UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JUAN HUERTAS, EVA MISTRETTA, JOSE VILLARREAL, JEREMY WYANT, JONATHAN MARTIN, DON PENALES, JR, MIKE POOVEY, SEAN STEINWEDEL, AND CHRISTOPHER CADORETTE, ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED, PLAINTIFFS, V. BAYER U.S. LLC, DEFENDANT.	Case No. 2:21-CV-20021-SDW-CLW HON. SUSAN D. WIGENTON HON. CATHY L. WALDOR

BAYER U.S. LLC'S
MOTION TO DISMISS FIRST AMENDED CLASS ACTION COMPLAINT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Other Authorities

INTRODUCTION

In October 2021, Bayer U.S. LLC ("Bayer") voluntarily recalled certain Lotrimin and Tinactin anti-fungal spray products due to potential contamination with benzene, offering purchasers of those products a full refund. Rather than accept the refund, Plaintiffs filed this class-action lawsuit seeking the same economic relief Bayer already offered to provide voluntarily.

This Court has already held that Plaintiffs lack Article III standing to recover economic damages, and the Amended Complaint fails to cure the defects this Court previously identified. Most significantly, Plaintiffs still have not alleged that their products failed to cure their fungal infections or that they otherwise did not work as advertised. Plaintiffs thus fail to allege that they "lost money" as a result of purported benzene contamination. *See* ECF No. 27 ("Opinion") at 9. To overcome that defect, each Plaintiff relies on a single copied-and-pasted sentence that they "wasted" a portion of their products due to benzene. That assertion is wholly conclusory: Plaintiffs make no attempt to plead facts showing that they "wasted" the products *because* they learned of potential benzene contamination as opposed to some other reason, such as the products' expiration. Plaintiffs' allegations thus "do not set out any facts that demonstrate actual loss from discarding or sacrificing any portions of the products." Opinion at 9.

Even if Plaintiffs had cleared Article III's standing requirements—and they have not—their claims would face other obstacles. As a threshold matter, Plaintiffs' claims are preempted by federal law. The Food, Drug, and Cosmetic Act ("FDCA") expressly preempts any attempt to impose on Bayer labeling requirements that are "different from or in addition to, or that is otherwise not identical with" federal law. 21 U.S.C. § 379r(a). To sidestep this requirement, Plaintiffs wrongly accuse Bayer of violating the FDCA and its implementing regulations setting forth appropriate manufacturing practices and disclosures that must appear on drug ingredient lists. Moreover, in focusing on purported violations of the FDCA, Plaintiffs run into a separate preemption problem: the Supreme Court held in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), that state-law claims like Plaintiffs' that are based solely upon violations of the FDCA are impliedly preempted.

Each of Plaintiffs' claims fails for additional reasons as well. The express warranty claim should be dismissed because Plaintiffs have not identified a single representation Bayer made to them about benzene. The implied warranty claims fail because Plaintiffs did not allege the products failed to fulfill their ordinary purpose. The unjust enrichment claims fail because Plaintiffs did not purchase their products directly from Bayer. Finally, Plaintiffs have not plausibly alleged that Bayer knew the products they sold to Plaintiffs contained benzene, as they must to avoid dismissal of their claims for fraud and under state consumer protection statutes.

Another federal court dismissed virtually identical claims against another manufacturer accused of selling contaminated products, *Harris v. Pfizer Inc.*, 586 F. Supp. 3d 231, 240-46 (S.D.N.Y. 2022), and this Court should reach the same result.

BACKGROUND

This case arises out of Bayer's issuance of a voluntary recall of certain lots of Lotrimin and Tinactin in October 2021 due to potential benzene contamination. The following month, Plaintiffs Huertas and Mistretta filed this lawsuit rather than accepting the full refund offered by Bayer. ECF No. 1.

On August 19, 2022, this Court dismissed the original complaint, holding that Plaintiffs failed to show a "cognizable economic harm" sufficient for Article III standing. Opinion at 12. This Court rejected Plaintiffs' contention that they suffered economic injury merely because Lotrimin and Tinactin "contain harmful levels of benzene." *Id.* at 3. Instead, after surveying Third Circuit law, this Court held that Plaintiffs were required to allege something more than the mere presence of a potential contaminant—namely, "that the Products did not work as intended," that "they purchased a replacement product and effectively paid for the same treatment twice," or that "they suffered wasted portions of the Products having to discard any or all of them." *Id.* at 12. The original complaint contained no such allegations and Plaintiffs therefore lacked standing to pursue claims for economic injury. *Id.* This Court also rejected Plaintiffs' contention that they have standing due to physical

injury because their allegations "do not demonstrate the risk of actual harm is anything other than mere speculation." *Id.* at 13.

On September 16, 2022, Plaintiffs Huertas and Mistretta, along with seven additional Plaintiffs,[1] filed a First Amended Class Action Complaint (the "Amended Complaint"). ECF No. 29. The Amended Complaint still does not allege Lotrimin and Tinactin "did not work as intended" by failing to treat Plaintiffs' fungal infections. Opinion at 9. Nor does the Amended Complaint allege that Plaintiffs tested their products for benzene or identify how much benzene (if any) was in the products that they purchased.

Instead, the Amended Complaint relies on the assertion that a third-party testing company (Valisure, LLC) tested 13 samples of Lotrimin and Tinactin and found that 11 of them had benzene levels that allegedly exceeded FDA limits. Am. Compl. ¶¶ 37, 38. But Plaintiffs do not allege that the products *they* purchased contained benzene, or that Valisure tested products in the same lots as the ones they purchased. *See id.* ¶¶ 37-38. The Amended Complaint also includes a new assertion that Plaintiffs "wasted" a portion of their product "as a result of the benzene contamination," but there are no accompanying allegations that Plaintiffs needed to

[1] After this lawsuit was initially filed, these seven Plaintiffs filed a separate putative class lawsuit in a Missouri federal court. Bayer moved to transfer that lawsuit to this Court under the first-to-file rule, and the Missouri plaintiffs opposed. Following this Court's motion-to-dismiss ruling, the Missouri plaintiffs dismissed their lawsuit and joined this case.

use their remaining product due to a recurrence of a fungal infection. *E.g.*, *id.* ¶ 81. Indeed, eight of nine Plaintiffs do not allege they needed to purchase a replacement product for a recurring infection; only Plaintiff Huertas (a New York resident) alleges he did so. *See id.* ¶¶ 83, 85, 87, 89, 91, 93, 95, 97.

PROCEDURAL STANDARD

To survive a Rule 12(b)(1) motion, Plaintiffs bear "the burden of proving jurisdiction to survive the motion." Opinion at 5 (citing *Dev. Fin. Corp. v. Alpha Hous. & Health Care, Inc.*, 54 F.3d 156, 158 (3d. Cir. 1995)). As this Court recognized, "[b]efore addressing whether Plaintiffs' claims are well pleaded, this Court must first consider whether Plaintiffs have standing." Opinion at 6.

To survive a Rule 12(b)(6) motion to dismiss, "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). But "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Id.* at 678. "If the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint should be dismissed." Opinion at 6 (citing *Iqbal*, 556 U.S. at 679) (quotations omitted)).

ARGUMENT

I. PLAINTIFFS STILL LACK ARTICLE III STANDING.

The Amended Complaint fails to overcome the standing defects this Court previously identified. As discussed below, Plaintiffs do not plausibly allege that

they suffered a cognizable economic injury from their purchase of the products. Nor do they adequately allege that they face a risk of future physical injury from any purported benzene exposure. The Court should therefore hold—once again—that Plaintiffs lack standing to assert their claims.

A. Plaintiffs Do Not Allege Any Plausible Economic Injuries.

In its prior Opinion, this Court surveyed Third Circuit law and held that the mere presence of a contaminant in a product is insufficient to establish that a consumer suffered economic harm. Opinion at 7-13. Instead, this Court identified three instances in which Plaintiffs can plead economic injury from an alleged contaminant: (1) "the Products did not work as intended," (2) consumers "purchased a replacement product and effectively paid for the same treatment twice," and (3) consumers "suffered wasted portions of the Products by having to discard any or all of them." *Id.* at 12. The Amended Complaint fails to allege that any of those circumstances happened here.

