No.

In the Supreme Court of the United States

PFIZER INC., ET AL., PETITIONERS

v.

LEONARD COTTRELL, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The question presented has arisen in two materially identical cases in which certain consumers of FDA-approved prescription eye drops allege that the drops are wastefully large. Those consumers assert that they suffered economic injuries on the theory that they would have paid less for their treatment if the bottles were designed differently to dispense smaller drops. In one such case, the Seventh Circuit held that a group of those consumers had not alleged injury in fact and therefore lacked standing under Article III of the United States Constitution. In the decision under review, the Third Circuit held, over the dissents of four judges, that another group of those consumers had alleged a sufficiently cognizable injury for standing purposes. The question presented is as follows:

Whether, for purposes of standing under Article III, a plaintiff's speculation that he might have paid less for treatment if a pharmaceutical product were packaged differently is sufficient to establish an economic injury in fact.

PARTIES TO THE PROCEEDING AND CORPORATE DISCLOSURE STATEMENT

Petitioners are Pfizer Inc.; Akorn, Inc.; Alcon Laboratories, Inc.; Alcon Research, Ltd.; Allergan, Inc.; Allergan Sales, LLC; Allergan USA, Inc.; Aton Pharma, Inc.; Bausch & Lomb Incorporated; Falcon Pharmaceuticals, Ltd.; Merck & Co., Inc.; Merck, Sharp & Dohme Corp.; Prasco, LLC; Sandoz Inc.; and Valeant Pharmaceuticals International, Inc.

Petitioner Pfizer Inc. has no parent corporation, and no publicly held company owns 10% or more of its stock.

Petitioner Akorn, Inc., has no parent corporation, and no publicly held company owns 10% or more of its stock.

Petitioners Alcon Laboratories, Inc.; Alcon Research, Ltd.; Falcon Pharmaceuticals, Ltd.; and Sandoz Inc. are all indirect wholly owned subsidiaries of Novartis AG. Novartis AG has no parent corporation, and no publicly held company owns 10% or more of its stock.

Petitioner Allergan USA, Inc., is a direct wholly owned subsidiary of petitioner Allergan Sales, LLC, which is a direct wholly owned subsidiary of petitioner Allergan, Inc., which is a direct wholly owned subsidiary of Allergan plc. Allergan plc has no parent corporation, and no publicly held company owns 10% or more of its stock.

Petitioners Aton Pharma, Inc., and Bausch & Lomb Incorporated are both indirect wholly owned subsidiaries of petitioner Valeant Pharmaceuticals International, Inc. Valeant Pharmaceuticals International, Inc., has no parent corporation, and no publicly held company owns 10% or more of its stock.

Petitioner Merck, Sharp & Dohme Corp. is a wholly owned subsidiary of Merck & Co., Inc. Petitioner Merck & Co., Inc., has no parent corporation, and no publicly held company owns 10% or more of its stock.

Petitioner Prasco, LLC, has no parent corporation, and no publicly held company owns 10% or more of its stock.

Respondents are Leonard Cottrell, Sandra Henon, William Reeves, George Herman, Simon Nazzal, Carol Freburger, Jack Liggett, Patricia Bough, Mack Brown, Dolores Gillespie, Deborah Harrington, Robert Ingino, Edward Rogers Jr., Deborah Rusignulolo, Dorothy Stokes, Josephine Troccoli, Hurie Whitfield, Thomas Layloff, Carolyn Tanner, Patsy Tate, John Sutton, Jesus Renteria, Glendelia Franco, and Nadine Lampkin.

