No. 17-2066

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

ROBERT GUSTAVSEN, et al., on behalf of themselves and all others similarly situated,

Plaintiffs-Appellants,

v.

ALCON LABORATORIES, INC., et al.,

Defendants-Appellees.

On Appeal from the United States District Court for the District of Massachusetts, Case No. 1:14-cv-11961

BRIEF OF THE AMERICAN TORT REFORM ASSOCIATION, THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, THE NATIONAL ASSOCIATION OF MANUFACTURERS, AND PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF APPELLEES

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, the *amici curiae* state that they have no parent corporations and no publicly held company owns 10% or more of any *amicus*'s stock.

/s/ Jeffrey S. Bucholtz
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INTEREST OF *AMICI CURIAE*[1]

Founded in 1986, the American Tort Reform Association ("ATRA") is a broad-based coalition of businesses, corporations, municipalities, associations, and professional firms that have pooled their resources to promote reform of the civil justice system with the goal of ensuring fairness, balance, and predictability in civil litigation. For over two decades, ATRA has filed *amicus* briefs in cases that have addressed important liability issues.

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation. It represents 300,000 direct members and indirectly represents the interests of more than three million businesses and professional organizations of every size, in every industry, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the

[1] All parties have consented to the filing of this *amicus* brief. No party's counsel authored this brief in whole or in part; no party or party's counsel contributed money that was intended to fund the preparation or submission of this brief; and no person other than *amici*, their members, and their counsel contributed money that was intended to fund the preparation or submission of this brief.

courts. To that end, the Chamber regularly files *amicus* briefs in cases raising issues of concern to the nation's business community.

The National Association of Manufacturers ("NAM") is the nation's largest manufacturing association, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs over 12 million men and women, contributes $2.25 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for more than three-quarters of all private-sector research and development. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's mission is to advocate for public policies that encourage the discovery of life-saving and life-enhancing medicines that help patients lead longer, healthier, and more productive lives. PhRMA closely monitors legal issues that affect the pharmaceutical industry and fre-

quently participates as *amicus* in cases raising matters of significance to its members.

ARGUMENT

Imagine you order an ice-cream sundae and it arrives with a larger portion of ice cream than you can eat. You might think it was too bad that some ice cream would go to waste. But you probably would not think the ice-cream parlor had caused you a concrete and particularized injury that could be redressed by a court. After all, the ice-cream parlor delivered what it promised; you did not suffer any physical or emotional harm; and you were not deceived into buying (or overpaying for) the sundae. While you might wish the ice-cream parlor had given you the option of buying less ice cream for less money, it had no obligation to offer such an option. In short, the ice-cream parlor's sundae design, even if inefficient, did not make you worse off in any legally cognizable way. And even if for some reason you felt the ice-cream parlor had injured you, you certainly would not conclude that it had caused the same injury to all of its other customers, regardless of their individual tastes and appetites.

The novel theory of standing advanced by Plaintiffs in this case is no less absurd than the above hypothetical. Plaintiffs received what they were promised: effective, FDA-approved prescription eye drops. Their speculative claim that they might have paid less for those medications if Defendants had packaged them differently—a claim that is not supported by concrete factual allegations and that runs contrary to basic economic logic—does not describe a cognizable injury in fact, let alone one that is fairly traceable to the conduct Plaintiffs challenge as unlawful.

In fact, Plaintiffs' theory is even more indefensible than the diner's hypothetical claim that the ice-cream parlor should have served him less ice cream. The ice-cream parlor is presumably free to adjust its portion sizes as it wishes, but federal law bars Defendants here from changing their eye droppers unless they devote significant resources to conducting new clinical trials to prove that the proposed new dropper design and drop sizes are safe and effective and then obtain approval from FDA to make the change. That requirement means that even if Plaintiffs had standing, their claims would be preempted. Their response, which implausibly asserts that FDA does not care how much

medicine is in each drop as long as it is still just "one drop," only highlights why a class action based on a novel theory of standing should not be used to second-guess FDA's expert judgment in approving Defendants' products.

