PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 23-2178

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

v.

BAYER US LLC

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On Appeal from the United States District Court
for the District of New Jersey
(District Court No. 2-21-cv-20021)
District Judge: Honorable Susan D. Wigenton

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Argued May 1, 2024

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Before: KRAUSE, CHUNG, and AMBRO, Circuit Judges.

(Filed November 7, 2024)

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OPINION OF THE COURT

CHUNG, Circuit Judge.

Bayer U.S. LLC ("Bayer") is a pharmaceutical company that sells a variety of healthcare products, including the antifungal Lotrimin and Tinactin spray products at issue in this litigation. Lotrimin and Tinactin are used to treat skin infections, such as athlete's foot and ringworm.[1] In October 2021, Bayer recalled millions of dollars' worth of Lotrimin and Tinactin spray products after discovering that products dating back to 2018 were contaminated with benzene. Plaintiffs here—nine individuals who purchased Lotrimin and Tinactin products during the recall period—do not allege that they have suffered any physical injuries from using contaminated products. Instead, they seek compensation for economic losses they allegedly suffered from purchasing products that they claim are worth less than the uncontaminated products for which they bargained. Because we conclude that the District Court erred in applying a heightened legal standard for standing, we will partially reverse the District Court's order dismissing the complaint for lack of standing as to some Plaintiffs and remand for proceedings consistent with this opinion.

[1] Both products are regulated by the Food and Drug Administration ("FDA") under the United States Food, Drug, and Cosmetics Act ("FDCA").

I. BACKGROUND[2]

Benzene is a chemical that has been labeled a human carcinogen and linked to cancers, such as leukemia and non-Hodgkin lymphoma, by various governmental agencies and cancer research institutions. In 2018, the Food and Drug Administration ("FDA") released guidance concerning the levels at which certain solvents are considered safe in pharmaceuticals. The FDA rated benzene among the few substances at issue that "should not be employed in the manufacture of drug substances … and drug products because of their unacceptable toxicity." Food and Drug Administration, Q3C – Tables and List Rev. 4: Guidance for Industry 5 (Aug. 2018), https://www.fda.gov/media/133650/download. However, if the "use [of benzene] is unavoidable in order to produce a drug product with a significant therapeutic advance, then [its] levels should be restricted" to 2 parts per million (the "FDA guideline limit").[3] Id. Benzene exposure can occur through inhalation, orally, or through skin absorption.

In October 2021, Bayer voluntarily recalled certain Lotrimin and Tinactin spray products after it discovered

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[2] We rely on the facts as stated in Plaintiffs' complaint and take them as true for purposes of this motion to dismiss under Rule 12(b)(1).

[3] This guidance is for products that cannot be produced without the use of benzene. Both parties acknowledge that benzene is not an ingredient of Lotrimin and Tinactin products, and neither asserts that the FDA guidance contemplates the inclusion of benzene in these products.

benzene in samples of the products. The recall covered unexpired "spray products with lot numbers beginning with TN, CV, or NAA" that were "distributed between September 2018 to September 2021." App. 135. The recall notice acknowledged that "[b]enzene is classified as a human carcinogen" and that "[e]xposure to benzene can occur … through the skin." App. 136. Despite the notice's admission that "[b]enzene is not an ingredient in any of Bayer[']s Consumer Health products," it clarified that its "decision to voluntarily recall these products is a precautionary measure and that the levels detected are not expected to cause adverse health consequences in consumers." App. 135–36. Shortly after the recall, pharmaceutical testing company Valisure, LLC ("Valisure") tested thirteen samples of recalled Lotrimin and Tinactin products. Twelve of the thirteen samples, all with lot numbers beginning with TN, contained detectable levels of benzene, and eleven of the samples' levels exceeded the FDA guideline limit.[4]

Plaintiffs Juan Huertas and Eva Mistretta filed a putative class action on November 16, 2021, alleging that they purchased Lotrimin and Tinactin products during the recall period and seeking damages for various state law causes of action. The District Court dismissed the original complaint without prejudice, and Plaintiffs filed their First Amended Complaint ("FAC") in September 2022, which added seven additional named plaintiffs.