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Pfizer Inc.; Akorn, Inc.; Alcon Laboratories, Inc.; Alcon Research, Ltd.; Allergan, Inc.; Allergan Sales, LLC; Allergan USA, Inc.; Aton Pharma, Inc.; Bausch & Lomb Incorporated; Falcon Pharmaceuticals, Ltd.; Merck & Co., Inc.; Merck, Sharp & Dohme Corp.; Prasco, LLC; Sandoz Inc.; and Valeant Pharmaceuticals International, Inc., respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Third Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 10a-45a) is reported at 874 F.3d 154. The order of the court of appeals denying rehearing and an opinion dissenting from the denial of rehearing (App., *infra*, 1a-9a) are not published in the Federal Reporter, but are reprinted at 709 Fed. Appx. 156. The order of the district court granting petitioner's motion to dismiss (App., *infra*, 46a-63a) is unreported. An earlier order of the district court granting petitioner's motion to dismiss respondents' original complaint (App., *infra*, 64a-80a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on October 18, 2017. A petition for rehearing was denied on December 22, 2017 (App., *infra*, 2a). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

CONSTITUTIONAL PROVISION INVOLVED

Article III, Section 2, of the United States Constitution provides:

> The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority; to all Cases affecting Ambassadors, other public Ministers and Consuls; to all Cases of admiralty and maritime Jurisdiction; to Controversies to which the United States shall be a Party; to Controversies between two or more States; between a State and Citizens of another State; between Citizens of different States; between Citizens of the same State claiming Lands under Grants of different States, and between a State, or the Citizens thereof, and foreign States, Citizens or Subjects.

STATEMENT

Faced with materially identical facts, two courts of appeals have reached irreconcilable conclusions as to whether consumers (like respondents here) have alleged injuries in fact from the design of pharmaceutical eye-drop bottles, such that they have Article III standing to bring claims alleging that the design of those bottles violates state consumer-protection statutes. The question presented is whether, for purposes of Article III standing, consumers can establish economic injury in fact simply by alleging that a pharmaceutical product should have been packaged in a differently designed bottle, while only speculating that they would have paid less for the treatment as a result of the hypothetical, differently designed bottle.

Petitioners manufacture prescription eye drops that treat glaucoma and other eye conditions and sell them in doses that are approved by the Food and Drug Administration (FDA). Their eye drops were prescribed by doctors to respondents, consumers who contend that petitioners' bottles dispense drops that are larger than medically necessary (resulting in alleged waste of a portion of each drop). Respondents assert that petitioners should sell bottles that dispense smaller drops, which are not sold by any manufacturer. Respondents further assert that, if petitioners had done so, respondents would have paid less for their treatment.

Respondents brought putative class-action claims under the consumer-protection statutes of various States. Petitioners moved to dismiss on the ground, *inter alia*, that respondents lacked standing. The district court granted petitioners' motion to dismiss, holding that respondents did not have standing because their theory of injury relied on speculative assumptions about how cost savings might result from a modified bottle design.

A divided panel of the Third Circuit reversed. Although the court recognized that the Seventh Circuit had reached the same conclusion as the district court in a case involving materially identical allegations, it held that respondents had alleged a sufficiently concrete injury to proceed in federal court. The en banc Third Circuit then divided evenly on whether to grant rehearing, leaving the panel's decision in place. Because of the acknowledged conflict between the courts of appeals on an important question of constitutional law, the petition for a writ of certiorari should be granted.

1. Article III limits the power of the federal courts to "Cases" or "Controversies." U.S. Const. Art. III, § 2. That "bedrock requirement" preserves the separation of powers by preventing federal courts from exercising power vested in the political branches. *Valley Forge Christian College* v. *Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 471-474 (1982). "No principle is more fundamental to the judiciary's proper role in our system of government" than Article III's "limitation of federal-court jurisdiction to actual cases or controversies." *Raines* v. *Byrd*, 521 U.S. 811, 818 (1997) (citation omitted).

A plaintiff has standing to proceed in federal court only if the plaintiff can establish that he "(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." *Spokeo* v. *Robins*, 136 S. Ct. 1540, 1547 (2016) (citations omitted). This case concerns injury in fact, the "[f]irst and foremost" of the three elements of Article III standing. *Steel Co.* v. *Citizens for a Better Environment*, 523 U.S. 83, 103 (1998). To establish an injury in fact, a plaintiff must have suffered "an invasion of a legally protected interest which

is (a) concrete and particularized and (b) actual or imminent." *Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (internal quotation marks and citations omitted). In other words, to provide a basis for access to the federal courts, an injury cannot be "conjectural" or speculative. *Ibid.*; see, *e.g.*, *DaimlerChrysler Corp.* v. *Cuno*, 547 U.S. 332, 344 (2006).

