Johnson*, 903 F.3d at 283. This Court analyzed relevant Third Circuit cases addressing the benefit of the bargain theory in its prior Opinion on this matter, (*see* D.E. 27), and again relies on those cases when reviewing Plaintiffs' FAC.

In *Johnson & Johnson*, the plaintiff alleged that she would not have purchased the baby powder product at issue if she had known it was unsafe and may cause health problems. *Johnson & Johnson*, 903 F.3d at 284–90. However, the plaintiff neither alleged facts indicating that she lost some or all of the value of the product, nor alleged that it did not work as intended. *Id.* The

Court found that the plaintiff did not establish economic injury by alleging that she would have bought another product, and instead needed to "allege that she purchased [b]aby [p]owder that was worth less than what she paid for" to establish an injury. *Id.* at 287. The Court additionally found that, despite the product allegedly containing a carcinogen, the plaintiff used the product without cognizable injury, and her "wish to be reimbursed for a functional product that she has already consumed without incident does not itself constitute an economic injury." *Id.* at 293.

In *Cottrell*, the plaintiffs alleged that the design of eye-drop bottles Defendant sold created economic injury due to wasted product that occurred when the drops were more than a person's eye could hold. *Cottrell*, 874 F.3d at 159–60. The Court determined that the plaintiffs had standing because the value of the wasted product was sufficient to constitute a cognizable economic injury. *Id.* at 168.

Here, the FAC does not include the requisite factual support for the allegations of economic injury. First, rather than pleading important facts that demonstrate that Plaintiffs received worthless Products and/or suffered wasted portions of the Products they purchased, the FAC contains a sentence in each individual Plaintiff's section indicating that each Plaintiff "did not use and was unable to use the remaining portion of [the Product(s)], and therefore wasted a portion of [the Products]." (D.E. 29 ¶¶ 81, 81, 83, 85, 87, 89, 91, 93, 95, 97.) The FAC fails to give factual detail about specifically when the product was purchased and how often used, how the product functioned during use, whether the individual Plaintiff's medical condition was alleviated, how much product remained after use, when and how each Plaintiff learned that there could be potential contamination (and if each learned of such when the product was still in use for a particular infection), and other such concrete and particularized facts that would demonstrate the conclusion that the product needed to be discarded and wasted—and, importantly, why. Plaintiffs appear to

have copied and pasted factual recitations—which are rife with conclusory legal allegations—from section to section for each individual Plaintiff, and in one instance even neglected to correctly list the individual Plaintiff's name when doing so. (*See id.* ¶¶ 80–97.) While Plaintiffs' allegations do include words asserting that they wasted portions of each Product, the factual allegations remain distinguishable from the argument in *Cotrell* because Plaintiffs here do not plead facts that support wasting of the product during use, and do not give factual details showing the circumstances surrounding each Plaintiff discarding some or all of the product. Plaintiffs do not even pinpoint when most of the Plaintiffs purchased the product, instead giving a multi-year, ballpark timeline, and fail to include relevant lot numbers for many of the Plaintiffs' Products. (*See id.* ¶¶ 84–97.)

Plaintiffs put forth conclusory assertions that the Products are worthless due to the purported benzene contamination and put forth conclusory allegations of damage from discarding some portion of the products, without specifying any specific information that shows damage or presenting facts regarding the products' effectiveness while in use. (*See id.* ¶¶ 80–97.) As with the plaintiff in *Johnson & Johnson*, Plaintiffs have not presented a particularized account of the actual harm caused, and instead present mere conjecture in asserting that they experienced some sort of loss due to the product's generally asserted "worthless[ness]," and that some hypothetical, future physical harm may befall them from use of the product. *See Johnson & Johnson*, 903 F.3d at 285. Plaintiffs' claims each amount to a "wish to be reimbursed for a functional product that [they] . . . already consumed without incident," which in and of itself "does not itself constitute an economic injury." *Id.* at 293.