According to the FAC, "[t]he notable consistency with

[4] Plaintiffs do not provide details about the product sample that did not contain detectable levels of benzene, so it is unclear to which lot this product belonged.

which unacceptable levels of benzene were detected by Valisure in the Products they tested indicates that the Products [that] Plaintiffs and members of the Classes purchased contained impermissible levels of benzene." App. 250. Plaintiffs argued that this manufacturing flaw (1) deprived them of the benefit of their bargain because they contracted for safe products that did not contain benzene, but they got benzene-contaminated products that were unusable and worthless, and (2) they "were forced to waste portions of the Products or to spend additional money to purchase replacement medications that they would not have spent but for the Products being contaminated." App. 256. Plaintiffs also argued that their exposure to benzene increased their risk of developing cancer in the future, requiring them "to undertake significant monitoring they otherwise would not have to detect the possible development of cancers and other ailments."[5] App. 256.

All of the Plaintiffs alleged that they purchased Lotrimin or Tinactin spray products during the recall period from September 2018 to September 2021. Each Plaintiff also alleged that his or her product(s) contained benzene, but only four of the nine Plaintiffs—Juan Huertas, Eva Mistretta, Jeremy Wyant, and Mike Poovey—provided lot numbers specified in the recall.[6]

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[5] Plaintiffs do not claim they contracted cancer or suffered any other physical ailments as a result of using the contaminated products in this litigation.

[6] Huertas alleged that he purchased a Lotrimin product with the lot number TN009K7 in approximately August 2021.

The District Court dismissed the FAC with prejudice in May 2023 for lack of standing. It concluded that the FAC's "addition of multiple Plaintiffs and a plethora of conclusory statements, copied and pasted vague assertions, and facts requiring inferential leaps" failed to "remed[y] the factual deficiencies that existed in the original Complaint." App. 14. As a result, the District Court held that "the FAC does not sufficiently allege facts to support the conclusion that Plaintiffs suffered economic loss," App. 16, or harm stemming from the increased risk of developing a physical injury in the future as a result of using a benzene-contaminated product. Plaintiffs timely appealed.

II. JURISDICTION AND STANDARD OF REVIEW

The District Court had jurisdiction over Plaintiffs' claims pursuant to 28 U.S.C. § 1332. We have jurisdiction over Plaintiffs' appeal under 28 U.S.C. § 1291. "[O]ur review of the grant of a motion to dismiss is plenary." Morse v. Lower Merion Sch. Dist., 132 F.3d 902, 906 (3d Cir. 1997). "A motion to dismiss for want of standing is ... properly brought

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Mistretta alleged that she purchased a Tinactin product with the lot number CV01E2X in approximately July 2021. Wyant alleged that he purchased several canisters of Lotrimin and Tinactin products between September 2018 and September 2021, but provided the lot number for only one Tinactin product. The lot number for that product was TN00273. Poovey alleged that he purchased a Lotrimin product with the lot number TN001NK sometime between September 2018 and September 2021. No one alleged purchasing a product with a lot number beginning in "NAA."

pursuant to Rule 12(b)(1), because standing is a jurisdictional matter." Ballentine v. United States, 486 F.3d 806, 810 (3d Cir. 2007). "In evaluating whether a complaint adequately pleads the elements of standing, courts apply the standard of reviewing a complaint pursuant to a Rule 12(b)(6) motion to dismiss for failure to state a claim: Court[s] must accept as true all material allegations set forth in the complaint, and must construe those facts in favor of the nonmoving party."[7] In re Schering Plough Corp. Intron/Temodar Consumer Class Action, 678 F.3d 235, 243 (3d Cir. 2012) (alteration in original) (quotations omitted). "To survive a 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) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "While the plausibility standard does not impose a 'probability requirement,' it does demand 'more than a sheer possibility that a defendant has acted unlawfully.'" In re Schering, 678 F.3d at 243 (quoting Iqbal, 556 U.S. at 678).