2. Petitioners produce medications for patients with glaucoma and other eye conditions. They package those medications in plastic bottles that contain a fixed volume of fluid. Each bottle incorporates various design features, including a dropper tip, designed to dispense a drop of medicine into a patient's eye. Both the contents and the size of those eye drops—that is, not just the medically active and inactive ingredients, but the amounts and ratios of those ingredients per dose—were approved by FDA after clinical testing. FDA also approved the labeling on petitioners' bottles, although the labeling does not state the number of doses or days of treatment in each bottle. App., *infra*, 7a, 11a, 47a, 62a.

In 2014, respondents filed a putative class action in the United States District Court for the District of New Jersey. After the district court dismissed their initial complaint without prejudice, App., *infra*, 64a-80a, respondents filed an amended complaint that is the operative version for purposes of this petition. In the amended complaint, respondents did not allege that petitioners' eye drops were either unsafe or ineffective in treating the conditions for which they are prescribed. *Id.* at 36a-37a. Instead, respondents alleged that petitioners had sold the eye drops in bottles that dispensed drops that were unnecessarily—according to respondents, wastefully—

large. *Id.* at 3a, 11a-14a, 29a-30a. Selling such drops, respondents asserted, violated various state consumer-protection statutes.[1]

Respondents did not allege that they had purchased their eye-drop prescriptions in anything other than a well-functioning market in which multiple companies offer competing products. Nor did they point to any actual product on the market that produced drops of their preferred size, or was sold at a price respondents would prefer; no such product exists. Instead, as the principal support for their claims, respondents cited studies suggesting that smaller eye drops could provide the same medical relief as the larger drops dispensed by the bottles sold by petitioners. App., *infra*, 12a-13a. As a result, respondents alleged, petitioners caused them to waste the medically unnecessary portion of each eye drop.

The "wasted" portion of each eye drop, respondents further alleged, caused them economic injury. App., *infra*, 13a-15a.[2] According to respondents, if petitioners designed bottles that dispensed smaller drops, respondents would waste less medicine and thus would pay less for their treatment. Respondents sought to quantify their economic injury through two theories. First, respondents advanced a "reimbursement theory," which posited that

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[1] The complaint asserts claims under the New Jersey Consumer Fraud Act, N.J.S.A. §§ 56:8-1 to 56:8-210; the California Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200-17210; the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.201-501.213; the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1-505/12; the North Carolina Unfair and Deceptive Trade Practices Act, N.C.G.S. §§ 75-1.1 to 75-42; and the Texas Deceptive Trade Practices-Consumer Protection Act, Tex. Bus. & Com. Code §§ 17.41-17.63.

[2] Respondents do not claim that the eye drops caused them to suffer harmful medical consequences. App., *infra*, 37a.

respondents were injured in the amount of the overflow from each drop administered. Second, respondents advanced a "pricing theory," under which respondents allegedly suffered harm amounting to the difference between the cost of the medication petitioners' bottles dispensed and the cost of the medication respondents actually used. *Id.* at 29a-30a. To support those theories, respondents primarily relied on articles that had appeared in medical and pharmaceutical journals for the proposition that smaller eye drops generally could be efficacious and result in a patient using less medicine over the course of treatment. *Id.* at 12a-13a, 31a-32a, 43a-44a.[3]

Respondents moved to dismiss the amended complaint for lack of standing, and the district court granted the motion. App., *infra*, 46a-63a. The court concluded that respondents had failed adequately to allege a nonspeculative injury. *Id.* at 55a-63a. As the court reasoned, respondents could have been injured only if, in a hypothetical world in which petitioners delivered smaller eye drops to patients through differently designed bottles, petitioners charged less for the smaller drops; in other words, respondents' theories of injury relied on the assumption that "pricing is solely based on volume." *Id.* at 59a. But respondents offered "no way of knowing whether [petitioners] would price their products in such a