1. Plaintiffs do not allege that the products failed to perform as advertised.

Plaintiffs still do not allege that the Lotrimin and Tinactin failed to cure them of their fungal infections, *e.g.*, Am. Compl. ¶¶ 80-81, and so they suffer from the same problem that plagued their prior complaint, *see* Opinion at 12. Plaintiffs nonetheless insist that they have standing because the products are "worth less than what [they] bargained for" due to alleged benzene contamination. *See* Am. Compl.

¶ 81. This Court already rejected that argument, holding that consumers lack standing based on the contention that a product contains "unsafe" contaminants absent allegations that the product "did not work as intended." *See* Opinion at 8-9 (citing *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Liab. Litig.*, 903 F.3d 278 (3d Cir. 2018)).

To avoid this Court's ruling, Plaintiffs cite *Barnes v. Unilever United States Inc.*, 2022 WL 2915629 (N.D. Ill. July 24, 2022), but that case reached a result inconsistent with Third Circuit precedent. The *Barnes* court concluded that a plaintiff can establish standing merely by alleging that "she would not have purchased the products, or would not have purchased them for the listed price, had she known they contained a human carcinogen." *Id.* at *1. As this Court noted, that conclusion cannot be reconciled with *Johnson & Johnson*. Opinion at 8-9. There, the Third Circuit held that a plaintiff cannot establish "standing simply because they purchased a product that a consumer would view as flawed" or because they purchased a product with a carcinogen "at a given price, [but] later wished they had not done so." *Johnson & Johnson*, 903 F.3d at 287-88. The out-of-circuit and unpublished decision in *Barnes* thus cannot help Plaintiffs establish standing here.

2. Plaintiffs do not allege they purchased any replacement products.

This Court next held that Plaintiffs could establish standing to recover economic damages if they purchased products with "specific high levels of

contamination that exceeded the FDA guidelines for the contaminants," *and* they were forced "to purchase alternative medications" as a result. Opinion at 11-12 (citing *In re Valsartan, Losartan, and Irbesartan Prods. Liab. Litig.*, 2021 WL 100204 (D.N.J. Jan. 12, 2021)). Plaintiffs fail to plead that either occurred here.

First, Plaintiffs do not allege that their products contained benzene above any applicable FDA limits. According to Plaintiffs, FDA guidelines prohibit the sale of products with more than 2 parts per million ("ppm") of benzene. *See* Am. Compl. ¶¶ 37-38. The source they cite says nothing about anti-fungal medications and consists of "***Nonbinding Recommendations***" that do "not establish any rights for any person and is not binding on [the] FDA or the public."[2] Even if there was such an FDA limit, Plaintiffs do not allege that *their* products contained benzene in excess of 2 ppm. That omission is fatal to Plaintiffs' attempt to establish standing. *See* Opinion at 11 (no standing because "the Complaint does not allege the specific level of benzene in the impacted Products").

To overcome this gap, Plaintiffs claim that a third party tested samples of the products and found benzene in some—but not all—of the samples. *See* Am. Compl. ¶ 38. But Plaintiffs do not allege that *their* products were among the ones tested, so

[2] *See Q3C - Tables and List Guidance for Industry*, U.S. Department of Health and Human Services Food and Drug Administration 1 (2018), https://www.fda.gov/media/133650/download.

it is impossible to draw any inference from the purported results.[3] Moreover, even if Plaintiffs' products were tested, the results show that not all of Bayer's products contained benzene at levels that exceed 2 ppm. *See* Am. Compl. ¶ 38 (alleging that "11 of the 13" products contained benzene above 2 ppm). Plaintiffs cannot rely on representative testing to establish an injury unless "they allege that all of the products sold by the defendant contain the alleged defect," and Plaintiffs own allegations confirm they cannot do that. *Kimca v. Sprout Foods, Inc.*, 2022 WL 1213488, at *4 (D.N.J. Apr. 25, 2022) (emphasis in original); *see also Schloegel v. Edgewell Pers. Care Co.*, 2022 WL 808694, at *2-3 (W.D. Mo. Mar. 16, 2022) (dismissing claims that sunscreen was contaminated with benzene where "representative sampling" did not find that all samples contained benzene).[4]

[3] Five of the nine Plaintiffs—Villarreal, Cadorette, Steinwedel, Martin, and Penales—do not allege the lot numbers of any of the products that they purchased, and so it is impossible to know whether the products they purchased contained any amount of benzene. *See* Am. Compl. ¶¶ 84, 90, 92, 94, 96. The other four Plaintiffs—Huertas, Mistretta, Wyant, and Poovey—allege the lot numbers of products they purchased, but none of those lot numbers match up with the lot numbers that were tested. *Compare* Am. Compl. ¶ 80 (Huertas alleges purchasing product with lot number TN009K7), ¶ 82 (Mistretta alleges purchasing product with lot number CV01E2X), ¶ 86 (Wyant alleges purchasing product with the lot number TN00273), ¶ 88 (Poovey alleges purchasing product with the lot number TN001NK), *with id.* ¶ 38 (table summarizing samples tested and not identifying any of those four lot numbers).

[4] *See also Wallace v. ConAgra Foods, Inc.*, 747 F.3d 1025, 1030 (8th Cir. 2014) ("[I]t is not enough for a plaintiff to allege that a product line contains a defect or that a product is at risk for manifesting this defect; rather, the plaintiffs must allege that *their* product *actually exhibited* the alleged defect." (quotations omitted; emphasis in original)).

Second, even if Plaintiffs alleged that their products contained benzene exceeding FDA limits, this Court previously held that a mere violation of FDA regulations is insufficient to confer standing. *See* Opinion at 11; *see also Spokeo, Inc. v. Robins*, 578 U.S. 330, 341 (2016) ("Article III standing requires a concrete injury even in the context of a statutory violation."). Plaintiffs must instead allege that they suffered "actual economic harm by having to purchase alternative medications" as a result of the potential contaminant. *See* Opinion at 11-12. With one exception (discussed below), Plaintiffs do not plead that they were forced to purchase replacement products due to the alleged benzene. Absent such allegations, Plaintiffs' allegations "amounts to speculative loss" and are insufficient to show a "cognizable economic harm." *Id.* at 12.

The one exception—Plaintiff Huertas—also cannot establish standing. According to the Amended Complaint, Huertas "was forced to buy a replacement product, boric acid . . . as a result of the benzene contamination in his Lotrimin product." Am. Compl. ¶ 81. That "conclusory assertion[]" does not contain facts from which this Court can infer that Huertas suffered an actual economic injury. Opinion at 9. For one, Huertas does not allege facts connecting his purchase of boric acid to the alleged benzene contamination in the Lotrimin product he purchased. For example, there are no allegations indicating that Huertas had sufficient leftover and non-expired product to treat a second fungal infection, but nevertheless discarded

the product due to Bayer's voluntary recall. In fact, Huertas affirmatively alleges that he "never received notice of the recall from Defendant," Am. Compl. ¶ 80, confirming that any purported benzene was *not* the cause of his replacement product. Finally, Huertas appears to have sought out a different remedy to treat his athlete's foot—boric acid—which is not FDA-approved for anything but is marketed as a treatment for vaginal yeast infections.[5] It is implausible to suggest that benzene contamination in Lotrimin was the cause of Huertas's purchase of a wholly incomparable product, when Huertas could have purchased any number of other treatments with the same active ingredient (clotrimazole) as Lotrimin.

3. Plaintiffs do not plausibly allege they "wasted" any product.

This Court's prior decision left one final avenue open to Plaintiffs to establish a cognizable economic injury—showing "that they suffered wasted portions of the Products by having to discard any or all of them." Opinion at 9, 12 (citing *Cottrell v. Alcon Lab'ys*, 874 F.3d 154 (3d Cir. 2017)). Each Plaintiff attempts to satisfy that requirement by asserting in a single, conclusory sentence that they "wasted" their products when they "learned of the benzene contamination." *E.g.*, Am. Compl. ¶ 81. For several reasons, that assertion is insufficient.

[5] *See Summary Report: Boric Acid*, University of Maryland Center of Excellence in Regulatory Science and Innovation, University of Maryland School of Pharmacy (2020), https://archive.hshsl.umaryland.edu/bitstream/handle/10713/12085/Boric%20acid_Final_2020_01.pdf.