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[7] A 12(b)(1) challenge can be either facial or factual. "A facial 12(b)(1) challenge, which attacks the complaint on its face without contesting its alleged facts, is like a 12(b)(6) motion in requiring the court to consider the allegations of the complaint as true." Hartig Drug Co. Inc. v. Senju Pharm. Co., 836 F.3d 261, 268 (3d Cir. 2016) (quotations omitted). A factual challenge, on the other hand, "attacks allegations underlying the assertion of jurisdiction in the complaint, and it allows the defendant to present competing facts." Id. Bayer's motion to dismiss is a facial challenge because it contests the sufficiency of Plaintiffs' allegations without challenging their truth.

III. DISCUSSION

"To establish standing, a plaintiff must have (1) suffered an injury[-]in[-]fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Liab. Litig., 903 F.3d 278, 284 (3d Cir. 2018) [hereinafter J&J] (quotations omitted). This appeal turns on the first prong of the standing inquiry—whether Plaintiffs' complaint plausibly alleged injury-in-fact. Injury-in-fact is comprised of three sub-elements: (1) "an invasion of a legally protected interest;" (2) "injury [that] is both concrete and particularized;" and (3) "injury [that] is actual or imminent, not conjectural or hypothetical." Id. (quotations omitted).

"While it is difficult to reduce injury-in-fact to a simple formula, economic injury is one of its paradigmatic forms." Danvers Motor Co. v. Ford Motor Co., 432 F.3d 286, 291 (3d Cir. 2005). One way "a plaintiff might successfully plead an economic injury [is] by alleging that she bargained for a product worth a given value but received a product worth less than that value." J&J, 903 F.3d at 283. This is known as the benefit-of-the-bargain theory of injury. Under this theory, "[t]he economic injury is calculated as the difference in value between what was bargained for and what was received." Id. Plaintiffs here rely on the benefit-of-the-bargain theory to establish injury-in-fact, arguing that they paid full purchase price for products "free of contaminants and dangerous substances," App. 255, but received products that were defectively manufactured with "harmful levels of benzene," causing them to be "adulterated" and therefore "worthless," App. 254. We conclude that Plaintiffs can rely on this theory

of economic injury.[8]

A. Plaintiffs Have Plausibly Alleged that Benzene-Contaminated Products Are Worth Less than Uncontaminated Products.

Plaintiffs' theory of economic standing is straightforward: benzene-contaminated products are worth less than a properly manufactured product, thereby depriving Plaintiffs of the benefit of their bargain. Plaintiffs' argument to that effect is straightforward: they "bargained for an antifungal product free of contaminants and dangerous substances," App. 255, but instead received products that were "unmerchantable and unfit for use," id., "as they [were] adulterated and contain[ed] harmful levels of benzene," App. 254. This defect, Plaintiffs allege, rendered their products worthless.

We conclude that Plaintiffs have plausibly alleged that Lotrimin and Tinactin products that are unusable due to the

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[8] Plaintiffs also contend that they suffered economic harm because they were forced to waste unused product as a result of the contamination, and Huertas alleges that he purchased a replacement product he would not have had to purchase but for the recall. Because we conclude that Plaintiffs can rely on a benefit-of-the-bargain theory, we do not reach these alternative bases for establishing injury-in-fact.

The FAC submits that Plaintiffs can establish injury-in-fact based on their increased risk of developing disease from using the recalled products and consequent need for medical monitoring. Plaintiffs do not raise this issue on appeal, however.

contamination are necessarily worth less than the product when properly manufactured.[9] The logic requires little elaboration: if a product contains a manufacturing flaw so severe that it cannot be used,[10] it is not worth the full price purchasers paid with the understanding they would be able to use all of the product. Here, Bayer's recall notice recognized that "[b]enzene is classified as a human carcinogen" and that it "is not an ingredient in any of Bayer Consumer Health products," including Lotrimin and Tinactin. App. 135, 136. In other

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[9] We do not decide whether contaminated products are necessarily "worthless," as Plaintiffs allege. Having concluded that Plaintiffs' theory is viable, we need not determine precisely how much less contaminated products are worth.