[3] As petitioners have noted elsewhere, their larger eye drops serve numerous benefits. Because patients' eyes differ as to how much fluid they can hold, a large drop ensures that every patient receives an effective dose. See *Eike* v. *Allergan, Inc.*, 850 F.3d 315, 317 (7th Cir. 2017) (summarizing petitioners' position). Moreover, many of petitioners' patients are either elderly or have conditions such as arthritis that affect hand stability. A larger drop helps those patients ensure they receive a therapeutic benefit from every drop without risking injury by pointing the dropper too close to their eyes, especially because a redesigned bottle would likely feature a smaller (and thus pointier) dropper tip. See *ibid.*

way, particularly since the pricing of pharmaceuticals is complex and multi-factored." *Ibid.*

The district court also noted that respondents' theories were insufficient because they rested entirely on respondents' disagreement with how petitioners had designed their bottles to dispense drops (which had been approved by FDA), and also on respondent's insistence that they should be reimbursed for "wasted" drops (even though petitioners had never represented that each bottle contained any particular number of doses). App., *infra*, 62a. That was insufficient, the court concluded, to establish a cognizable Article III injury. *Id.* at 63a.

3. A divided panel of the court of appeals reversed and remanded. App., *infra*, 10a-45a.

a. The court of appeals held that respondents had sufficiently pleaded injury in fact for purposes of Article III standing. App., *infra*, 10a-36a. In so holding, the court of appeals acknowledged that, in *Eike* v. *Allergan, Inc.*, 850 F.3d 315 (2017), the Seventh Circuit had held just months earlier that plaintiffs making "materially identical allegations against many of the same defendants" did not have Article III standing. App., *infra*, 23a.

The court of appeals first addressed the question whether the plaintiffs had identified a legally protected interest. App., *infra*, 20a-28a. Of particular relevance here, the court then concluded that respondents had adequately pleaded a non-speculative economic injury. *Id.* at 28a-33a. At the outset, the court observed that respondents' reimbursement and pricing theories were "two ways of calculating the same thing: the cost of 'wasted' medication that [respondents] allege they were compelled to purchase but could not use." *Id.* at 30a. To support those theories, the court of appeals emphasized, respondents made reference to scientific literature that "illustrated

* * * how smaller tipped bottles would reduce the number of bottles needed for a one-year therapy regimen, and the resulting cost savings." *Id.* at 31a.

The court of appeals determined the district court had erred in interpreting respondents' allegations as resting on the assumptions that a smaller dropper tip would have caused petitioners to create correspondingly smaller bottles of medication and that petitioners would have charged less for those smaller bottles. App., *infra*, 31a-32a. The court acknowledged that it "might be inclined to agree with the [d]istrict [c]ourt that the pricing theory was too speculative if it, in fact, had depended on those presumptions," but it asserted that respondents had also pleaded that petitioners could have left the bottle size the same, with the result that, if a smaller dropper tip were used, each bottle would result in more drops. *Ibid.* Under that theory, the court asserted, respondents would have been able to "extract more doses of medication" without "any changes from the status quo in bottle pricing, physicians' prescribing practices, or the volume of the medication in each bottle." *Id.* at 31a.

b. Judge Roth dissented. App., *infra*, 36a-45a. She contended that the majority had ignored "clear precedent from the Supreme Court" and had eroded the Article III standing requirement by allowing respondents to "manufacture a purely speculative injury in order to invoke [a federal court's] jurisdiction." *Id.* at 36a.

