

In the
United States Court of Appeals
For the Seventh Circuit

No. 23-2525

IN RE: RECALLED ABBOTT INFANT
FORMULA PRODUCTS LIABILITY LITIGATION

APPEAL OF: ECONOMIC LOSS PLAINTIFFS.

Appeal from the United States District Court for the
Northern District of Illinois, Eastern Division.
No. 1:22-cv-04148 — **Matthew F. Kennelly**, *Judge*.

ARGUED FEBRUARY 5, 2024 — DECIDED APRIL 2, 2024

Before ROVNER, BRENNAN, and KIRSCH, *Circuit Judges*.

BRENNAN, *Circuit Judge*. Plaintiffs here are a potential class of consumers who purchased infant formula manufactured by Abbott Laboratories at a facility later deemed unsanitary. As a result of a Food and Drug Administration investigation, Abbott initiated a voluntary recall of all infant formula produced at that plant. After the recall, these plaintiffs sued, claiming economic harm based on a potential risk of injury due to the unclean conditions. Because the injury claimed does not support Article III standing, we affirm the district court's dismissal.

I

Abbott Laboratories produces powdered infant formula at multiple facilities, including one in Sturgis, Michigan. Plaintiffs assert that the Sturgis plant has a long history of quality control problems. The FDA conducted multiple inspections of that facility and issued an Establishment Inspection Report in September 2021. That report contained at least sixteen complaints about harmful bacteria in formula manufactured at the Sturgis facility between 2019 and 2021. The report also identified harmful bacteria in two batches of formula and in several environmental samples. On September 21, 2021, after issuing the report, the FDA learned of the first illness in infants. The agency notified Abbott the next day. Between September and December 2021, the FDA received two additional reports of illness in infants purportedly caused by the harmful bacteria.

On February 17, 2022, the FDA and the Center for Disease Control announced an investigation into consumer complaints of bacterial illness potentially related to Abbott formula products manufactured at the Sturgis plant. That same day, the FDA and CDC issued a warning to consumers not to use Abbott products if they bore certain codes indicating they were produced at Sturgis between October 2020 and January 2022. The FDA did not mandate a recall. Abbott announced a voluntary recall of certain products manufactured at Sturgis and offered a full refund to consumers who possessed such formula.

In the aftermath of the agencies' actions and Abbott's recall, numerous plaintiffs sued Abbott. All cases were consolidated for pretrial proceedings. The cases include two categories of claims: (i) personal injury plaintiffs—complaints

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seeking recovery for personal (i.e., medical) injuries to children purportedly caused by consumption of Abbott's formula; and (ii) economic harm plaintiffs—putative class claims asserting purely economic losses on account of Abbott's conduct. This appeal concerns only the second category. The personal injury cases remain pending in the district court.

In February 2023, the economic loss plaintiffs filed an Amended Consolidated Class Action Complaint. They allege violations of various state consumer fraud acts, and claims for unjust enrichment, breach of the implied warranty of merchantability, and negligent misrepresentation on behalf of a nationwide class and twenty state sub-classes of consumers who purchased later-recalled Abbott products dating back to April 1, 2018.

Plaintiffs allege “there was a risk the products were contaminated with [harmful] bacteria,” and the products “may [have] be[en] adulterated” and were “potentially” contaminated. *See* Complaint ¶ 116, *In re Recalled Abbott Infant Formula*, No. 22 C 4148 (N.D. Ill. Sept. 2, 2022), ECF No. 16 [hereinafter “*Compl.*”]. Those allegations are styled as both a “benefit of the bargain” and a “premium price” theory of injury. For the benefit of the bargain theory, plaintiffs argue that because the formula had a risk of contamination, they did not get what they bargained for, safe and nutritious infant formula. For the premium price theory, plaintiffs seek economic loss stemming from a premium paid for Abbott's infant formula they would not have otherwise paid if they had known of the risk of contamination.

Abbott moved to dismiss the complaint. The district court granted the motion, and this appeal followed.

II

We review a decision to dismiss for lack of standing de novo. *Dinerstein v. Google, LLC*, 73 F.4th 502, 511 (7th Cir. 2023).