[10] Bayer points out that the FDA's guideline limit is nonbinding guidance, implying that Plaintiffs could only rely on this guideline if it established a strict legal limit for benzene. To the contrary, companies are frequently subject to legal liability for manufacturing defects that are not specifically regulated by law. Though lack of federal laws or regulations may, in some cases, impact a party's liability, their absence is not dispositive in determining whether a plaintiff has plausibly alleged an injury for standing purposes. Moreover, this argument conflicts with Bayer's own reliance on the FDA guidance in its complaint against Aeropres Corporation, including that Bayer issued the recall after discovering that samples of "Lotrimin and Tinactin products were above the FDA's acceptable limit of 2 parts per million." Compl. & Demand for Jury Trial, Bayer HealthCare LLC v. Aeropres Corporation, No. 1:23-cv-04391 ¶ 40 (N.D. Il. July 7, 2023) [hereinafter "Aeropres Complaint"]; see infra, discussion of Aeropres Complaint.

words, the contaminated products contained a manufacturing defect because they contained a carcinogenic component that is not an ingredient of the products. The recall notice went on to instruct that consumers "should stop using" the recalled products, meaning that, as a result of the defect, the products were no longer fit for use. App. 137. Since the contaminated products contained a defect that rendered them unusable, the products were worth less than their full purchase price.[11] To hold otherwise would be to conclude that an unusable product is worth the same as a usable one—a conclusion that resists logic.

Bayer argues that our decision in J&J forecloses Plaintiffs' theory of economic injury. There, the plaintiff sued Johnson & Johnson under the benefit-of-the-bargain theory, arguing that she suffered economic injury by purchasing baby powder that allegedly increased the risk of developing ovarian cancer. 903 F.3d at 281–82. She contended that baby powder had been marketed as a safe product, and had she known of its risks, she would not have purchased the product. Id. at 283.

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[11] Contrary to Bayer's claim that "Plaintiffs here do not allege that they stopped taking Lotrimin or Tinactin because they learned of the possibility that their products contained benzene," Resp. Br. 27, each Plaintiff alleges that he or she "still had a portion" of their Lotrimin or Tinactin products and that they "did not use and [were] unable to use the remaining portion[s]" of those products "*as a result* of [the] contamination." App. 263–277. (emphasis added). Construing these allegations in the light most favorable to Plaintiffs, they can plausibly allege they intended to use their products but were unable to do so "as a result" of the benzene contamination.

We explained that the plaintiff failed to allege standing because she "entirely consumed a product that … functioned for her as expected," id. at 280, and her "theory of recovery [wa]s simply that she suffered an economic injury by purchasing improperly marketed Baby Powder," id. at 282 (emphasis omitted). We rejected the theory because it amounted to no more than an allegation that she purchased a product at a given price and "later wished [she] had not done so." Id. at 288. Instead, we explained that a plaintiff must "allege facts that would permit a factfinder to determine that the economic benefit she received in purchasing the powder was worth less than the economic benefit for which she bargained." Id. at 285. More simply, she was required to "allege that she purchased Baby Powder that was worth less than what she paid for." Id. at 287.

According to Bayer, however, J&J did something more. Bayer reads J&J to mean that "the mere presence of an unwanted attribute does not render a product defective and 'worth less' than what it otherwise would be worth." Resp. Br. at 23. In other words, Bayer argues that J&J forecloses Plaintiffs' position that a "contaminated product is inherently worth less than the risk-free, properly manufactured product." Resp. Br. 23. J&J applies here, Bayer contends, because "Plaintiffs here have not alleged that the products they purchased failed to cure their fungal infections as expected." Resp. Br. 23.