That Plaintiffs' theory is novel and baseless, however, does not mean it is innocuous. If that theory were accepted, it would trigger a new wave of abusive, no-injury class-action litigation, with potentially devastating effects on businesses and consumers. It would encourage plaintiffs' lawyers to bring large class actions challenging any business practice that could be portrayed as inefficient, based on conjecture that greater efficiency might have translated into savings for customers. No one but the lawyers would benefit from such suits—not the businesses that would pay millions in litigation and nuisance settlement costs; not the employees, investors, and consumers who would ultimately bear those costs; and certainly not the patients who take the medications at issue in this case and who could be denied those critical medications if Plaintiffs' theory were accepted.

The Court should hold that Plaintiffs lack Article III standing or, in the alternative, that Plaintiffs' claims are preempted.

I. Plaintiffs' Novel Standing Theory Fails To Establish Either Injury Or Causation.

"[N]o principle is more fundamental to the judiciary's proper role in our system of government" than the requirement that a plaintiff demonstrate standing under Article III of the Constitution to sue in federal court. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016) (quotation marks omitted); *see Hochendoner v. Genzyme Corp.*, 823 F.3d 724, 731 (1st Cir. 2016) ("Standing doctrine . . . reflects concern about the proper—and properly limited—role of the courts in a democratic society." (quotation marks omitted)).

Plaintiffs have not adequately pleaded that they were injured as a result of Defendants' failure to adopt (and seek FDA approval for) a supposedly more efficient product design. Even if Plaintiffs were right that Defendants' products could have been designed to work more efficiently by dispensing smaller drops, "[t]he fact that a seller does not sell the product that you want, or at the price you'd like to pay, is not an actionable injury; it is just a regret or disappointment." *Eike v. Allergan, Inc.*, 850 F.3d 315, 318 (7th Cir. 2017); *see also Cottrell v. Alcon Labs.*, 874 F.3d 154, 171 (3d Cir. 2017) (Roth, J., dissenting) (plaintiffs cannot "manufacture" standing by asserting "that the defendants *could have*

manufactured a more efficient product, which in turn *could have* lowered plaintiffs' overall treatment costs"); *Cottrell v. Alcon Labs.*, 709 F. App'x 156, 157 (3d Cir. 2017) (Smith, C.J., dissenting from denial of rehearing en banc) (while plaintiffs "would prefer that the eye drops prescribed for them be sold in a different type of packaging," their "unfulfilled preferences do not constitute an 'injury'" under Article III).[2]

While Plaintiffs insist that they have standing because they are seeking reimbursement for money spent (Pl. Br. 53–54), "[m]erely asking for money does not establish an injury in fact." *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 319–20 (5th Cir. 2002). In *Rivera*, the court found no Article III standing where the plaintiff had "paid for an effective pain killer, and she received just that—the benefit of her bargain." *Id.*; *cf. Shaulis v. Nordstrom, Inc.*, 865 F.3d 1, 11–12 (1st Cir. 2017) (no injury under Mass. Gen. Laws ch. 93A where plaintiff "received everything [she] had bargained for"). Just demanding recovery of a supposed "overpayment" does not automatically entitle a plaintiff to standing. *See Kerin v. Titeflex Corp.*, 770 F.3d 978, 983 (1st Cir. 2014) (no standing for

[2] As Defendants point out, the allegations in *Eike* and *Cottrell* were materially identical to those at issue here, and seven of the ten appellate judges to consider those allegations concluded that they did not support Article III standing.

plaintiff who claimed to have overpaid for stainless steel tubing where allegations failed to show that tubing was defective); *Katz v. Pershing, LLC*, 672 F.3d 64, 77 (1st Cir. 2012) (no standing for plaintiff who claimed to have overpaid for brokerage services where allegations failed to show that any overpayment was "ascribable to the defendant's misrepresentations").

Plaintiffs do not assert any traditional theory of injury. For instance, they do not claim that the medications they purchased were ineffective or failed to work as intended or that they suffered any physical or emotional harm from using the medications. They do not claim that they were misled into purchasing products they would not otherwise have purchased or into paying more for those products than they otherwise would have paid. Nor do Plaintiffs claim that Defendants acted in concert to prevent any seller from using their preferred design. *See* Pl. Br. 53 n.12 (conceding that Plaintiffs are not bringing "an antitrust-type or misrepresentation claim"). In short, Plaintiffs do not and cannot dispute that they "got exactly what [they] paid for," *Shaulis*, 865 F.3d at 12—FDA-approved medications that worked as promised.