There are “two forms of standing challenges.” *Flynn v. FCA U.S. LLC*, 39 F.4th 946, 952 (7th Cir. 2022). “A facial challenge attacks standing on the pleadings, arguing that the plaintiff lacks standing even if the well-pleaded allegations in the complaint are taken as true. A factual challenge, by contrast, asserts that there is in fact no standing.” *Id.* (citation omitted). Abbott purports to raise facial and factual challenges to standing. But, as the district court correctly noted, Abbott’s contention that plaintiffs did not adequately plead standing is a facial challenge.

A

“As the party invoking federal jurisdiction, [the] plaintiff bears the burden of establishing the elements of Article III standing.” *Silha v. ACT, Inc.*, 807 F.3d 169, 173 (7th Cir. 2015). This means that to survive dismissal for lack of standing, the plaintiff must meet a pleading burden paralleling the “*Twombly-Iqbal* facial plausibility requirement,” and allege sufficient factual matter to support the inference that standing exists. *Id.* at 173–74. “Where, as here, a case is at the pleading stage, the plaintiff must clearly ... allege facts demonstrating each element” of the standing inquiry. *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). “Courts must accept as true all material allegations of the complaint, and must construe the complaint in favor of the complaining party.” *Silha*, 807 F.3d at 173 (cleaned up).

“Article III of the Constitution limits federal judicial power to certain ‘cases’ and ‘controversies,’ and the ‘irreducible constitutional minimum’ of standing contains three elements.” *Silha*, 807 F.3d at 172–73 (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 559–60 (1992)). Those three elements are (1) an injury in fact that is (2) fairly traceable to the challenged action of the defendant and (3) is likely, not merely speculative, that the injury will be redressed by a favorable decision. *Friends of the Earth, Inc. v. Laidlaw Env’t Servs. (TOC), Inc.*, 528 U.S. 167, 180–81 (2000) (citing *Lujan*, 504 U.S. at 560–61). This case concerns only the first element, “injury in fact.”

An “injury in fact” is “concrete and particularized” and “actual or imminent, not conjectural or hypothetical.” *Spokeo*, 578 U.S. at 339. “For an injury to be ‘particularized,’ it must affect the plaintiff in a personal and individual way.” *Id.* (cleaned up); see *Lujan*, 504 U.S. at 560 n.1. “Requiring a plaintiff to demonstrate a concrete and particularized injury caused by the defendant and redressable by the court ensures that federal courts decide only ‘the rights of individuals[.]’” *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021) (citing *Marbury v. Madison*, 5 U.S. 137, 170 (1803)). And the injury-in-fact requirement ensures “that federal courts exercise ‘their proper function in a limited and separated government,’ Roberts, *Article III Limits on Statutory Standing*, 42 DUKE L. J. 1219, 1224 (1993).” *Id.*

Economic harm can be a concrete injury sufficient to confer standing. *In re Aqua Dots Prods. Liab. Litig.*, 654 F.3d 748, 751 (7th Cir. 2011). That includes when, “as a result of a deceptive act or an unfair practice,” a plaintiff is “deprived of the benefit of his bargain.” *Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1084 (11th Cir. 2019); see *McGee v. S-L Snacks*

Nat'l, 982 F.3d 700, 706–07 (9th Cir. 2020); *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Liab. Litig.*, 903 F.3d 278, 283 (3d. Cir. 2018).

B

The gravamen of plaintiffs' alleged injury is a past potential risk of harm resulting in economic losses. Plaintiffs say they "would not have paid the purchase price for the products had they known the products were at substantial risk of being contaminated with ... harmful bacteria at the time of purchase." Compl. ¶ 15. They describe this theory as both a benefit of the bargain and premium price theory. But plaintiffs' risk-of-harm theory of injury does not support Article III standing.

Plaintiffs' alleged injury is hypothetical or conjectural. When purchasing the infant formula, plaintiffs received what they asked for. At that point, there was no known risk of contamination and no loss of the benefit of the bargain or premium price paid. Once plaintiffs learned of the unsanitary conditions at the Sturgis facility and potential risk of contamination, then they were told not to use the formula, and Abbott offered a refund. So, there was not a time when plaintiffs were at a risk of harm.

Plaintiffs' claimed injury is also not particularized because they do not allege that any of the products they purchased were contaminated. Nor do plaintiffs plead facts suggesting that contamination of Abbott's products was sufficiently widespread to plausibly affect any given unit of infant formula, including the ones they purchased. Plaintiffs claim only that there was a "potential risk" the products may have been

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contaminated, but they do not say they were subject to that risk in a personal and individual way.