Judge Roth began by "defining the exact nature of the harm that [respondents] claim to have suffered as a result of [petitioners'] conduct." App., *infra*, 36a. She reasoned that respondents' sole claimed injury was "the money spent on that portion of a single eye drop which exceeds the medically necessary volume." *Id.* at 37a. According to Judge Roth, respondents argued that "[petitioners] *could* manufacture a hypothetical eye dropper that would

dispense the exact amount of fluid needed to maximize efficacy without waste"; if petitioners did so, it would "reduce[] [respondents'] long-term treatment costs by reducing the number of bottles each plaintiff would have to purchase." *Ibid.*

Critically, Judge Roth reasoned, the foregoing theory of economic injury assumed that no changes would occur in the market to prevent respondents from obtaining the additional value of allegedly "wasted" drops at no extra cost. App., *infra*, 37a. As Judge Roth explained, however, courts cannot simply "isolate and change one variable while assuming that no downstream changes would also occur" when "analyzing economic injuries in the context of marketwide effects." *Id.* at 41a. Such an approach, Judge Roth continued, departed from other court of appeals decisions, *id.* at 39a-42a, and ignored this Court's "reluctance" to endorse standing theories that "rest on speculation about the decisions of independent actors." *Id.* at 38a (quoting *Clapper* v. *Amnesty International USA*, 568 U.S. 398, 414 (2013)). Because respondents had "offer[ed] nothing more than speculation about complex and industry-specific pricing models," Judge Roth concluded that respondents had failed adequately to plead injury in fact because their alleged economic injury was "overly speculative and untenable under existing precedent." *Id.* at 42a, 45a.

Any other conclusion, Judge Roth warned, "invites judges—rather than industry experts, market forces, or agency heads—to second-guess the efficacy of product design even in the most opaque of industries." App., *infra*, 45a. Indeed, respondents' theory was a "particularly bad fit for the market of pharmaceuticals," where manufacturers "engage in 'value-based pricing' which deemphasizes the overall volume of medicine received by the patient in favor of an assessment of the value—measured in part by

effective doses—received by a patient." *Id.* at 42a-43a. Accordingly, respondents' core assumption that a smaller eye drop would result in lower costs—which the majority had accepted—was inconsistent with market conditions in the pharmaceutical industry. *Id.* at 42a-44a.

4. Petitioners filed a petition for rehearing, which the court of appeals subsequently denied. App., *infra*, 1a-2a. Only six of the court of appeals' eleven active judges participated in the decision to deny petitioners' petition for rehearing en banc; those judges voted to deny the petition by a 3-3 vote. *Id.* at 2a.[4]

Chief Judge Smith, joined by Judges Ambro and Jordan, dissented from the denial of rehearing en banc. App., *infra*, 3a-9a. Chief Judge Smith agreed with the panel dissent and the Seventh Circuit's decision in *Eike* that respondents' theories of damages rested on conjecture as to what the hypothetical market might have looked like if petitioners had designed their bottles to meet respondents' preferred specifications. *Id.* at 4a.

Chief Judge Smith explained that there was no reason to assume petitioners would "decide to internalize the costs" associated with redesigning their bottles and getting approval for the revised designs. App., *infra*, 6a-7a. More fundamentally, "even if a [manufacturer] were to internalize those costs, [respondents'] theory also requires us to assume that a [manufacturer] would not charge more for a bottle capable of delivering more doses." *Id.* at 7a. To the contrary, Chief Judge Smith noted, manufacturers could charge even more for the same treatment. *Ibid.* Chief Judge Smith warned that, if such speculative

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[4] As a senior judge, Judge Roth did not participate in the en banc vote. Judges McKee, Hardiman, Greenaway, Vanaskie, and Krause also did not participate.

harms opened the door to federal court, "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." *Id.* at 8a.

REASONS FOR GRANTING THE PETITION

This is the rare case in which the Court is asked to resolve a circuit conflict on a question of constitutional law in cases involving essentially identical facts and overlapping parties. In the decision under review, the Third Circuit held that respondents have standing to pursue consumer-protection claims based on an allegation that they would pay less for eye drops if petitioners were to redesign their bottles. As the Third Circuit acknowledged, that holding was directly contrary to a Seventh Circuit holding "concerning materially identical allegations against many of the same defendants." App., *infra*, 23a.