Instead, Plaintiffs rely on a novel theory of standing: that they might have saved money if Defendants had redesigned their products. They contend that their injury is the money they spent on medication that Defendants "forced them to waste" by not using Plaintiffs' alternative, supposedly more efficient product design. Pl. Br. 53. The Court should reject this theory of injury-by-inefficiency.

Plaintiffs' theory fails at the outset because their allegations do not establish that an alternative product design would have saved them money. It is far more likely that Defendants would have priced their products based on how many therapeutic doses (not how many milliliters of fluid) they contained, so that improvements in the products' efficiency would not have saved Plaintiffs any money. *See* Def. Br. 43–44; *see also Cottrell*, 874 F.3d at 174–75 (Roth, J., dissenting) (observing that medicine is normally priced by dose rather than volume). Defendants are businesses operating in a market where prices reflect supply and demand—and patients demand treatment, not fluid volume. Moreover, the overwhelming majority of the cost of delivering an FDA-approved medication lies not in the cost of manufacturing the liquid in

the bottle, but in the research, trials, regulatory approvals, and numerous other costs associated with getting the medication to market.

Plaintiffs nonetheless ask the Court to "assume," contrary to common sense and basic economic logic, "that a Defendant would not charge more for a bottle capable of delivering more doses." *Cottrell*, 709 F. App'x at 159 (Smith, C.J., dissenting from denial of rehearing en banc). But a plaintiff's standing cannot be based on speculative (and, in this case, highly dubious) assumptions about prices in a hypothetical market. *See, e.g.*, *Finkelman v. Nat'l Football League*, 810 F.3d 187, 201–02 (3d Cir. 2016) (no standing based on "pure conjecture about what the ticket resale market might have looked like if the NFL had sold its tickets differently"); *Katz*, 672 F.3d at 77 (no standing based on plaintiff's "bare hypothesis" that her brokerage company "might push [one] aspect of its operational costs onto her"); *Dominguez v. UAL Corp.*, 666 F.3d 1359, 1364 (D.C. Cir. 2012) (no standing based on "speculation . . . that United would continue to offer discounted tickets if it could no longer price discriminate"); *see also Summers v. Earth Island Inst.*, 555 U.S. 488, 499 (2009) (injury in fact "is not an ingenious academic

exercise in the conceivable," but requires "a factual showing of perceptible harm" (quotation marks omitted)).[3]

Plaintiffs cannot overcome the fact that their claim of standing is conjectural by pointing to conclusory statements cherry-picked from "medical and scientific literature." Pl. Br. 8–9, 55. The authors of those publications were not economists, did not claim any expertise in product pricing, and did not explain their offhand suggestions that smaller drops might save patients money. That they appear to have made the same assumption as Plaintiffs does not make that assumption any more reasonable as a basis for standing. *Cf. Gerlinger v. Amazon.com Inc.*, 526 F.3d 1253, 1255–56 (9th Cir. 2008) (affirming dismissal for lack of standing where plaintiff relied on "academic articles" that "did not establish that [he] personally paid a higher price for a book" as a result of the challenged conduct). It would eviscerate Article III's limitations on

[3] Following remand, the plaintiff in *Finkelman* was found to have adequately pleaded standing by amending his complaint to allege "specific, plausible" "economic facts," supported by an expert economist, that described "a causal chain justifying *why* the NFL's withholding . . . raised prices on the secondary market." *Finkelman v. Nat'l Football League*, 877 F.3d 504, 509, 512–13 (3d Cir. 2017). By contrast, Plaintiffs here have not offered a specific, plausible explanation (let alone one supported by an expert) as to why Defendants would price their products by volume rather than by dose.

federal jurisdiction if Plaintiffs could establish standing by showing that they were not the first to indulge in a particular bit of speculation.