For this reason, this case differs from *In re Aqua Dots*, in which this court held that a universal defect in a toy that rendered the toy valueless was an economic harm that conferred standing. *See* 654 F.3d at 751. In that case, a toy manufacturer substituted a nontoxic adhesive with an adhesive, which, if ingested, could induce serious illness and had already done so for some children. *See id.* at 749. Every unit of the toy contained the toxic adhesive, and it was undisputed that the products were defective. *See id.* This court ruled that “[t]he plaintiffs’ loss is financial: they paid more for the toys than they would have, had they known of the risks the beads posed to children. A financial injury creates standing.” *Id.* at 751. The toys were essentially valueless for each plaintiff because they were toxic and could not be used as intended. *See id.*; *see also In re Evenflo Co., Inc., Mktg., Sales Pracs. & Prods. Liab. Litig.*, 54 F.4th 28, 35–36 (1st Cir. 2022) (holding that defendant’s car seats contained a universal defect as not tested and safe as advertised, so plaintiffs overpaid for all products based on defendant’s false or misleading statements); *Debernardis*, 942 F.3d at 1084–85 (holding that defendant’s dietary supplements all contained “DMBA ... a new dietary ingredient” so all products with that illegal ingredient were “worthless.”).

A universal defect inherent in a product—such as a design defect or a fundamental flaw—renders each product valueless to each plaintiff, as in *Aqua Dots* and similar cases. Here, though, there is only a potential risk of harm or defect, not a universal defect, and no way to tell how widespread the defect was in Abbott’s formula. Plaintiffs do not claim that the specific product they bought was contaminated. They plead

some facts about a persistent problem at Abbott's Sturgis facility which could have affected many batches of the powdered infant formula. But plaintiffs did not allege facts suggesting that contamination of Abbott's products was sufficiently widespread so as to plausibly affect any given product, including the ones they purchased. The potential risk of contamination is not enough to confer standing.

Plaintiffs' claims are more like those in *Wallace v. ConAgra Foods, Inc.*, 747 F.3d 1025 (8th Cir. 2014). That case concerned a risk of a defect, not a universal defect, and the Eighth Circuit held that the plaintiffs' alleged risk was speculation that could not confer standing. *Id.* at 1030. In *Wallace*, the plaintiffs claimed that the defendant mislabeled its hot dogs as 100% kosher when, in fact, some of the defendant's beef products were not kosher. *Id.* at 1028. The Eighth Circuit ruled that this claim was insufficient under Article III to allege standing. *Id.* at 1030. Acknowledging the plaintiffs' assertion that they would not have paid as much for the defendant's products if they "were not kosher," plaintiffs' problem, the court ruled, was that they "fail[ed] to show that any of the *particular* packages of [defendant's products] they *personally* purchased contained non-kosher beef." *Id.* at 1030 (emphasis added).

The *Wallace* plaintiffs alleged that "some" units of the defendant's products contained the defect. But those allegations were insufficient to satisfy Article III's "particularized" injury requirement. The court ruled, "[i]n the context of defective products, it 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; ... the plaintiffs must allege that their product actually exhibited the alleged defect." *Id.*; see also *In re Polaris Mktg., Sales Pracs., & Prods. Liab. Litig.*, 9 F.4th 793,

797 (8th Cir. 2021). Because it was “pure speculation to say the particular packages sold to the consumers were tainted ... while it [wa]s quite plausible [the defendant] sold the consumers *exactly what was promised*: a higher quality, kosher meat product,” the court ordered dismissal of their claims for lack of standing. *Wallace*, 747 F.3d at 1031.

The Eleventh Circuit concluded much the same in *Doss v. General Mills Inc.*, 816 F. App’x 312 (11th Cir. 2020). Although an unpublished per curiam opinion, there, the Eleventh Circuit affirmed a thorough district court order dismissing claims premised on purported glyphosate contamination in Cheerios. *See id.* at 314 (affirming *Doss v. Gen. Mills, Inc.*, 2019 WL 7946028 (S.D. Fla. June 14, 2019)). The Eleventh Circuit accepted the district court’s recognition that the plaintiffs “d[id] not ... even allege that the Cheerios she herself bought actually contain any glyphosate—just that some Cheerios that have been tested do.” *Doss*, 2019 WL 7946028, at *2. On that ground, the Eleventh Circuit affirmed the dismissal, holding that the plaintiff failed to “allege[] that she purchased any boxes of Cheerios that contained any glyphosate, much less a level of glyphosate that is so harmful the Cheerios are ‘presumptively unsafe’ and therefore worthless.” *Doss*, 816 F. App’x at 314. Plaintiff’s injury was thus only conjectural or hypothetical, at least as to the cereal plaintiff bought. *Id.*