The resulting circuit conflict, on an obviously important question of constitutional law, provides sufficient reason to grant the petition. What is more, the Third Circuit's decision cannot be reconciled with this Court's decisions rejecting speculative injuries as insufficient to confer standing under Article III. Because this case readily satisfies the criteria for the Court's review, the petition for a writ of certiorari should be granted.

A. The Decision Below Creates A Conflict In The Courts Of Appeals On Materially Identical Facts

The Third Circuit's decision creates an express, direct conflict with the Seventh Circuit on the question whether allegations such as respondents' that they suffered economic harm by purchasing a pharmaceutical product and then questioning the efficiency of the design of its packaging are too speculative to establish an injury in fact.

1. In *Eike* v. *Allergan, Inc.*, 850 F.3d 315 (2017), the Seventh Circuit considered essentially the same allegations at issue here. The plaintiffs in that case, like respondents here, alleged that "the defendants' eye drops are unnecessarily large" and thus violated state consumer-protection statutes. *Id.* at 316. There, as here, the plaintiffs made no allegations of physical harm, fraud, or collusion in setting prices. *Id.* at 316-317. Instead, in both cases, the plaintiffs claimed that they suffered only "the 'pocketbook' injury of paying * * * an unnecessarily high price for the defendants' eye drops because of the size of those drops." *Id.* at 317.

The Seventh Circuit held that the case should be dismissed for lack of standing. See *id.* at 318. It noted that the plaintiffs "just want the defendant companies to start manufacturing smaller drops," on the theory that the plaintiffs could pay less if they did. *Ibid.* But the court explained that a plaintiff "cannot sue a company and argue only—'it could do better by us.'" *Ibid.* "The fact that a seller does not sell the product that you want, or at the price you'd like to pay," in other words, is not "an actionable injury; it is just a regret or disappointment." *Ibid.* Because that was all the plaintiffs alleged, they failed to plead that the defendants had "injured [them] in some way" and their "suit fail[ed] at the threshold." *Ibid.*

2. The Third Circuit acknowledged that *Eike* "concern[ed] materially identical allegations against many of the same defendants," but it "decline[d] to adopt the [Seventh Circuit's] rationale." App., *infra*, 23a-24a. The Third Circuit charged the Seventh Circuit with "blend[ing] standing and merits together," starting with "a determination that the plaintiffs had no cause of action" and concluding that "[b]ecause they had no cause of action * * * they had no injury." *Id.* at 25a.

That characterization of *Eike* is incorrect. To be sure, the Seventh Circuit suggested that "dissatisfaction with a product made by multiple firms, or with its price," did not give rise to a cause of action, without more, under the state consumer-protection statutes at issue. *Eike*, 850 F.3d at 317. But the Seventh Circuit also—and separately—addressed whether the plaintiffs had standing under Article III and, in particular, whether they had sufficiently alleged an injury in fact. See *id.* at 318. It explained that "[o]ne cannot bring a suit in federal court without pleading that one has been injured in some way * * * by the defendant." *Ibid.* Because the plaintiffs had alleged "regret or disappointment," but no concrete injury, they could not meet that standard. *Ibid.* Consequently, the Seventh Circuit dismissed the claim in *Eike* "[f]or reasons similar to those" expressed by Judge Roth and Chief Judge Smith in their dissenting opinions in this case. App., *infra*, 4a (Smith, C.J., dissenting from the denial of rehearing en banc).

In any event, however one characterizes the Seventh Circuit's reasoning, there can be no doubt that the Third Circuit's decision in this case gave rise to a circuit conflict. As noted above, the Third Circuit acknowledged that this case and *Eike* involved "materially identical allegations against many of the same defendants." App., *infra*, 23a. And contrary to the Third Circuit in the decision below, the Seventh Circuit held in *Eike* that identically situated plaintiffs lacked standing. See 850 F.3d at 318. There is therefore a direct and acknowledged circuit conflict on the question whether plaintiffs have Article III standing on the facts of this case, where plaintiffs allege they suffered economic harm as a result of the efficiency of the design of the packaging of a pharmaceutical product.