Plaintiffs fail Article III's traceability requirement as well as its injury-in-fact requirement. Even if the Court were willing to assume that Defendants would have charged the same price for a bottle containing more doses, Plaintiffs still would not have standing, because it is undisputed that Defendants had discretion to price their drugs on a per-dose basis and were not obligated to price them on a per-milliliter basis. While Plaintiffs claim that state law required Defendants to redesign their products, they do not claim that Defendants would have been *compelled* (by law or market forces) to price those redesigned products in a way that would have saved Plaintiffs money—only that Defendants *might* have done so in their discretion. So any additional cost that Plaintiffs paid for Defendants' actual products, as compared to what they might have paid for hypothetical, more-efficient products, was "fairly traceable" not to Defendants' "putatively illegal conduct," *United States v. U.S. Currency, $81,000.00*, 189 F.3d 28, 34 (1st Cir. 1999), but to their lawful and separate price-setting decisions.

Plaintiffs therefore cannot rely on cases affording standing to consumers who claim they paid higher prices because of a business's unlawful conduct. When courts find standing in such cases, they require plausible allegations that the defendant *could not have charged the same price* if it had complied with the law—not merely that the defendant might have chosen, in its discretion, to charge a lower price. For example, in the case on which the district court relied (Add. 63), this Court upheld plaintiffs' standing because the defendants' misrepresentations "*directly resulted* in an increase to the payments the plaintiffs were *required* to make." *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 161 (1st Cir. 2009) (emphases added).

Unlike the plaintiffs in those cases, Plaintiffs here cannot plausibly claim that Defendants would have *had* to charge a lower per-dose price if they had designed their medications to use a smaller drop, only that they might have *chosen* to do so. But they cannot base their standing on the possibility that Defendants might have made a completely discretionary choice that would have saved Plaintiffs money. *Cf. DH2, Inc. v. SEC*, 422 F.3d 591, 597 (7th Cir. 2005) (plaintiff lacked standing to challenge rules requiring "fair value pricing" for certain securities

where mutual funds would have had "discretion to use fair value pricing" regardless).

II. Plaintiffs' Claims, Which Demand A Major Redesign of FDA-Approved Products, Are Also Preempted.

Even if Plaintiffs had standing, their claims would be preempted by the Federal Food, Drug, and Cosmetic Act. That is because Plaintiffs contend that *state* law requires Defendants to make significant changes to the design of their FDA-approved prescription drug products, whereas *federal* law prohibits Defendants from making those changes without FDA's prior approval.

The Constitution's Supremacy Clause bars a state-law claim, under what is often called "conflict preemption," where it is "impossible for a private party to comply with both state and federal requirements." *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). The Supreme Court has specifically addressed what "impossibility" means in the context of claims that state law requires changes to an FDA-approved drug product, holding that the "question for 'impossibility' is whether the private party could *independently* do under federal law what state law [supposedly] requires." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011) (emphasis added). In other words, the manufacturer must have been able to

make the change at issue "unilaterally," without prior FDA approval. *Id.*; *see also Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 483–84 (2013); *Wyeth v. Levine*, 555 U.S. 555, 573 (2009); *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 41 (1st Cir. 2015).

Plaintiffs are therefore quite right to concede that "if changes to dropper design to reduce drop size are 'major' changes that require prior FDA approval," then their claims are preempted. Pl. Br. 14; *see* 21 C.F.R. § 314.70(b) (requiring "approval prior to distribution" for all "major changes" in approved drug products). It makes no difference whether Defendants might have been able to obtain FDA's "permission" to redesign their products, because any such permission would have been "dependent on the exercise of judgment by [the] federal agency." *PLIVA*, 564 U.S. at 623–24. What matters is whether Defendants had the right under federal law to make those changes by themselves, of their "own volition." *Celexa*, 779 F.3d at 41 (quoting *PLIVA*, 564 U.S. at 624).