As an initial matter, J&J is distinguishable because the Court explicitly recognized that it did "not involve allegations of a defective product." 903 F.3d at 281. Here, however, Bayer's products were not supposed to contain benzene, and

Plaintiffs plausibly alleged that the benzene contamination[12]—the product's defect—rendered it unusable, making it inherently worth less than if it had been manufactured properly.[13]

Moreover, J&J did not hold that the *only* way to prove that an unsafe product is worth less is by alleging that the product did not perform therapeutically as expected. This is evident from J&J's reliance on our earlier case, Cottrell v. Alcon, Lab'ys, 874 F.3d 154 (3d Cir. 2017). In Cottrell, plaintiffs demonstrated an injury-in-fact when they purchased an eye medication because the medication's dropper dispensed excessive product. Id. at 159. Thus, the source of their economic injury was a design defect resulting in waste. J&J

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[12] Bayer uses the term "contamination" imprecisely to refer to any product that contains an undesirable component, even when properly manufactured. However, Plaintiffs here use the term specifically to describe products that "were contaminated" by a component that is not an ingredient of the properly manufactured product, resulting in "a manufacturing defect." Opening Br. 37.

[13] Our decision in J&J also confronted unique facts not present here. Specifically, in J&J, we could not "presume that [the plaintiff] would spend more for safe powder than she would for unsafe powder" because she "desire[d] to continue purchasing Baby Powder in the future despite being aware of its alleged health risks," regardless of whether "the powder [was] sold at a discounted price." Id. at 288-89. "In the absence of that condition, we [could not] presume that [plaintiff] wishe[d] to continue to buy Baby Powder at anything other than its … market price." Id. at 289.

explained that key to Cottrell's outcome was that "plaintiffs' economic theory of harm was based on more than mere conjecture." J&J, 903 F.3d at 285; see also id. at 286–87. By contrast, the J&J plaintiff "fail[ed] to allege … that the Baby Powder provided her with an economic benefit worth one penny less than what she paid." Id. at 288. Instead, she only "offer[ed] conclusory assertions of economic injury." Id. at 285.

As in Cottrell, Plaintiffs' theory of economic injury here is more than mere conjecture. Similar to the allegation in Cottrell that plaintiffs' products contained a design defect leading to product waste, Plaintiffs here allege that a manufacturing defect rendered contaminated products unusable. These unusable products were worth less than the products when properly manufactured and fit for human use.

Our conclusion that contaminated products are worth less than uncontaminated products is consistent with decisions from other Courts of Appeals. For example, in In re Aqua Dots Products Liab. Litig., several parents sued a manufacturer that produced a toy with defective components that, when ingested, metabolized into a chemical substance that can cause a variety of side effects and could even lead to death. 654 F.3d 748, 749 (7th Cir. 2011). The parents' children were not harmed by the toy, but the Seventh Circuit nonetheless concluded that the parents had standing to sue under a benefit-of-the-bargain theory because "they paid more for the toys than they would have, had they known of the risks the beads posed to children." Id. at 751. Similarly, in Debernardis v. IQ Formulations, LLC, 942 F.3d 1076 (11th Cir. 2019), the Eleventh Circuit held that plaintiffs who purchased adulterated dietary supplements under the FDCA "received … defective product[s] that had no

value." Id. at 1085. The Eleventh Circuit explained that its "conclusion [was] consistent with the well-established benefit-of-the-bargain theory of contract damages, which recognizes that some defects so fundamentally affect the intended use of a product as to render it valueless."[14] Id.

In sum, Plaintiffs alleged that they purchased recalled Lotrimin and Tinactin products based on the understanding that those products would be fit for topical use in treating fungal infections. Instead, they received products that they were instructed to "stop using" and to "discard … appropriately." App. 137, 136. Given that contaminated products are unfit for their intended use, they are inherently worth less than the uncontaminated products Plaintiffs thought they were purchasing.

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[14] We recognize, as Bayer points out, that Debernardis is distinguishable to the extent that it concluded that adulterated supplements were worthless based on the FDCA's explicit prohibition on "the sale of adulterated dietary supplements," which was in turn based on Congress's judgment that "such substances could not safely be ingested." 942 F.3d at 1085. Bayer, however, cites no authority suggesting that a legal prohibition is the sole basis upon which our conclusion here can be reached. Indeed, whether through a legal prohibition or a product recall, the end result is the same: if their products are contaminated, they are unusable. Although Bayer's recall notice explained "the levels detected are not expected to cause adverse health consequences," App. 136, the economic injury addressed here is not for costs associated with adverse health consequences.