First, seven Plaintiffs do not plausibly allege that they discarded their products when they learned of potential benzene contamination. Five Plaintiffs—Villarreal, Cadorette, Steinwedel, Penales, and Martin—do not allege that their products bore lot numbers that were subject to Bayer's voluntary recall. *See* Am. Compl. ¶¶ 84, 90, 92, 94, 96. As such, they cannot claim to have been forced to discard a product that was potentially contaminated with benzene. Two Plaintiffs—Huertas and Mistretta—allege that they "never received notice of the recall from Defendant," *id.* ¶¶ 80, 82, which confirms that they did not discard the product due to the alleged presence of benzene. Because these seven Plaintiffs do not plausibly allege that they "wasted" products as a result of benzene contamination, they lack a cognizable economic injury.

Second, Plaintiffs' allegations about "wasted" products are wholly "conclusory assertions" that are not entitled to the presumption of truth. Opinion at 9. Each Plaintiff relies on the same copied-and-pasted assertion that "[a]s a result of this [benzene] contamination, [Plaintiff] did not use and was unable to use the remaining portion of [the] product, and therefore wasted a portion of [the] product as a result of the benzene contamination." Am. Compl. ¶¶ 81, 83, 85, 87, 89, 91, 93, 95, 97. There are no accompanying allegations explaining how Plaintiffs learned that their products contained benzene or suggesting that they discarded their products for that reason—as opposed to some other reason, such as that the products

were expired or no longer needed. Plaintiffs thus "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." Opinion at 9-10; *see also Johnson & Johnson*, 903 F.3d at 285 ("[A] plaintiff must do more than offer conclusory assertions of economic injury . . . to establish standing.").

Finally, even if Plaintiffs plausibly alleged that they discarded products due to benzene, that *still* would not be sufficient to establish economic harm. With the exception of Huertas, Plaintiffs do not allege they had any further need for the products due to a recurring fungal infection. That is a fatal omission. Unlike most consumer products like shampoo or eye drops, Lotrimin and Tinactin are not intended for daily, ongoing use. They are used to treat acute infections, and use stops when that infection is cured or when improvement does not occur. *See, e.g.*, Am. Compl. ¶ 26 (product labels state that use should "[s]top use and ask a doctor if" improvement does not occur within 2 or 4 weeks). In the typical case, the product is used once to treat an infection and any leftover product sits in a medicine cabinet until it expires. *See id.* For most people, having leftover product that expires—and that is discarded with product remaining—does not cause economic harm. Put another way, after a first successful use, a consumer has generally received the desired result sought from the product and suffers no injury from discarding any

unneeded product. *See Johnson & Johnson*, 903 F.3d at 293 (no injury where plaintiff purchased "a functional product that she has already consumed").

Plaintiffs' conclusory allegations of "waste" stand in stark contrast to the allegations in *Cottrell*. *See* Opinion at 9. At issue in *Cottrell* were eye drops used to treat glaucoma, a chronic condition that requires ongoing treatment. 874 F.3d at 159. The *Cottrell* plaintiffs alleged that because of how the bottles were designed, each drop contained more liquid than was medically necessary, resulting in wasted liquid in each oversized drop. *Id.* at 160. The wasted liquid caused plaintiffs to purchase more bottles—and thus spend up to $1,100—each year. *Id.* Here, by contrast, Plaintiffs do not allege that they purchased any additional bottles of Lotrimin or Tinactin to treat a recurring fungal infection as a result of allegedly "wasting" a portion of the first bottle. Accordingly, Plaintiffs fail to plead a plausible economic injury.

B. Plaintiffs Have Not Adequately Alleged Any Physical Injury or Risk of Future Physical Injury.

After this Court ruled that Plaintiffs' prior allegations of "cellular and genetic injury" were too conclusory to give them standing, Opinion at 12-13, Plaintiffs removed them. Although they replaced them with allegations that they suffered the kind of injuries that require medical monitoring, Am. Compl. ¶¶ 67-78, these allegations likewise are insufficient to give them standing to sue for three reasons.

First, even assuming Plaintiffs had adequately alleged a risk of future physical injury from benzene exposure, a future physical injury would not give them standing to seek economic damages. A plaintiff "bears the burden of showing that [s]he has standing for *each* type of relief sought." *Johnson & Johnson*, 903 F.3d at 284 (emphasis in original). None of Plaintiffs' claims seeks recovery for physical harm or medical monitoring. Instead, the Amended Complaint only seeks to recover economic damages in the form of the price they paid to purchase the products. *See* Am. Compl. ¶ 302. Plaintiffs may therefore not rely on allegations of future physical injury and medical monitoring to recover claims for economic damages. *See Johnson & Johnson*, 903 F.3d at 284-85.[6]

[6] There is a good reason why Plaintiffs did not assert any medical monitoring claims: such claims are foreclosed under the laws of their states of residence. *See Riva v. Pepsico, Inc.*, 82 F. Supp. 3d 1045, 1053, 1057 (N.D. Cal. 2015) (California law requires "[a] plaintiff must demonstrate sufficient severity of exposure (its significance and extent) and that 'the need for future monitoring is a reasonably certain consequence of [the] toxic exposure'"); *Baker v. Croda Inc.*, 2021 WL 7209363, at *2 (D. Del. Nov. 23, 2021) (Delaware law prohibits medical monitoring claims); *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 546 F. Supp. 3d 1152, 1164 (S.D. Fla. 2021) ("Indiana state and federal courts have held that medical monitoring is not a cognizable claim."); *Genereux v. Raytheon Co.*, 754 F.3d 51, 56 (1st Cir. 2014) (Massachusetts law requires "a showing of subcellular or other physiological change"); *Meyer ex rel. Coplin v. Fluor Corp.*, 220 S.W.3d 712, 718 (Mo. 2007) (Missouri law requires "a significantly increased risk of contracting a particular disease relative to what would be the case in the absence of exposure"); *Caronia v. Philip Morris USA, Inc.*, 5 N.E.3d 11, 18 (N.Y. 2013) (New York law prohibits "recover[ing] medical monitoring costs without first establishing physical injury); *Easler v. Hoechst Celanese Corp.*, 2014 WL 3868022, at *5 n.5 (D.S.C. Aug. 5, 2014) ("South Carolina has yet to recognize a cause of action for medical monitoring.").

Second, in any event, no Plaintiff alleges that he or she suffered any physical injury. The Amended Complaint identifies a series of side effects associated with benzene exposure, such as "vomiting, irritation of the stomach, dizziness, sleepiness, convulsions, rapid heart rate, coma, and death." *Id.* ¶ 28. But Plaintiffs do not allege that *they* suffered any of those side effects from using the products. Each Plaintiff's failure to allege that they developed any physical injury from using a product supports the conclusion that the product was "*safe as to her*," depriving them of standing to sue for any alleged future physical injuries. *Johnson & Johnson*, 903 F.3d at 289 (emphasis in original).

Finally, no Plaintiff plausibly alleges that they were exposed to benzene at levels that place them at any increased risk of future harm. As discussed above, Plaintiffs fail to plead that they were exposed to benzene at levels in excess of any FDA limit. *See supra* at 8–9. Even if they had, the Amended Complaint does not allege that the potential exposure period—a maximum of four weeks, when the product is used at most twice a day—expose them to any "increased risk of future harm," much less a risk that is "credible and substantial," as is required to establish standing. *See Kimca*, 2022 WL 1213488, at *6 (plaintiffs failed to show "substantially increased risk of future harm" from exposure to contaminants); *S.F. Herring Ass'n v. Pac. Gas & Elec. Co.*, 2020 WL 6736930, at *5 (N.D. Cal. June 15, 2020) ("While standing may be based on a latent increased risk of injury where

there is a credible risk of harm, [plaintiff] has failed to establish that the alleged risk of developing cancer is both credible and substantial.").

II. PLAINTIFFS' CLAIMS ARE PREEMPTED.

Plaintiffs' claims are also preempted by the FDCA, which bars state-law claims related to over-the-counter medications.