B. The Decision Below Was Erroneous

The Third Circuit incorrectly held that respondents had suffered a sufficiently cognizable injury for purposes of Article III standing. That holding warrants further review.

1. a. As seven of the ten circuit court judges to have considered the issue have concluded, respondents do not have standing. Article III limits the judicial power to "Cases" and "Controversies." U.S. Const. Art. III, § 2. That limitation "define[s] the role assigned to the judiciary" in the Constitution's "tripartite allocation of power." *Flast* v. *Cohen*, 392 U.S. 83, 95 (1968). And it ensures that "the Federal Judiciary respects the proper—and properly limited—role of the courts in a democratic society." *DaimlerChrysler*, 547 U.S. at 341 (internal quotation marks and citation omitted). Put simply, "[i]f a dispute is not a proper case or controversy, the courts have no business deciding it, or expounding the law in the course of doing so." *Ibid.*

It is a familiar principle that "the irreducible constitutional minimum of standing consists of three elements." *Spokeo*, 136 S. Ct. at 1547 (internal quotation marks and citation omitted). A plaintiff must "(1) suffer[] 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." *Ibid.* (citation omitted).

b. This case concerns injury in fact, the "[f]irst and foremost" of the three elements of Article III standing. *Steel Co.*, 523 U.S. at 103. An injury in fact must be a "concrete and particularized" injury that is "actual or imminent, not conjectural or hypothetical." *Defenders of Wildlife*, 504 U.S. at 560 (internal quotation marks omitted). In other words, "unadorned speculation will not suffice to invoke the federal judicial power." *Simon* v. *Eastern*

Kentucky Welfare Rights Organization, 426 U.S. 26, 44 (1976).

Consistent with that requirement, the Court has long rejected efforts to establish standing through conjectural theories of injury. *Diamond* v. *Charles*, 476 U.S. 54 (1986), illustrates the point. There, an Illinois pediatrician sought to intervene in defense of the constitutionality of a state abortion law. See *id.* at 57-58. His asserted injury—like respondents' here—was economic: "if the Abortion Law were enforced," he claimed, more children would be born and "the pool of potential fee-paying patients would be enlarged." *Id.* at 66. The Court rejected the argument as just the kind of "unadorned speculation" that does not give rise to standing. *Ibid.* (citation omitted); see also, *e.g.*, *Whitmore* v. *Arkansas*, 495 U.S. 149, 156-161 (1990); *Simon*, 426 U.S. at 42-44; *Warth* v. *Seldin*, 422 U.S. 490, 505-506 (1975); *Linda R.S.* v. *Richard D.*, 410 U.S. 614, 618 (1973).

The Court has been particularly skeptical of theories of injury that "rest on speculation about the decisions of independent actors." *Clapper* v. *Amnesty International USA*, 568 U.S. 398, 414 (2013). In *DaimlerChrysler*, for example, a group of Ohio taxpayers challenged a series of state and local tax credits for a vehicle manufacturer. See 547 U.S. at 337-338. The plaintiffs claimed that the tax credit "deplete[d] the funds of the State of Ohio to which the [p]laintiffs contribute through their tax payments and thus diminish[ed] the total funds available for lawful uses and impos[ed] disproportionate burdens on" the plaintiffs. *Id.* at 343-344 (internal quotation marks and citation omitted).

The Court concluded that those alleged injuries were "conjectural or hypothetical." *Id.* at 344. In addition to the threshold problem that the tax breaks may actually have *increased* tax revenue by stimulating other economic

activity, the alleged injury was too speculative because it "depend[ed] on how legislators respond to a reduction in revenue, if that is the consequence of the credit." *Ibid.* In particular, "[e]stablishing injury require[d] speculating that elected officials will increase a taxpayer-plaintiff's tax bill to make up a deficit." *Ibid.* That "sort of speculation," the Court reasoned, does not "suffice[] to support standing." *Ibid.*; see also, *e.g.*, *Clapper*, 568 U.S. at 410-414; *Arizona Christian School Tuition Organization* v. *Winn*, 563 U.S. 125, 136-138 (2011); *Summers* v. *Earth Island Institute*, 555 U.S. 488, 492-496 (2009); *ASARCO Inc.* v. *Kadish*, 490 U.S. 605, 614 (1989) (plurality opinion).