While Plaintiffs contend that the economic standing issue in *Valsartan II* supports standing here, important factual distinctions undercut Plaintiffs' argument. *See Valsartan II*, 2021 WL 100204, at *6–12 (collecting cases). In *Valsartan II*, the plaintiffs alleged that they purchased one

or more of the defendants' generic drugs, which were designed to control blood pressure. *Id.* at *1–3. The FDA then discovered that the valsartan-containing drugs ("VCDs") had been contaminated by two probable human carcinogens "—n-nitrosodimethylamine ("NDMA") and n-nitrosodiethylamine ("NDEA")—" and that the amounts of the contaminants exceeded specifically delineated levels acceptable for human ingestion. *Id.* at *1–2. The defendants instituted a voluntary recall, and various plaintiffs sued the manufacturers, arguing that "had they known the product was not the same as the brand-name drug, they would not have paid for it, and had [the d]efendants' deception about the product's impurities been made known earlier, they would not have paid for it." *Id.* at *2. "[C]lasses of consumers and third-party payors [sued] in order to recoup the amounts they paid for [the d]efendants' allegedly worthless VCDs," arguing that "the VCDs were adulterated and misbranded"; "[the consumers] paid to replace the recalled VCDs with substitute drugs, effectively paying twice for drugs intended to treat the same medical conditions and for use over the same (or an overlapping) time period, when they should only have paid once"; and the VCDs "were worth less than their non-contaminated equivalents." *Id.* at *3–4 (internal citations omitted). During the recall, the plaintiffs alleged that they needed to keep taking the drugs due to the seriousness of the conditions they treated, but then were forced to stop taking the drug due to the seriousness of the impurity and had to purchase non-contaminated drugs as a safe alternative to the contaminated drugs. *Id.* at *4. Considering all of these facts, the District Court found that the plaintiffs had standing to sue for economic injury. *Id.* at *11.

Here, Plaintiffs' allegations have some resemblance to those in *Valsartan II* in that Plaintiffs allege that the Products were worthless due to the presence of a carcinogen contaminant. (D.E. 29 ¶¶ 80–97.) However, the similarities are limited in that the *Valsartan II* plaintiffs alleged specific high levels of contamination in the products at issue that exceeded the FDA guidelines for

the contaminants, and they alleged actual economic harm by having to purchase alternative medications to continue treating their high blood pressure conditions and being forced to stop taking the medications at issue due to the seriousness of the impurity. *Valsartan II*, 2021 WL 100204, at *4. Conversely, the FAC does not allege the specific levels of benzene in the Products Plaintiffs purchased, and instead relies upon results of testing performed on the Tested Products, which are representative and do not pertain to the same lot numbers or batches of the Products at issue here. (*Compare* D.E. 29 ¶¶ 38–41, *with id.* ¶¶ 80–97.) The FAC notes that FDC guidelines do not allow for sale of products with more than 2 parts ppm of benzene, but does not specifically allege that the Products at issue in this matter contained more than 2 parts ppm. Instead, the FAC alleges that 12 of the 13 Tested Products contained benzene, and 11 of the 13 Tested Products contained benzene that exceeded the FDC allowable limit. (*Id.*) The Tested Product lots do not match any of the lot numbers that individual Plaintiffs purchased and, in fact, most of the lot numbers for Products that individual Plaintiffs purchased are unreported. Tests performed on other batches of similar products cannot translate to the assumption that all of the Products at issue here contained benzene, and/or contained excessive levels of such. (*Id.* ¶ 38.) Because Plaintiffs have not and cannot allege that all of the representative products contained benzene and contained excessive levels of benzene, Plaintiffs are unable to establish a plausible inference that every Product at issue, including those purchased by Plaintiffs, also contained benzene and excessive levels of such. *See Kimca v. Sprout Foods, Inc.*, 2022 WL 1213488, at *4 (D.N.J. Apr. 25, 2022) (noting that "plaintiffs can establish standing using representative testing where they allege that *all* of the products sold by the defendant contain the alleged defect. (*emphasis added*)).

Additionally, Plaintiffs allege that they stopped taking and discarded remaining portions of the Products at some point, and, in the specific instance of Huertas purchased a replacement

alternative product. (*See* D.E. 29 ¶¶ 80–97.) However, the FAC is devoid of factual circumstances demonstrating the timing and circumstances surrounding each Plaintiff's use of the Products, each Product's effectiveness during use, when the Product was used and for how long, whether the Products treated each Plaintiff's infection, how much of the Products remained after use, when Plaintiffs decided to discard their Products and why, whether the Products had expired, and other pertinent details that would demonstrate the circumstances leading to the Plaintiffs discarding the remainder of the Products. Plaintiffs repetitive, conclusory statement that the individual Plaintiffs were "unable to use the remaining portion[(s)] of [the Products]" is not undergirded by any factual support. (*Id.* ¶¶ 81, 81, 83, 85, 87, 89, 91, 93, 95, 97.)