A. Plaintiffs' Claims Are Expressly Preempted Because They Seek to Impose Requirements Beyond the FDCA.

The FDCA expressly preempts any state "requirement" on over-the-counter drugs that is "different from or in addition to, or that is otherwise not identical with" federal law. 21 U.S.C. § 379r(a). Over-the-counter drug product labels are strictly regulated by federal law: the FDA "issues a detailed regulation—a 'monograph'" that "[l]ike a recipe . . . sets out the FDA-approved active ingredients for a given therapeutic class of OTC drugs and provides the conditions under which each active ingredient is" generally recognized as safe and effective. *Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 710 F.3d 71, 75 (2d Cir. 2013), *as amended* (Mar. 21, 2013). The FDA monograph for topical antifungal drug products sets forth the *exact language* that must appear on labels for Lotrimin and Tinactin, including what the label can state about the usage of the product, what warnings must be included, the dosage the consumer should take, and directions the consumer should follow. *See* 21 C.F.R. §§ 333.201-280.

Plaintiffs' claims seek to impose labeling requirements "different from or in addition to" those imposed by the FDA monograph. The Amended Complaint hinges on the allegation that Plaintiffs were injured because Bayer failed to disclose the presence of benzene on the label of the products. *See, e.g.*, Am. Compl. ¶ 1 (alleging Bayer violated the law by failing to "disclos[e] that the Products contain dangerously high levels of benzene"); *see also id.* ¶¶ 123, 143, 156, 159, 165-66, 182-84, 193, 195-96, 214-16, 228, 231, 237, 248, 258, 265, 275, 277, 289, 299-301. Plaintiffs' claims are therefore preempted because they seek to impose labeling disclosures about benzene that are "different from or in addition to" FDA regulations. 21 U.S.C. § 379r(a); *see also Crozier v. Johnson & Johnson Consumer Cos.*, 901 F. Supp. 2d 494, 504 (D.N.J. 2012) (dismissing state law claims related to the labeling of over-the-counter product because "[f]ederal regulations . . . specify the required content on over-the-counter medication labels").

B. Plaintiffs Cannot Overcome Preemption By Citing to Alleged Violations of FDA Regulations.

Plaintiffs attempt to overcome preemption by asserting that the products are "misbranded" and "adulterated" under FDA regulations by failing to disclose the presence of benzene. *See* Am. Compl. ¶¶ 2, 49-58. That is wrong.

First, the products were not "misbranded" by the presence of benzene. Under the FDCA, a product is "misbranded" if it fails to disclose all of its "active ingredients" and "inactive ingredients" on its label. 21 U.S.C. § 352(e)(1)(A)(ii)-

(iii). By definition, however, a drug's "active ingredients" and "inactive ingredients" consist only of substances that are *intended* to be included in the product. *See* 21 C.F.R. § 201.66(b)(2) & (8) ("active ingredient" and "inactive ingredients" are defined in terms of "components"); 21 C.F.R. § 201.3(3) (defining "component" as "any ingredient *intended for use* in the manufacture of a drug product" (emphasis added)).[7] There are no allegations that Bayer intended to include benzene in the manufacture of the products, as would be necessary for benzene to be an ingredient that is required to be listed on the label. To the contrary, the Amended Complaint adopts Bayer's position that "[b]enzene is ***not*** an ingredient in any of Bayer Consumer Health products." Am. Compl. ¶ 35. Plaintiffs have therefore failed to plausibly allege that the products are "misbranded" under the FDCA. *See Herrington v. Johnson & Johnson Consumer Cos.*, 2010 WL 3448531, at *9 (N.D. Cal. Sept. 1, 2020) (rejecting allegation that cosmetic is misbranded by a contaminant because "incidental ingredients … need not be disclosed").

[7] FDA recognizes and allows all drugs to contain some degree of impurities. According to FDA guidance, however, impurities below a certain threshold need not be reported in manufacturing records or even identified. Above a certain threshold (*i.e.*, 0.15% or 1.0 mg per day intake (whichever is lower)), impurities should be qualified by studying their safety at specified levels. *See Guidance for Industry, Q3A Impurities in New Drug Substances*, U.S. Department of Health and Human Services Food and Drug Administration 11 (2008) https://www.fda.gov/media/71727/download. In no cases, however, does FDA or applicable law require that such unintended impurities be identified on product labels.

Second, the products were not "adulterated" by the presence of benzene. A product is considered "adulterated" if the manufacturing processes "are not operated or administered in conformity with current good manufacturing practice." 21 U.S.C. § 351(1). The FDA has issued regulations outlining current good manufacturing practices ("cGMP"), which require manufacturers to adopt a variety of policies and practices to ensure the quality of drug products. 21 C.F.R. parts 210 & 211. None of these cGMP regulations requires testing for benzene in the products or places a limit on the amount of benzene that may be in the products. In fact, the cGMP regulations do not speak to benzene at all.[8]

Plaintiffs therefore are reduced to the assertion that this Court should *infer* that Bayer violated cGMP regulations because benzene was found in some samples of the products. Am. Compl. ¶ 53. But Plaintiffs make no attempt to describe how Bayer's manufacturing process fell short of cGMP requirements or demonstrate that the levels of benzene in the products resulted from manufacturing deficiencies. *See id.* As a result, Plaintiffs fail to plausibly allege that the products are adulterated

[8] *See, e.g.*, 21 C.F.R. §§ 211.25–34 (requiring personnel and consultants to have certain qualifications and responsibilities); *id.* §§ 211.42–211.58 (requiring manufacturing sites to have certain specifications, such as proper lighting, ventilation, and plumbing; *id.* §§ 211.63–72 (requiring equipment to be properly designed, constructed, and maintained); *id.* §§ 211.80–211.94 (requiring components to be properly stored and tested); §§ 211.100–211.115 (requiring appropriate sampling and testing to avoid contamination); *id.* §§ 211.122–176 (requiring appropriate packaging, labeling, warehousing, distribution, and laboratory controls and testing); *id.* §§ 211.180–208 (requiring maintenance of records and procedures for returned drugs).

under the FDCA. *See Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011) ("This complaint is impermissibly conclusory and vague; it does not specify the manufacturing defect . . . . Nor does the complaint tell us how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process.").

C. Plaintiffs' Claims Are Also Impliedly Preempted.

Even if Plaintiffs could allege a violation of FDA "misbranding" and "adulteration" regulations (they cannot), their claims would be *impliedly* preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Under *Buckman*, a claim is impliedly preempted "when the state-law claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist." *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769 (D. Minn. 2009) (citing *Buckman*, 531 U.S. at 352-53). In other words, "the conduct on which the plaintiffs' claim is premised must be the type of conduct that would traditionally give rise to liability under state law, and that would give rise to liability under state law even if the FDCA had never been enacted." *Freed v. St. Jude Med., Inc.*, 364 F. Supp. 3d. 343, 352 (D. Del. 2019); *see also Roncal v. Aurobindo Pharma USA, Inc.*, 2022 WL 1237888, at *5 (D.N.J. Apr. 27, 2022) ("[I]f a violation of an FDCA requirement is the basis for a state law claim, then the state law claim is preempted.").

The Amended Complaint does not identify any state law that would independently give rise to their claims. Instead, Plaintiffs rely exclusively on allegations that the products are "adulterated" and "misbranded" in violation of FDA regulations. Am. Compl. ¶ 2. But these are statutorily defined terms that are given meaning only through FDA regulations, *see supra* § II.B, and alleging a product is "adulterated' or "misbranded" is simply another way of saying Bayer violated these federal regulations. Plaintiffs' attempt to convert purported violations of the FDCA into state-law claims is foreclosed by *Buckman*. *See Williams v. Cyberonics, Inc.*, 388 F. App'x 169, 171 (3d Cir. 2010) (warranty claim based on allegations that the product was "unsafe or ineffective" was preempted); *Millman v. Medtronic*, 2015 WL 778779, at *6 (D.N.J. Feb. 24, 2015) (New Jersey fraud claim preempted because theories of liability all "relat[ed] to the safety or effectiveness of the" product).

III. THIS COURT SHOULD DISMISS EACH OF PLAINTIFFS' CLAIMS WITH PREJUDICE.

Plaintiffs' claims should also be dismissed because they have failed to plead the elements of their claims. Plaintiffs reside in New York, Missouri, Indiana, California, South Carolina, Delaware, and Massachusetts, *see* Am. Compl. ¶¶ 9-17, and so Bayer assumes without conceding that the laws of each named Plaintiff's home state apply to his or her claims. *See Amato v. Subaru of Am. Inc.*, 2019 WL 6607148, at *12 (D.N.J. Dec 5, 2019).