As the district court correctly held, redesigning Defendants' products to deliver much smaller eye drops would entail changing the products' "containers" and "container closure systems." Such a redesign would therefore be a "major change" requiring prior FDA approval un-

der 21 C.F.R. § 314.70(b)(2)(iii) and FDA's guidance interpreting that provision. *See* Add. 21–24; Def. Br. 15–19. Moreover, as Defendants explain, such a redesign would also require prior FDA approval for several additional reasons, including that it would alter a "drug product container closure system that controls the drug product delivered," § 314.70(b)(2)(vi), and that it would have a "substantial potential" to adversely affect the "strength" of the product, § 314.70(b)(1). *See* Def. Br. 19–24.

Plaintiffs suggest (Br. 25–30) that FDA may not always apply the standards that its regulations and guidance require, but they offer no persuasive evidence that this is true. *See* Def. Br. 29–36. And certainly the Court should not assume that it is. *See, e.g.*, *FCC v. Schreiber*, 381 U.S. 279, 296 (1965) (noting "presumption [that] administrative agencies . . . will act properly and according to law"). In any case, impossibility preemption does not depend on what FDA might have done if Defendants had redesigned their eye droppers without the required permission. What matters is the legal standard established in FDA's regulations and whether Defendants could have made the changes Plaintiffs demand while complying with that standard. *See Celexa*, 779 F.3d at 41.

And to the extent what FDA might have done is relevant, it would be improper for courts to assume that FDA would have done anything other than faithfully apply its own regulations. *See Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1102–03 (10th Cir. 2017) (plaintiffs could not avoid preemption by "suggest[ing] that the FDA disobeys its own regulations").

Defendants' brief (at 15–24) shows why those regulations, properly understood, do not allow Defendants to unilaterally make the changes that Plaintiffs contend they should have made. *Amici* will not repeat those detailed arguments. But it is worth stepping back to consider how extreme Plaintiffs' position is. According to Plaintiffs, a drug manufacturer has free rein to redesign an FDA-approved drug product, without any prior review or approval by the agency, with the specific goal of substantially changing—in some cases by more than 70%, *see* Pl. Br. 6—the amount of active drug ingredient delivered to the patient in each dose. If that seems at odds with FDA's core "[m]ission" of "protect[ing] the public health by ensuring" that "drugs are safe and effective," 21 U.S.C. § 393(b)(2)(B), Plaintiffs tell the Court not to worry: FDA, they

say, does not actually care how much active ingredient is in each dose, so long as the dose could still be described as "one drop." Pl. Br. 34.

Plaintiffs' position is self-refuting, and it underscores why class actions premised on novel theories of standing should not be allowed to subvert FDA's role as the expert federal regulator in this area. As the Seventh Circuit recognized, a court "cannot bypass the agency and make its own evaluation of the safety and efficacy of an unconventionally sized eye drop." *Eike*, 850 F.3d at 318. Therefore, whether "a smaller drop would be as or even more effective," as Plaintiffs claim, is a "matter[] for the class members to take up with the FDA." *Id.*; *see also Cottrell*, 709 F. App'x at 159–60 (Smith, C.J., dissenting from denial of rehearing en banc) ("Although I would still not hold Plaintiffs to have shown standing even if Defendants did not have to submit new packaging designs to a lengthy FDA approval process, courts should hesitate before permitting plaintiffs to use the federal judiciary as a tool to second-guess factual decisions made by agencies that are presumed to be subject-matter experts").

III. Allowing This Case To Move Forward Would Invite Abusive Class-Action Litigation.

If Plaintiffs' novel theory of standing to challenge allegedly inefficient product design were accepted, it would open up a wide new frontier for abusive, "no-injury" class actions. *Rivera*, 283 F.3d at 320. And if that theory were accepted as a basis for demanding that manufacturers redesign even drug products (like those at issue here) that are subject to strict federal regulation, the effect would be even more pronounced. That would be disastrous for everyone but the lawyers.

It is no secret that class actions are a "powerful tool [that] can give a class attorney unbounded leverage." S. Rep. No. 109-14, at 21 (2005) (Class Action Fairness Act). One of the most important limitations on that tool is the need to show that the class members suffered a common injury. Courts are not supposed to certify large classes of consumers claiming to have suffered physical or emotional injuries, because such injuries generally require individualized proof. As a result, enterprising class-action lawyers are always on the lookout for expansive theories of injury that can be applied to thousands of consumers at once and that make it possible to bypass the need to prove that each class member was truly injured.