Further, Plaintiffs do not plead facts that demonstrate that the Products did not perform and clear up their infections, or that they experienced recurring infections that required use of the remaining Products they discarded. (*Id.* ¶¶ 80–97.) And, only Huertas alleges purchasing boric acid as a replacement product. (*Id.* ¶ 81.) This allegation, however, is not supported by facts that demonstrate that he purchased the boric acid due to any contamination in the Product, whether the boric acid was purchased to treat an infection that was untreated by the Product or whether it was purchased to treat a subsequent infection, or that he even knew of the recall when he purchased the subsequent product. Importantly, the facts presented indicate the opposite, as the FAC states that "Huertas never received notice of the recall from Defendant for his contaminated Lotrimin product." (*Id.* ¶ 80.) If Huertas did not receive such notice, it is not clear why he discarded some portion of his Product and tried another remedy, and whether that remedy was purchased to treat the same infection the Product treated.

In sum, Plaintiffs have not presented particularized facts that demonstrate cognizable economic harm, and their allegations of "worthless" Products amount to speculative loss. Viewing

the allegations in a light most favorable to Plaintiffs, the facts are not well pleaded and, therefore, Plaintiffs have not established standing due to a cognizable economic injury. Because Plaintiffs have not established the first element of standing relating to injury-in-fact, *see Cottrell*, 874 F.3d at 162, analyses of the causal connection between injury and conduct and the redressability of injury are unnecessary. *Const. Party of Pa.*, 757 F.3d at 361 ("When standing is contested, 'the injury-in-fact element is often determinative.'" (quoting *Schering Plough*, 678 F.3d at 245)).

B. Physical Injury

The FAC does not allege that Plaintiffs suffered specific physical injuries, and instead alleges that Plaintiffs have "a significantly increased risk of contracting [b]enzene-caused [c]ancers," thus have a need for a "medical monitoring program." (D.E. 29 ¶¶ 67–78.) To demonstrate an injury in fact, a plaintiff must show particularization—"it 'must affect the plaintiff in a personal and individual way,'" and concrete injury—it "must be 'de facto'; that is, it must actually exist." *Spokeo, Inc*, 578 U.S. at 339–40 (internal citations omitted). A plaintiff is required to "*show* that his or her injury is 'actual or imminent, not conjectural or hypothetical.'" *Johnson & Johnson*, 903 F.3d at 284 (emphasis added) (quoting *Spokeo, Inc.*, 578 U.S. at 339).

Here, the FAC does not set out any facts indicating that the named Plaintiffs have suffered injuries and/or that any of the specific Products at issue exposed Plaintiffs to levels of benzene exceeding the FDA limit. The FAC, rather, pleads only a future risk of injury—not a concrete, present-day particularized injury. As such, Plaintiffs have not demonstrated physical injuries that actually exist, and rather rely on the risk of future harm. Plaintiffs, therefore, have not established standing due to physical injury. Because Plaintiffs have not established the first element of standing relating to injury-in-fact, *see Cottrell*, 874 F.3d at 162, analyses of the causal connection between injury and conduct and the redressability of injury are unnecessary.

Consequently, because Plaintiffs have not demonstrated standing, this Court cannot address the merits of Plaintiffs' claims. *See Adam*, 41 F.4th at 233 ("[I]f a plaintiff does not have standing, courts 'lack the authority under Article III of the Constitution to consider the merits' of any claim." (quoting *In re Boy Scouts of Am.*, 35 F.4th 149, 156 (3d Cir. 2022))).

IV. CONCLUSION

For the reasons set forth above, Defendant's Motion to Dismiss is **GRANTED**. An appropriate order follows.

/s/ Susan D. Wigenton
SUSAN D. WIGENTON, U.S.D.J.

Orig: Clerk
cc: Cathy L. Waldor, U.S.M.J.
Parties