A. The Breach of Warranty Claims Should Be Dismissed.

Plaintiffs assert claims for breach of express and implied warranty in connection with their purchases of Lotrimin and Tinactin products. A New York court recently dismissed identical warranty claims arising from a manufacturer's recall of a product due to the presence of a contaminant, and this Court should do the same. *See Harris v. Pfizer Inc.*, 586 F. Supp. 3d. 231, 244-45 (S.D.N.Y. 2022).

1. Plaintiffs have not identified any express warranty that was breached.

"[A] plaintiff complaining of breach of express warranty must 'set forth the terms of the warranty upon which [it] relied.'" *Wedra v. Cree, Inc.*, 2020 WL 1322887, at *9 (S.D.N.Y. Mar. 20, 2020).[9] Plaintiffs have not done so here.

Instead, Plaintiffs merely assert that Bayer breached "written warranties" that (1) "the Products were antifungal medications that contained only those active and inactive ingredients listed on the Products' labels"; (2) "the Products are antifungal medications used for the treatment of certain infections and are equivalent to the formulation of the Products as approved by the FDA"; and (3) "the Products were

[9] *See also Pelayo v. Hyundai Motor Am., Inc.*, 2021 WL 1808628, at *7 (C.D. Cal. May 5, 2021) (California); *Barba v. Carlson*, 2014 WL 1678246, at *5 (Del. Super. Ct. Apr. 8, 2014) (Delaware); *Richard's Paint & Body Shop, LLC v. BASF Corp.*, 2012 WL 4052069, at *2 (W.D. Tex. Sept. 12, 2012) (Indiana); *Exum v. Stryker Corp.*, 2013 WL 3786469, at *3 (D. Mass. July 17, 2013) (Massachusetts); *Pfitzer v. Smith & Wesson Corp.*, 2014 WL 636381, at *2 (E.D. Mo. Feb. 18, 2014) (Missouri); *Ellis v. Smith & Nephew, Inc.*, 2016 WL 7319397, at *6 (D.S.C. Feb. 16, 2016) (South Carolina).

the brand-name equivalents of Clotrimazole and Tolnaftate." Am. Compl. ¶ 123. These allegations do not quote any specific statements from Bayer—located either on the product's label or elsewhere—containing this language. *See id.* ¶ 26 (showing purported warranties do not appear on product labels). Plaintiffs' failure to identify the terms of any specific warranty from Bayer requires dismissal of the express warranty claims. *See Harris*, 586 F. Supp. 3d. at 244 (dismissing warranty claim because the manufacturer did not issue "any express warranty that their medication was completely safe or free from" contaminants); *Teixeria v. St. Jude Med. S.C., Inc.*, 193 F. Supp. 3d 218, 224-25 (W.D.N.Y. 2016) ("bare-bone allegations" that defendant warranted products were "safe" and "free from defects" were "too generic to set forth a claim for breach of express warranty").

The recent decision in *Harris* is directly on point. There, the plaintiff argued that product contamination amounted to a breach of the "promise that the medication sold was Chantix, with the active ingredient varenicline." 586 F. Supp. 3d. at 244 The court dismissed an express warranty claim because "the presence of a [contaminant] does not mean that the medication they received was not Chantix, or that it did not contain the active ingredient varenicline." *Id.* The same is here true: the mere presence of benzene does not mean that the products Plaintiffs purchased were not Lotrimin or Tinactin, or that they did not contain the active ingredients clotrimazole and tolnaftate.

2. Plaintiffs' implied warranty claims fail.

Plaintiffs' implied warranty claims fail for two reasons.

First, Plaintiffs do not allege the products failed to fulfill their purpose. "The implied warranty of merchantability 'does not require that the goods be perfect or that they fulfill a buyer's every expectation; it only requires that the goods sold be of a minimal level of quality.'" *Harris*, 586 F. Supp. 3d. at 245. Although Plaintiffs allege that Bayer's products contained benzene, they have not alleged that the presence of benzene prevented the products from performing their central purpose of treating fungal infections. The presence of benzene alone "does not establish that the [product] was unfit for its ordinary purpose," so Plaintiffs' implied warranty claims must be dismissed. *Id.* (dismissing implied warranty claim where complaint did not allege product "failed to fulfill its purpose of helping its users to quit smoking").[10]

Second, Plaintiffs' New York and California implied warranty claims fail for a separate reason: Plaintiffs did not purchase the products directly from Bayer, and therefore privity does not exist. *See* Am. Compl. ¶¶ 80, 82 (alleging purchases from

[10] *See also Hawes v. Macy's Inc.*, 346 F. Supp. 3d 1086, 1093 (S.D. Ohio 2018) (dismissing similar California and Missouri claims); *Charles Messina Plumbing & Elec. Co. v. Smith*, 2006 WL 2641591, at *3 (Del. Com. Pl. Aug. 24, 2006) (dismissing similar Delaware claim); *In re: Elk Cross Timbers Decking Mktg.*, 2015 WL 6467730, at *32 (D.N.J. Oct. 26, 2015) (dismissing similar Indiana claim); *Lee v. Samsung Elecs. Am., Inc.*, 2022 WL 4243957, at *15 (S.D. Tex. Sept. 13, 2022) (dismissing similar Massachusetts and South Carolina claims).

CVS and Walgreens). Under New York and California law, "absent any privity of contract between Plaintiff and Defendant, a breach of implied warranty claim cannot be sustained as a matter of law except to recover for personal injuries." *Gould v. Helen of Troy Ltd.*, 2017 WL 1319810, at *5 (S.D.N.Y. Mar. 30, 2017); *see also Colpitts v. Blue Diamond Growers*, 527 F. Supp. 3d 562, 591 (S.D.N.Y. 2021) (similar).

B. The Fraud Claims Should Be Dismissed.

To maintain a fraud claim under any of the relevant states' laws, a plaintiff must plead that defendant made "a misrepresentation or omission of material fact[,] . . . with the intent to defraud."[11] Plaintiffs fail to allege either. In addition, Plaintiffs' fraud claims under New York, Missouri, South Carolina, and California law are barred by the economic loss doctrine.

1. Plaintiffs fail to allege a fraudulent misrepresentation.

Plaintiffs only cite one alleged misstatement in connection with their fraud claims: that Bayer purportedly "misrepresented that the Products were the brand-name equivalents of Clotrimazole and Tolnaftate when there were not." Am. Compl.

[11] *Overton v. Todman & Co.*, 2009 WL 3154307, at *4 (S.D.N.Y. Sept. 24, 2009) (New York); *accord Zetz v. Boston Sci. Corp.*, 398 F. Supp. 3d 700, 712 (E.D. Cal. 2019) (California); *Crawford-Brunt v. Kruskall*, 2019 WL 2453783, at *5 (D. Mass. June 12, 2019) (Delaware and Massachusetts); *Oakwood Prods., Inc. v. SWK Techs.*, 2022 WL 2107423, at *10 (D.S.C. June 10, 2022) (South Carolina); *Mudd v. Ford Motor Co.*, 178 F. App'x 545, 547 (7th Cir. 2006) (Indiana); *Trimble v. Pracna*, 167 S.W.3d 706, 712 n.5 (Mo. 2005) (Missouri).

¶ 165. The *Harris* court dismissed an identical theory of fraud, explaining that the "presence of a contaminant does not render the brand name on the label false." *Harris*, 586 F. Supp. 3d. at 241. Similarly, here, "neither the product label nor the medication guide state that [clotrimazole and tolnaftate] [are] the *only* biologically ingredients in [Lotrimin and Tinactin]," and Plaintiffs allege "no facts to suggest that the [sprays] differ[ed] so much" from Lotrimin and Tinactin "as to no longer be" those brand-name products. *See id.* (emphasis in original). Because Plaintiffs have not identified any affirmative misstatement by Bayer, their fraudulent misrepresentation theory fails.