B. Whether Plaintiffs Plausibly Alleged They Purchased Defective Products

Having determined that Plaintiffs have plausibly alleged economic injury, we must still determine whether they sufficiently alleged that *their* products were defectively manufactured and contained benzene. See J&J, 903 F.3d at 289 (explaining that allegations that a product is "unsafe *as to others* are not relevant to determining whether [named plaintiffs] ha[ve] standing [themselves]"). Otherwise, their claim that they purchased a product worth less than the product for which they bargained necessarily fails, and they are not entitled to relief under the benefit-of-the-bargain theory.

Plaintiffs need only demonstrate standing "with the manner and degree of evidence required at the successive stages of the litigation." Lujan v. Defs. of Wildlife, 504 U.S. 555, 561 (1992). At the motion-to-dismiss stage, "courts cannot inject evidentiary issues into the plausibility determination," Schuchardt v. President of the United States, 839 F.3d 336, 347 (3d Cir. 2016), because "the [subsequent] discovery process is designed to enable [plaintiffs] … to un[ ]cover evidence that may support the allegations set forth in a complaint," Evancho v. Fisher, 423 F.3d 347, 354 (3d Cir. 2005). Thus, as a general matter, Plaintiffs need not assert with specificity the extent of the contamination across all products, so long as they provide sufficient details to plausibly allege that *their* products were contaminated. In evaluating such an allegation, we must "accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom[ ] and view them in the light most favorable to the plaintiff." Id. at 350. The key, though, is that we only draw "*reasonable*" inferences in a plaintiff's favor. See id.

(emphasis added).

Plaintiffs urge us to infer from Bayer's recall itself that Plaintiffs' products were contaminated. We agree with the District Court that this was insufficient to establish that they purchased contaminated products. The mere fact that a product was recalled would "not nudge[ ] [Plaintiffs'] claims across the line from conceivable to plausible." Twombly, 550 U.S. at 570.[15]

In addition to the recall itself, Plaintiffs offer Valisure's testing results to establish that they purchased contaminated products. In finding that Plaintiffs had not plausibly alleged that their products contained benzene, the District Court rejected Plaintiffs' reliance on the Valisure testing and explained that "[b]ecause Plaintiffs … 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." App. 20. While we understand the challenge the District Court faced in assessing the limited testing results presented by Plaintiffs,[16] we conclude that the District Court's

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[15] That is particularly true here, where Valisure's testing is consistent with Bayer's claim in the recall notice that benzene was discovered in "some samples" of the product. App. 135.

[16] Valisure did not test Plaintiffs' products. Instead, Valisure tested thirteen Lotrimin and Tinactin samples. Twelve of these samples, all with lot numbers beginning TN,

reasoning was flawed.

Plaintiffs need only plausibly allege that they purchased contaminated products. This does not require a showing that *all* products in the recall were contaminated, as this would impose a heightened standard requiring that it be more likely than not—or probable—that Plaintiffs purchased a defective product. See Twombly, 550 U.S. at 556 ("Asking for plausible grounds to infer [contamination] does not impose a probability requirement at the pleading stage; it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of [an injury]."); see also In re Recalled Abbott Infant Formula Prod. Liab. Litig., 97 F.4th 525, 529-30 (7th Cir. 2024) (suggesting that injury is adequately particularized when facts allege that "contamination of [ ] products was sufficiently widespread to plausibly affect any given [product], including the ones [Plaintiffs] purchased"); John v. Whole Foods Mkt. Grp., Inc., 858 F.3d 732, 734-36 (2d Cir. 2017) (holding injury was plausibly alleged when third-party testing conducted during the relevant period determined that the challenged