Like in *Wallace*, where the plaintiffs could not claim they had non-kosher beef in their hot dogs, and in *Doss*, where the plaintiffs could not allege they had a harmful chemical in their cereal, plaintiffs here cannot and do not maintain that the infant formula they purchased was contaminated. Plaintiffs have no economic injury because the products they

purchased were not rendered valueless; they received the infant formula for which they bargained.

Other circuits have agreed there is no economic injury sufficient to confer standing where plaintiffs received what they bargained for. In *In re Johnson & Johnson*, the Third Circuit affirmed dismissal of financial harm claims where the plaintiff consumed a product that “functioned for her as expected.” 903 F.3d at 280–81 (noting that the case “concern[ed] a non-durable product that has already been consumed in its entirety”). There, the plaintiff purchased baby powder but claimed that had she known the powder carried a “risk of developing ovarian cancer,” she would not have done so. *Id.* at 289. But the plaintiff “d[id] not allege that she ha[d] ovarian cancer,” nor even that she had any “increased risk of developing cancer.” *Id.* at 281. Under those circumstances, the plaintiff’s allegations required the court “to conclude that the powder she received was, in fact, *safe as to her*.” *Id.* at 289. Given that the plaintiff had “fail[ed] to allege even that the Baby Powder provided her with an economic benefit worth one penny less than what she paid,” the court held that she “received the benefit of her bargain and [had] suffered no economic injury.” *Id.* at 288. Plaintiffs’ “buyer’s remorse, without more, [was] not a cognizable injury under Article III of the United States Constitution.” *Id.* at 281.

The Fifth Circuit has reached the same conclusion on similar facts. In *Rivera v. Wyeth-Ayerst Labs.*, that court vacated an order certifying a class of drug purchasers and remanded with instructions to dismiss their claims for lack of standing. 283 F.3d 315, 316 (5th Cir. 2002). The court succinctly described the plaintiffs’ injury theory:

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Wyeth sold Duract; Rivera purchased and used Duract; Wyeth did not list enough warnings on Duract, and/or Duract was defective; other patients were injured by Duract; Rivera would like her money back. The plaintiffs do *not* claim Duract caused them physical or emotional injury, was ineffective as a pain killer, or has any future health consequences to users. Instead, they assert that their loss of cash is an “economic injury.”

Id. at 319. These facts were insufficient to allege Article III standing, the Fifth Circuit reasoned, because the “wrongs ... suffered by other, non-class member patients ... cannot constitute an injury in fact” as to plaintiffs who had taken the drug yet did not suffer any ill-effects. *Id.* at 320. Instead, “[b]y plaintiffs’ own admission, Rivera paid for an effective pain killer, and she received just that—the benefit of her bargain.” *Id.* at 320.

As in *In re Johnson & Johnson* and *Rivera*, plaintiffs here received the benefit of their bargain and suffered no economic loss. They purchased and received infant formula. Plaintiffs do not claim the product they bought suffered from the defect and thus was valueless. And they do not allege the economic benefit they received from the formula was anything less than the price paid.

A hypothetical shows why plaintiffs’ theory of injury does not confer standing. Consider a popular restaurant at which a diner gets food poisoning. An investigation reveals the restaurant did not meet the sanitation code, so its food was at risk of contamination. The sick diner had a real, particularized injury. But any patron who has ever eaten at the restaurant

does not have a real, particularized injury. The risk that other patrons' food could have been contaminated because it was prepared and served at a restaurant that did not meet the sanitation code does not mean that the other patrons' food was ever contaminated. Any injury to those other patrons is hypothetical or conjectural, and they have no particular or individual harm. So, the other patrons would not have standing to sue the restaurant under a risk-of-harm theory of injury, unlike the diner with food poisoning who suffered an actual harm.

III

Plaintiffs' risk-of-harm theory of injury does not support Article III standing. So, we AFFIRM the district court's dismissal for lack of standing.