2. Plaintiffs' omission theory fails.

Plaintiffs also accuse Bayer of "fraudulent omission," Am. Compl. ¶ 165, based on their contention that Bayer "had a duty to disclose . . . that it was in fact manufacturing, distributing, and selling harmful products unfit for human use," *id.* ¶ 166. When a plaintiff "pleads fraud by omission, 'it must prove additionally that the [defendant] had a duty to disclose the concealed fact.'" *Sher v. Allstate Ins. Co.*, 947 F. Supp. 2d 370, 385 (S.D.N.Y. 2013) (New York); *accord Matanky v. Gen. Motors LLC*, 370 F. Supp. 3d 772, 789 (E.D. Mich. 2019) (applying Missouri, Indiana, California, South Carolina, Delaware, and Massachusetts law). The problem for Plaintiffs is Bayer owed them no duty of disclosure.

Plaintiffs first seek to establish a duty to disclose based on "their relationship [with Bayer] as contracting parties and intended users of the Products." Am. Compl. ¶ 166. But Plaintiffs never entered into a contractual agreement with Bayer; they say that Bayer's products were "sold at retail stores." *See id.* ¶ 18. And a manufacturer does not have a duty to disclose all material facts about a product to an intended user.[12]

Plaintiffs next attempt to ground a duty on Bayer's supposed "superior knowledge" of the alleged benzene contamination, *see* Am. Compl. ¶ 166, but only "*actual* knowledge of [a] purported defect give[s] rise to a duty to disclose," *Woods v. Maytag Co.*, 807 F. Supp. 2d 112, 128 (E.D.N.Y 2011) (emphasis added). Plaintiffs merely assert that Bayer "knowingly, or at least negligently, introduced contaminated, adulterated, and/or misbranded antifungal medications containing dangerous amounts of benzene into the U.S. market." Am. Compl. ¶ 55. This threadbare allegation cannot withstand a motion to dismiss. *See Holmes v. Apple*, 2018 WL 3542856, at *9 (S.D.N.Y. July 23, 2018) (conclusory allegations that defendant "had full knowledge of the defects" do not establish duty to disclose).

[12] *See Garcia v. Chrysler Grp. LLC*, 127 F. Supp. 3d 212, 239 (S.D.N.Y. 2015) (New York); *In re Gen. Motors Corp. Anti-Lock Brake Prods. Liab. Litig.*, 966 F. Supp. 1525, 1535 (E.D. Mo. 1997) (Missouri); *Comfax Corp. v. North Am. Van Lines, Inc.*, 587 N.E.2d 118, 125–26 (Ind. Ct. App. 1992) (Indiana); *Ardis v. Cox*, 431 S.E.2d 267, 270 (S.C. Ct. App. 1993) (South Carolina); *Costa v. FCA US LLC*, 542 F. Supp. 3d 83, 102 (D. Mass. 2021) (Massachusetts); *Ocimum Biosolutions (India) Ltd., Trustee of Ocimum Biosolutions Inc. v. LG Chem. Ltd.*, 2020 WL 3354708, at *8 n.11 (D. Del. July 31, 2022) (Delaware).

3. Plaintiffs fail to allege fraudulent intent.

To comply with Rule 9(b)'s heightened pleading standard, Plaintiffs must "'allege facts that give rise to a strong inference of fraudulent intent.'" *See, e.g.*, *Lerner v. Fleet Bank, N.A.*, 459 F.3d 273, 290 (2d Cir. 2006). Plaintiffs may attempt to do so by "show[ing] that defendants had both motive and opportunity to commit fraud," or through "strong circumstantial evidence of conscious misbehavior or recklessness." *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 276 (3d Cir. 2006) (internal marks omitted) (New York law).[13]

The Amended Complaint contains no such allegations. Instead, Plaintiffs rely on the conclusory allegation that Bayer "intended to hide" the presence of benzene in the products. *See* Am. Compl. ¶ 169. Those types of "conclusory" allegations that a defendant "knew" of and "concealed the allegedly defective" products are insufficient to plead fraudulent intent. *Zottola v. Eisai, Inc.*, 564 F. Supp. 3d 302, 317 (S.D.N.Y. 2021). Insofar as Plaintiffs ask this Court to infer fraudulent intent merely from the fact that the products allegedly contained benzene or violated regulatory or industry standards, those allegations are inadequate. Rather, there must

[13] *Accord Alanann Props., LLC v. Morris Invest., LLC*, 2020 WL 3402873, at *5 (S.D. Ind. June 19, 2020) ("knowledge of or reckless disregard for the falsity of the statement" required under Indiana law); *Christian v. Mooney*, 511 N.E. 2d 587, 593 (Mass. 1987) (requiring "knowledge of the falsity of the misrepresentation or . . . reckless disregard of the actual facts" under Massachusetts law); *DRR, LLC v. Sears, Roebuck & Co.*, 949 F. Supp. 1132, 1137 (D. Del. 1996) ("knowledge or belief that the representation was false, or [was] made with reckless indifference to the truth" under Delaware law).

be allegations, which are not present here, "that significant 'red flags' were ignored." *In re Suprema Specialties*, 438 F.3d at 280; *see also Chill v. Gen. Elec. Co.*, 101 F.3d 263, 270 (2d Cir. 1996) (alleged violations of general accounting principles and SEC regulations are not "adequate proof of recklessness" to plead fraudulent intent).

Any inference of fraudulent intent is also undermined by the fact that Bayer voluntarily disclosed the existence of trace amounts of benzene, announced a recall, and has given affected consumers the opportunity to obtain a full refund. *See* Am. Compl. ¶ 79(a). The only reasonable inference that can be drawn from Bayer's conduct is that it moved promptly to announce a recall and offer refunds to consumers as soon as it learned of the issues. For this reason as well, Plaintiffs' fraud claims should be dismissed. *See Zottola*, 564 F. Supp. 3d at 317 ("[A]ny notion that Defendants acted with fraudulent intent is undercut by Plaintiff's own description [that] Defendants affirmatively disclosed the findings of the 2007 rat study [showing cancer risks] to the FDA."); *Nat'l Union Fire Ins. Co. of Pittsburgh, PA v. Brezill*, 1990 WL 108392, at *3 (S.D.N.Y. 1990) (finding it "highly implausible that [defendant] with intent to defraud, would have obligated itself to make significant payments on behalf of the very people it was supposed to be defrauding").

4. The economic loss doctrine bars Plaintiffs' claims under New York, Missouri, South Carolina, and California law.

Under New York, Missouri, South Carolina, and California law, the economic loss doctrine precludes recovery "where the loss was purely economic" and the complaint "contains no allegations that [the] plaintiff suffered physical or emotional injury."[14] Because Plaintiffs only seek to recover for economic damages stemming from their purchases of Lotrimin and Tinactin products, *see supra* at 15, the economic loss doctrine bars their fraud claims in these states.

C. The Negligent Misrepresentation Claims Should be Dismissed.

None of Plaintiffs' negligent misrepresentation claims can proceed because Plaintiffs have failed to identify any misrepresentation made by Bayer about the products. *See supra* at 27. Nor can Plaintiffs base negligent misrepresentations claims on an omission theory because they have not pleaded that Bayer had a duty to disclose the alleged defects. *See supra* § III.B.2; *see also* Am. Compl. ¶¶ 296-304 (alleging a duty to "exercise reasonable and ordinary care" but not to disclose product defects). For these reasons, Plaintiffs' negligent misrepresentation claims should be dismissed. *See Harris*, 586 F. Supp. 3d. at 242 (dismissing negligent

[14] *Orlando v. Novurania of Am., Inc.*, 162 F. Supp. 2d 220, 226 (S.D.N.Y. 2001) (New York); *Nestle Purina Petcare Co. v. Blue Buffalo Co.*, 181 F. Supp. 3d 618, 639 (E.D. Mo. 2016) (Missouri); *In re Takata Airbag Prods. Liab. Litig.*, 464 F. Supp. 3d 1291, 1308 (S.D. Fla. 2020) (South Carolina); *UMG Recordings, Inc. v. Global Eagle Ent., Inc.*, 117 F. Supp. 3d 1092, 1105-06 (C.D. Cal. 2015) (California).

misrepresentation claim where plaintiff failed to allege parties "had a special relationship" conferring a duty "to give correct information") (internal quotation omitted); *Jasper v. Abbott Lab'ys, Inc.*, 834 F. Supp. 2d 766, 772 (N.D. Ill. 2011) (dismissing negligent misrepresentation claim predicated on product recall where complaint "includes no marketing statements . . . that claim [product] is safe").[15]