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contained detectable levels of benzene and levels in eleven of those samples exceeded the FDA guideline limit. The FAC provides no context for this testing, however, and Plaintiffs' arguments on appeal do not fully address this weakness. For example, Plaintiffs do not explain why positive tests of twelve "TN" samples out of the hundreds of thousands of products recalled is sufficient to extrapolate that their products were plausibly contaminated, nor whether Valisure's testing of TN samples is representative of products bearing CV and NAA lot numbers.

mislabeling practices were "systematic" and "routine").[17]

Even applying this standard, we might still have reservations about the reasonable inferences that could be drawn from Plaintiffs' allegations, but on appeal, Plaintiffs have offered additional support. Specifically, Plaintiffs notified us of a complaint in a separate, later action filed by Bayer against Aeropres Corporation, the manufacturer of the component in Lotrimin and Tinactin that was contaminated with benzene, for costs associated with the recall. SeeAeropres Complaint. Plaintiffs requested that we take judicial notice of the Aeropres Complaint, and we granted the motion. Because Bayer filed the Aeropres Complaint after the District Court dismissed Plaintiffs' FAC with prejudice, Plaintiffs raise this

[17] Requiring Plaintiffs to show that *all* tested products were contaminated is flawed for another reason – such results would not necessarily reflect that Plaintiffs' products were contaminated. For example, if 1,100 products were recalled, a result reflecting that one hundred percent of samples were contaminated based on a sample size of two products would tell us less about the plausibility of contamination than a ninety percent positive rate based upon a sample size of 1,000 products. This example is not to suggest that there is a specific level of sampling we deem to be representative, nor a specific percentage of defective products that must ultimately be established from that sampling. Quite the contrary. We recognize the inherent challenges in obtaining contamination data at the dismissal stage, as well as the relatively low burden set by notice pleading. The example is simply meant to demonstrate the importance of assessing what testing results plausibly suggest, rather than applying arbitrary metrics to determine their significance.

argument, necessarily, for the first time on appeal.

According to the Aeropres Complaint, "Bayer commissioned … testing of Lotrimin and Tinactin samples[,] which revealed that Lotrimin and Tinactin samples manufactured beginning in September 2018, the date of manufacture of the oldest unexpired lots, were contaminated with benzene." Id. ¶ 41. The Aeropres Complaint refers to "data [Bayer] relied upon in deciding to proceed with the recall" as well as "communications with [the] FDA regarding the recall." Id. ¶ 47. That data led to a recall that has "caused Bayer to incur millions of dollars in losses." Id. ¶ 45. According to Bayer, "[t]hese damages include approximately $9 million to refund stores in the U.S. for on-shelf and in-store inventory, $1 million to refund U.S. consumers who purchased product from stores, $1.2 million in fees to a refund service provider, and $800,000 to recall products in Mexico and Canada." Id. ¶ 52. Additionally, "Bayer had to destroy and write-off millions of dollars' worth of damaged Lotrimin and Tinactin product that was unsaleable due to Aeropres' contamination." Id. ¶ 53. By signing the complaint, Bayer's counsel certified that "to the best of [their] knowledge, information, and belief, … the factual contentions have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery." Fed. R. Civ. P. 11(b)(3).

Plaintiffs ask us to consider the allegations in the Aeropres Complaint as lending support for the plausibility of Plaintiffs' allegations of contamination. While before the District Court, Plaintiffs were given the opportunity to amend their original complaint, but at that time, the Aeropres Complaint had not yet been filed. Therefore, Plaintiffs' FAC

was necessarily devoid of allegations regarding Bayer's contentions in the Aeropres Complaint, which may have supported a potential finding of plausibility.[18] Rather than