Plaintiffs' novel standing theory would provide countless opportunities for adventurous class actions. As Defendants point out, there are numerous everyday products, from toothpaste to ketchup to hairspray, that could be said to involve "forced" wastage. *See* Def. Br. 42. It would only take a creative lawyer to argue that those products should be packaged more efficiently and that the failure to do so "injures" consumers. Consider, for example, the recent introduction of peanut butter jars that unscrew at both ends so that less of the product goes to waste. *See, e.g.*, Adam Fusfeld, *Today's Million-Dollar Idea: A Double-Sided Peanut Butter Jar So You Can Get Every Last Bit*, BUSINESS INSIDER, Oct. 5, 2010, http://goo.gl/RzxTXs. A clever idea, but it hardly follows that every company selling peanut butter in traditional jars is injuring consumers.

Or consider the unsuccessful attempt to bring a class action against a lip-balm manufacturer for designing its products in a way that did not allow consumers to access all of the balm in the tube. *See Ebner v. Fresh, Inc.*, 838 F.3d 958 (9th Cir. 2016). That suit was premised on a claim that the defendant's conduct was deceptive, a claim that failed because no reasonable consumer would have been misled. *Id.* at

965. But if Plaintiffs' theory is right, then the would-be class in *Ebner* should not have bothered alleging deception. Instead, they should have just alleged that the defendants' lip-balm tubes *could* have been redesigned to be more efficient and that the defendants *might* have chosen to charge the same price for a more efficiently designed product.

Nor would the adventures end there. Nothing about Plaintiffs' novel theory of injury-by-inefficiency is logically limited to inefficiency at the point of use. If that theory is valid, it is easy to imagine plaintiffs' lawyers arguing that companies are "injuring" their customers through any number of allegedly uneconomical practices, from using suboptimal manufacturing techniques to employing too many workers to spending money on ineffective advertising. After all, if Plaintiffs here can create standing by speculating that Defendants might have charged less for their products if they had used fewer microliters of fluid per drop, why not suppose that a defendant that eliminated inefficiencies in its factories or its work force might have passed the resulting savings on to consumers?

As Chief Judge Smith observed, if Plaintiffs can "establish standing simply by speculating about the additional efficiencies they might

have captured had a defendant acted in accordance with the rules of a plaintiff's hypothetical marketplace," then "everyday business decisions may be subject to litigation by creative plaintiffs capable of theorizing a way that those business decisions could have been made to serve plaintiffs more efficiently." *Cottrell*, 709 F. App'x at 160 (dissenting from denial of rehearing en banc). In short, accepting Plaintiffs' theory would encourage a new wave of nonsensical class actions claiming that companies could have produced their products more efficiently and sold them more cheaply—even where, as here, a regulatory scheme precludes the proposed change.

Class actions already take an enormous toll on U.S. businesses, and ultimately on the public at large, even without opening up a new frontier of no-injury claims. Class actions often drag on for years. *See, e.g.*, U.S. Chamber Inst. for Legal Reform, *Do Class Actions Benefit Class Members? An Empirical Analysis of Class Actions* 1 (Dec. 2013), http://goo.gl/um3toQ ("Approximately 14 percent of all class action cases remained pending four years after they were filed, without resolution or even a determination of whether the case could go forward on a class-wide basis." (emphasis omitted)). And the costs of defending against

them continue to rise. *See* Carlton Fields Jorden Burt, *Class Action Survey: Best Practices in Reducing Cost and Managing Risk in Class Action Litigation* 17 (2017), http://goo.gl/mKjnJn (in the highest-risk class actions, companies spend between $3 and $30 million per year per case on outside counsel). In 2017 alone, companies spent a total of $2.17 *billion* on legal services related to class actions, which accounted for 11.2 percent of all litigation spending in the United States. *See id.* at 2–3.[4]

Given these factors, it is not surprising that, as this Court has recognized, certification of a large class can "alter the usual dynamics of litigation and bring to bear on defendants . . . intense," if not "irresistible," "pressure to settle." *Am. Nat'l Fire Ins. Co. v. York Cty.*, 575 F.3d 112, 114 (1st Cir. 2009) (quotation marks omitted). The reason is sim-