In addition, Plaintiffs' negligent misrepresentation claims arising under Missouri, New York, and South Carolina law are barred by the economic loss doctrine because Plaintiffs are not seeking to recover for any personal injuries. *See* Am. Compl. ¶¶ 302-03; *see also Warren v. Whole Foods Mkt. Grp., Inc.*, 574 F. Supp. 3d 102, 118 (E.D.N.Y. 2021) (dismissing New York negligent misrepresentation claim as barred by economic loss doctrine).[16]

D. The State Consumer Protection Act Claims Should Be Dismissed.

Plaintiffs next assert claims under eight states' consumer protection statutes.[17] To state a claim under any of these statutes, a plaintiff must allege that the defendant

[15] *See In re Rust-Oleum Restore Mktg., Sales Pracs. & Prods. Liab. Litig.*, 155 F. Supp. 3d 772, 821 (N.D. Ill. 2016) (California and Indiana); *Arcelik, A.S. v. E.I. Du Pont de Nemours & Co.,* 2022 WL 3139086, at *9 (D. Del. Aug. 5, 2022) (Delaware); *Berenson v. Nat'l Fin. Servs., LLC*, 403 F. Supp. 2d 133, 147 (D. Mass. 2005) (Massachusetts); *McGowan v. Am. Fam. Ins. Co.*, 2017 WL 11680965, at *3 (W.D. Mo. Dec. 15, 2017) (Missouri); *Dombek v. Adler*, 2019 WL 459019, at *5 (D.S.C. Feb. 5, 2019) (South Carolina).

[16] *See also Dannix Painting, LLC v. Sherwin-Williams Co.*, 732 F.3d 902, 906 (8th Cir. 2013) (holding Missouri's economic loss doctrine bars negligent misrepresentation claim) (Missouri); *Bishop Logging Co. v. John Deere Indus. Equip. Co.*, 317 S.C. 520, 530 (S.C. Ct. App. 1995) (South Carolina).

[17] Counts III & IV (violations of New York General Business Law ("GBL") §§ 349 & 350); Count VII (violation of New Jersey Consumer Fraud Act); Count VIII

engaged in deceptive conduct that resulted in cognizable injury.[18] No such allegations exist here. Several claims also suffer independent defects as well.

1. Plaintiffs fail to allege any affirmative misrepresentations.

As a threshold matter, although the Complaint is littered with allegations that Bayer violated the FDCA, this Court must "analyze the sufficiency of [Plaintiffs'] claims . . . without reliance on any purported violations" of the FDCA. *Colpitts v Blue Diamond Growers*, 527 F. Supp. 3d 562, 580 (S.D.N.Y. 2021) (collecting cases). In other words, "Plaintiff's allegations about the Product's compliance or lack thereof with the FDCA are irrelevant to its [consumer protection act] claims." *Budhani v. Monster Energy Co.*, 527 F. Supp. 3d 667, 683 (S.D.N.Y. 2021). Courts therefore consistently dismiss consumer protection act claims predicated solely upon purported FDCA violations. *Barreto v. Westbrae Nat. Inc.*, 518 F. Supp. 3d 795, 805 (S.D.N.Y. 2021) ("[T]he Complaint does not and could not allege a claim for

(violation of Missouri Merchandising Practices Act); Count IX (violation of the Indiana Deceptive Consumer Sales Act); Count X (violation of South Carolina's Unfair Trade Practices Act); Count XI (violation of Massachusetts Consumer Protection Act); Count XII (violation of Delaware Consumer Fraud Act); Counts XIII–XV (violations of California's Consumer Legal Remedies Act, Unfair Competition Law, and False Advertising Law).

[18] *Fink v. Time Warner Cable*, 714 F.3d 739, 741 (2d Cir. 2013) (New York); *see also Shaulis v. Nordstrom, Inc.*, 865 F.3d 1, 6 (1st Cir. 2017) (Massachusetts); *Shanks v. Jarrow Formulas, Inc.*, 2019 WL 4398506, at *4 (C.D. Cal. Aug. 27, 2019) (California); *Carroll v. Philip Morris USA, Inc.*, 163 A.3d 91, 108, 112 (Del. Super. Ct. 2017) (Delaware); *N.J. Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174, 176 (N.J. Super. Ct. 2003) (New Jersey); *Anderson v. Bass Pro Outdoor World, LLC*, 355 F. Supp. 3d 830, 835 (W.D. Mo. 2018) (Missouri); *Poole v. MED-1 Sols., LLC*, 2020 WL 1317450, at *5 (S.D. Ind. Mar. 20, 2020) (Indiana).

private enforcement of FDA regulations. . . . Nor does [the New York General Business Law] fill the gap by creating a state law claim solely as a result of a violation of federal labelling regulations."); *Samet v. Procter & Gamble Co.*, 2013 WL 3124647, at *8 (N.D. Cal. June 18, 2013) ("Plaintiffs must offer more than their legal conclusion that . . . the products were 'misbranded' and contained fat content in excess of the amounts set forth in FDA regulation" to plead violations of California's consumer protection laws).

Perhaps recognizing this authority, Plaintiffs contend that Bayer affirmatively "misrepresent[ed] that the Products (i) would not contain dangerously high levels of benzene, (ii) are generally recognized as safe for human use, and (iii) are equivalent to the formulation of the Products approved by the FDA." Am. Compl. ¶ 142. Again, Plaintiffs never identify any specific representations by Bayer to that effect on the label or otherwise, which alone is fatal to their claims. *See Zottola*, 564 F. Supp. 3d at 312 (dismissing New York GBL claims because plaintiff "only refer[red] to unspecified misleading representations contained in the Medications' 'labels and disclosures'" regarding safety "as opposed to challenging a particular representation"); *Lieberson v. Johnson & Johnson Consumer Cos.*, 865 F. Supp. 2d 529, 539 (D.N.J. 2011) (dismissing NJCFA claim where "other than putting quotations around the alleged statements themselves, Plaintiff has provided absolutely no details concerning their origins or identity").

To the extent that Plaintiffs argue that the products' *names* represented that the products were benzene-free, *Harris* rejected that exact argument. That court held that a consumer fraud violation cannot be predicated on the allegation that a brand name is a representation that a drug is free of contaminants. 586 F. Supp. 3d. at 243-44. This Court should reach the same result.

2. Plaintiffs' omission theory fails.

Plaintiffs' omission theory fares no better. To maintain omission-based claims under consumer protection statutes, a complaint must "plausibly allege[] that the . . . defendants had knowledge of the [material information] and failed to disclose or actively concealed such information."[19] As explained above, Plaintiffs do not plausibly allege that Bayer knew of the presence of benzene when it sold the products, which alone warrants dismissal. *See supra* § III.B.3; *see also Harris*, 586 F. Supp. 3d. at 244 (dismissing omission-based GBL claim because plaintiff did "not plausibly allege that [the defendant] knew about the . . . contamination before it issued its recall"); *Woods v. Maytag Co.*, 2010 WL 4314313, at *16 (E.D.N.Y. Nov.

[19] *In re Sling Media Slingbox Advert. Litig.*, 202 F. Supp. 3d 352, 359 (S.D.N.Y. 2016) (New York) (cleaned up); *see also Demarco v. Avalonbay Cmtys., Inc.*, 2015 WL 6737025, at *5 (D.N.J. Nov. 3, 2015) (New Jersey); *Johnsen v. Honeywell Int'l Inc.*, 2016 WL 1242545, at *3 (E.D. Mo. Mar. 29, 2016) (Missouri); *McQueen v. Yamaha Motor Corp.*, 488 F. Supp. 3d 848, 859 (D. Minn. 2010) (Indiana); *Underwood v. Risman*, 414 Mass. 96, 99 (Mass. 1993) (Massachusetts); *Ridley v. Bayhealth Med. Ctr. Inc.*, 2018 WL 1567609, at *5 (Del. Super. Ct. Mar. 20, 2018) (Delaware); *Wilson v. Hewlett-Packard Co.*, 668 F.3d 1136, 1145 (9th Cir. 2012) (California).

2, 2010) (dismissing omission-based GBL claim where plaintiff "vaguely allege[d] that Defendants knew of the alleged defect").