[18] Plaintiffs noted a number of inconsistencies between Bayer's position here and in the Aeropres Complaint. See, e.g., Answering Br. 20 ("Bayer recalled certain lots 'as a precautionary measure,' and the mere inclusion of a lot in the recall does not support an inference that any product in that lot ... contained benzene."), with Aeropres Compl. ¶ 44 ("Bayer commissioned additional testing of Lotrimin and Tinactin samples which revealed that Lotrimin and Tinactin samples manufactured beginning in September 2018, the date of manufacture of the oldest unexpired lots, were contaminated with benzene."), id. ¶ 47 (reflecting that Bayer "relied upon [data] in deciding to proceed with the recall" as well as "communications with [the] FDA regarding the recall"), id. ¶ 42 (the recall was "a direct result of Aeropres's supply of benzene contaminated Propellant A-31"), id. ¶ 59 ("Aeropres provided Bayer with Propellant A-31 containing benzene in amounts exceeding acceptable limits established by FDA and causing the products to be recalled."), and id. ¶ 88 ("Bayer's Lotrimin and Tinactin products were damaged beyond use or repair.").

We requested supplemental briefing to address whether Bayer's allegedly inconsistent positions implicated judicial estoppel, a doctrine rooted in the principle that "[w]here a party assumes a certain position in a legal proceeding, and succeeds in maintaining that position, [it] may not thereafter, simply because [its] interests have changed, assume a contrary position." New Hampshire v. Maine, 532 U.S. 742, 749 (2001) (quotations omitted).

consider the impact of the Aeropres Complaint in the first instance, though, we think the better course is to remand for the District Court to apply the plausibility standard articulated above. Upon remand, the District Court is free to consider any motion for leave to amend the FAC that may be filed. See Finkelman v. Nat'l Football League, 810 F.3d 187, 203 (3d Cir. 2016); Fed. R. Civ. P. 15(a); cf. Max's Seafood Café ex rel. Lou-Ann, Inc. v. Quinteros, 176 F.3d 669, 677 (3d Cir. 1999) (noting that a motion for reconsideration may be granted where the moving party demonstrates "the availability of new evidence that was not available when the court granted the motion[.]").

We decline to address judicial estoppel here because it is still incumbent upon Plaintiffs to establish standing in the FAC. See Grondal v. United States, 21 F.4th 1140 (9th Cir. 2021) ("Judicial estoppel is not a substitute for subject matter jurisdiction.") (quotations omitted); Hansen v. Harper Excavating, Inc., 641 F.3d 1216, 1227-28 (10th Cir. 2011) ("[W]e cannot simply ... allow judicial estoppel to substitute for subject-matter jurisdiction."); Gray v. City of Valley Park, Mo., 567 F.3d 976, 982 (8th Cir. 2009) ("[W]e must have Article III jurisdiction to entertain any claim even though the change in tactics in this case does seem to result in the sort of extreme perversion of the judicial process that normally justifies the use of judicial estoppel."); Wight v. BankAmerica Corp., 219 F.3d 79, 89 (2d Cir. 2000) ("As an equitable doctrine, judicial estoppel does not rest easily with the concept of standing."). Thus, even if we were to agree that Bayer's Aeropres position essentially asserts that its data raises a plausible inference that recalled products contained benzene, Plaintiffs still have an independent obligation to adequately plead the elements of standing in the FAC.

Finally, because neither the recall itself, nor the Valisure testing, nor the Aeropres Complaint, have any relevance to Plaintiffs who have failed to allege a TN, CV, or NAA lot number, we conclude that the District Court properly dismissed their claims for lack of standing. To conclude otherwise would require an inference that all products sold during the recall window contained the specified prefixes, or that those prefixes dominated Bayer's Lotrimin and Tinactin sales during that time frame. Neither the FAC nor the Aeropres Complaint allege facts that would support this inference. Without any information to tie these Plaintiffs' products to the recall other than the timeframe during which they made their purchases, these Plaintiffs' allegations "stop[ ] short of the line between possibility and plausibility." Twombly, 550 U.S. at 546; see also id. at 555 ("Factual allegations must be enough to [assure a court of jurisdiction] above the speculative level.").

IV. CONCLUSION

For the foregoing reasons, we will reverse the District Court's dismissal of the complaint as to Plaintiffs Huertas, Mistretta, Wyant, and Poovey and remand for further proceedings consistent with this opinion.