[4] Although those costs are high enough to impact the bottom line of even large companies, the ramifications of meritless and overreaching class actions for small businesses are particularly concerning "because it is the small business that gets caught up in the class action web without the resources to fight." 151 Cong. Rec. 1664 (Feb. 8, 2005) (statement of Sen. Grassley). *See, e.g.*, *Creative Montessori Learning Ctrs. v. Ashford Gear LLC*, 662 F.3d 913, 916 (7th Cir. 2011) (class certification turned a minor, $3,000 dispute into an $11 million suit against a home-furnishings retailer with three employees and annual sales of $500,000).

ple: "[W]hen damages allegedly owed to tens of thousands of potential claimants are aggregated and decided at once, the risk of an error will often become unacceptable. Faced with even a small chance of a devastating loss, defendants will be pressured into settling questionable claims." *AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 350 (2011); *see also Coopers & Lybrand v. Livesay*, 437 U.S. 463, 476 (1978) ("Certification of a large class may so increase the defendant's potential damages liability and litigation costs that he may find it economically prudent to settle and to abandon a meritorious defense."); *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 740 (1975) (recognizing that class certification gives a case "settlement value to the plaintiff out of any proportion to its prospect of success at trial").

In the end, businesses subjected to these kinds of suits can either fight on, bearing the significant costs of litigation and opening themselves up to potentially ruinous liability, or they can acquiesce to what amounts to a "blackmail settlement[]." Henry J. Friendly, *Federal Jurisdiction: A General View* 120 (1973). For companies facing that decision, class certification is "often the whole ballgame." *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 591 n.2 (3d Cir. 2012). In fact, a "study of

certified class actions in federal court in a two-year period (2005 to 2007) found that all 30 such actions had been settled." *Eubank v. Pella Corp.*, 753 F.3d 718, 720 (7th Cir. 2014) (citing Emery G. Lee III, et al., *Impact of the Class Action Fairness Act on Federal Courts* 2, 11 (Fed. Judicial Ctr. 2008)); *see also* Brian T. Fitzpatrick, *An Empirical Study of Class Action Settlements and Their Fee Awards*, 7 J. EMPIRICAL LEGAL STUD. 811, 812 (2010) ("[V]irtually all cases certified as class actions and not dismissed before trial end in settlement.").

The costs of defending against meritless, no-injury class actions, as well as the costs of settlement payouts, are ultimately borne by businesses' customers, employees, and investors. Consumers are further harmed when products they like and depend on are changed or removed from the market entirely. This suit, for example, threatens to prevent patients from accessing important medications while compelling defendants to incur millions of dollars in costs to seek FDA approval for product changes that will not benefit most, if any, patients. Overturning the district court's decision would result in many more consumers, who doubtless do not consider themselves injured, being wrongly caught up in litigation that runs counter to their interests.

Class actions will probably always "present opportunities for abuse." *Hoffman-La Roche Inc. v. Sperling*, 493 U.S. 165, 171 (1989). But the likelihood of abuse is particularly great in cases like this one, where Plaintiffs cannot plausibly allege that Defendants' challenged conduct has injured *anyone*. These sorts of baseless class actions can and should be resolved quickly through challenges to standing in order to deter such meritless suits and spare defendants the costs and settlement pressures that accompany such litigation. In this "era of frequent litigation [and] class actions . . . , courts must be more careful to insist on the formal rules of standing, not less so." *Ariz. Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125, 146 (2011).

CONCLUSION

The Court should hold that Plaintiffs lack Article III standing or, in the alternative, that Plaintiffs' claims are preempted.

Respectfully submitted,

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April 11, 2018

CERTIFICATE OF COMPLIANCE

This brief complies with the length limitations set forth in Rule 29(a)(5) because it contains 5,248 words, as counted by Microsoft Word, excluding the items that may be excluded.

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I certify that on April 11, 2018 I electronically filed the foregoing document with the United States Court of Appeals for the First Circuit by using the CM/ECF system which will serve all counsel of record as described below.

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