It makes no difference that Plaintiffs allege that additional testing might have detected benzene. *See* Compl. ¶ 54. Courts reject attempts to predicate knowledge of a defect on alleged failures to "inspect" or "test" a product. *See Morales v. Kimberly-Clark Corp.*, 2020 WL 2766050, at *6 (S.D.N.Y. May 27, 2020) (rejecting "attempts to impute knowledge" that product carried health risk based on alleged failure to "inspect, test, or maintain instruments" used in manufacturing process). Instead, courts look for plausible allegations that defendant "knew of the defect before they sold the product"—and the Complaint lacks any. *See In re Frito-Lay N. Am., Inc. All Nat. Litig.*, 2013 WL 4647512, at *26 (E.D.N.Y. Aug. 29, 2013) (allegation that defendant could have learned truth by testing products did not plausibly establish "knowledge of the falsity of [defendant's] representation that the products were 'All Natural'").

3. Plaintiffs' claims fail to plead a cognizable injury.

All of Plaintiffs' state consumer protection claims should also be dismissed because the full refund program that Bayer has offered in connection with its recall eliminates Plaintiffs' ability to demonstrate any cognizable injury. As courts have observed, there are no cases "in which a court has held that a plaintiff sustained actual damages where a defendant has an unrestricted refund policy that fully

compensate[s] the plaintiff." *Preira v. Bancorp Bank*, 885 F. Supp. 2d 672, 678 (S.D.N.Y. 2012). Since Bayer already provided Plaintiffs an "adequate remedy for the problem" in the form of a full refund, their state consumer protection act claims should be dismissed. *Kommer v. Ford Motor Co.*, 2017 WL 3251598, at *5 (N.D.N.Y. July 28, 2017) (finding no harm where the product for which plaintiff overpaid "can be repaired for free as part of the warranty").

4. Plaintiffs' claims suffer from additional defects.

Plaintiffs' consumer protection claims merit dismissal on additional grounds.

Counts III & IV (New York GBL §§ 349 & 350). Plaintiffs' GBL claims should be dismissed for an additional reason: they fail to plead actual damages. Plaintiffs seek to proceed on a "price premium" theory of recovery, which requires factual allegations that a defendant "charges a premium for its products" based on its alleged misrepresentations and that the plaintiff would not have paid that premium "but for the deceptive practice." *Colella v. Atkins Nutritionals, Inc.*, 348 F. Supp. 3d 120, 143 (E.D.N.Y. 2018). But here, the "premium" Plaintiffs claim they paid is equivalent to "the full purchase price of the Products." Am. Compl. ¶¶ 149, 161. This exposes Plaintiffs' premium-pricing theory as nothing more than a claim for a full refund, and a claim that Plaintiffs were "injured in the amount of the entire 'purchase price' fails as a matter of law." *Hu v. Herr Foods, Inc.*, 2017 WL

11551822, at *2 (E.D. Pa. Sept. 26, 2017); *see also Zottola*, 564 F. Supp. 3d at 310-11 n.6 (same).

Count IX (Indiana Deceptive Consumer Sales Act). To the extent that Plaintiffs allege Bayer engaged in "incurable deceptive acts," under the Indiana Deceptive Consumer Sales Act ("IDCSA"), *see* Am. Compl. ¶ 217, Plaintiffs must allege "[a]n intent to defraud," meaning that Bayer "knowingly or intentionally omitted material facts relating to the . . . [d]efect." *McQueen.*, 488 F. Supp. 3d at 859 (dismissing IDCSA claim on this basis). For the reasons explained above, *see supra* § III.B.3, Plaintiffs have failed to make this showing.

Count X (South Carolina Unfair Trade Practices Act). Plaintiffs' class action claims under the South Carolina Unfair Trade Practices Act must be dismissed because such claims "may not be brought by a private party in a representative capacity." *Fejzulai v. Sam's West, Inc.*, 205 F. Supp. 3d 723, 725 (D.S.C. 2016).

Counts XIII, XIV, and XV (California's Consumer Legal Remedies Act, Unfair Competition Law, and False Advertising Law). Plaintiffs' claims under California's state consumer protection statutes fail for two additional reasons. First, under California law, a manufacturer does not owe a duty to disclose consumer product defects to end users of the product unless "the manufacturer makes an affirmative misrepresentation or the defect relates to a safety issue." *Taleshpour v. Apple, Inc.*, 2022 WL 1577802, at *1 (9th Cir. May 19, 2022). Here, for the reasons

explained, Plaintiffs have not identified any affirmative misrepresentations about the products or plausibly alleged that the benzene levels detected in the products they purchased posed any safety concerns sufficient to give rise to a duty to disclose. Second, Plaintiffs cannot pursue claims for equitable relief under California's Consumer Legal Remedies Act (CLRA) or Unfair Competition Law (UCL) because they have not "establish[ed] that [they] lack[] an adequate remedy at law," as required under California law. *Sonner v. Premier Nutrition Corp.*, 971 F.3d 834, 844 (9th Cir. 2020). To the contrary, because Plaintiffs have "an adequate remedy at law" in the form of their other state law claims, they cannot seek equitable relief under the CLRA or UCL. *See id.*

E. The Unjust Enrichment Claim Should Be Dismissed.

Although Plaintiffs' original complaint included an unjust enrichment claim, Plaintiffs "withdr[e]w their claim for unjust enrichment" in their opposition to Bayer's motion to dismiss. *See* ECF No. 21 at 40 n.6. To the extent Plaintiffs intend to re-assert an unjust enrichment claim, that claim fails for three reasons.

First, the unjust enrichment claims should be dismissed as duplicative to Plaintiffs' other claims. "An unjust enrichment claim cannot survive 'where it simply duplicates, or replaces, a conventional contract or tort claim.'" *Harris*, 586 F. Supp. 3d. at 246. Here, Plaintiffs' unjust enrichment claim is entirely duplicative

with their other causes of action: it relies on the same factual allegations, the same theory of liability, and seeks the same relief. *See* Am. Compl. ¶¶ 175-77.

Second, Plaintiffs do not adequately allege that they conferred any direct benefits on Bayer. Instead, Plaintiffs either admit or do not deny they purchased the products from a third party, *see id.* ¶¶ 80, 82, 84, 86, 88, 90, 92, 94, 96, and such claims cannot support an unjust enrichment claim because the third party, not the product manufacturer, receives the benefit of the transaction. *See In re Keurig Green Mountain Single-Serve Antitrust Litig.*, 383 F. Supp. 3d 187, 272 (S.D.N.Y. 2019); *Fenerjian v. Nongshim Co.*, 72 F. Supp. 3d 1058, 1091 (N.D. Cal. 2014).

Third, Plaintiffs do not plausibly allege that Bayer was unjustly enriched at their expense. As noted above, Plaintiffs received the benefit of their bargain by receiving products that functioned as intended. *Supra* § I.A.1. Plaintiffs also cannot plausibly allege that Bayer was unjustly enriched at their expense when they made a tactical decision not to accept Bayer's offer of a full refund. *See Tasini v. AOL, Inc.*, 851 F. Supp. 2d 734, 739-40 (S.D.N.Y. 2012) ("'The essential inquiry in any action for unjust enrichment . . . is whether it is against equity and good conscience to permit the defendant to retain what is sought to be recovered.'"), *aff'd*, 505 F. App'x 45 (2d Cir. 2012).

CONCLUSION

This Court should dismiss the First Amended Complaint with prejudice.

Dated: October 28, 2022

Respectfully submitted,

McCarter & English, LLP

By: *s/ Edward J. Fanning Jr.*
Edward J. Fanning, Jr.

Edward J. Fanning, Jr.
Four Gateway Center
100 Mulberry St.
Newark, NJ 07102
Telephone: (973) 639-7927
Facsimile: (973) 297-3868
Email: efanning@mccarter.com

Covington & Burling LLP

Henry Liu, *Pro Hac Vice*
Andrew Soukup, *Pro Hac Vice*
Marianne Spencer, *Pro Hac Vice*
One CityCenter
850 Tenth Street, NW
Washington, DC 20001
Telephone: (202) 662-6000
Facsimile: (202) 778-5536
Email: hliu@cov.com
asoukup@cov.com
mspencer@cov.com

Alexander Setzepfandt, *Pro Hac Vice*
Salesforce Tower
415 Mission Street
San Francisco, CA 94105-2533
Telephone: (415) 591-7077
Facsimile: (415) 955-6577
Email: asetzepfandt@cov.com

Counsel for Defendant Bayer U.S., LLC