2. The decision below flouts that settled line of precedent. Respondents pursued two purportedly distinct theories of economic harm below. First, they characterized their injury as "the total overflow from each drop administered that was impossible for them to use." App., *infra*, 29a-30a. Second, they cited "the cost differential between what they would have paid for their course of medication from smaller tipped bottles and what they actually paid for the larger tipped bottles." *Ibid.* As the court of appeals recognized, both of those theories were "ways of calculating the same thing": namely, "the cost of 'wasted' medication that [respondents] allege they were compelled to purchase but could not use." *Id.* at 30a. Accordingly, as Judge Roth noted in her dissent, both theories depended on the same "critical assumption": namely, that petitioners exclusively priced their drops "based on volume." *Id.* at 37a n.1.

That "inferential step[]" dooms respondents' claim of standing, because the proposition that respondents would have paid less for their treatment if petitioners had adopted respondents' preferred (and hypothetical) design of bottles that produced smaller drops "depends on premises as to which there remains considerable doubt."

Winn, 563 U.S. at 138; see, *e.g.*, *Diamond*, 476 U.S. at 66; *Linda R.S.*, 410 U.S. at 618. It is possible that petitioners would charge the same per-volume price, thus resulting in an overall cost savings to respondents. But it is "just as plausible," if not more so, that petitioners would charge based on the number of *doses*—that is, drops—not on the amount of liquid dispensed. *Simon*, 426 U.S. at 43.

Put differently, respondents have offered no theory as to why any one of the petitioners would not "need to alter its pricing strategy" if it changed its drop size (or simply decide that altering its strategy would be beneficial). *Dominguez* v. *UAL Corp.*, 666 F.3d 1359, 1364 (D.C. Cir. 2012). In that case, respondents would be uninjured, because they would have paid the same amount for the same number of smaller drops. See *ibid.* (holding that the defendant's right to modify its pricing strategy meant that the plaintiff's claimed economic injury was speculative).

Indeed, it is possible that respondents would pay *more* for their treatment. Petitioners would incur costs in redesigning their bottles and dropper tips to dispense equally effective doses of their medication in the "micro" drops that respondents would prefer—assuming, *arguendo*, that petitioners could simply redesign the bottles without "redesigning" the medications themselves (to deliver an equally effective dose of medicine in a smaller drop). And after redesigning their products in that fashion, petitioners would incur additional costs in obtaining FDA approval for the revised designs and marketing the new, smaller drops to physicians and patients. See App., *infra*, 6a-7a (Smith, C.J., dissenting from denial of rehearing en banc). Petitioners could, of course, pass those costs on to consumers rather than internalizing them. See *ibid.* For present purposes, the salient point is that, in light of all of these considerations, it is entirely speculative whether respondents have suffered any injury at all.

If anything, the above analysis vastly oversimplifies the myriad considerations that go into a pharmaceutical company's pricing of eye drops. See App., *infra*, 42a-45a (Roth, J., dissenting) (discussing pricing in the pharmaceutical industry). The price of a product involves competing corporate obligations, such as manufacturing and shipping. It is also naturally affected by external considerations, such as what doctors and patients prefer, as well as what competing manufacturers offer. See p. 7 n.3, *supra*. Whether petitioners would be able to offer smaller drops (and, if so, at what price) is itself significantly affected by FDA and its approval process and post-approval requirements. And whether any respondent would then even pay less for the hypothetical smaller drops that would be sold at hypothetically lower prices would also depend on independent prescribing choices of the respondent's treating physician.

That is to say, whether respondents suffered any injury at all would turn on the hypothetical "decisions of independent actors" in the government and across the pharmaceutical market. *Clapper*, 568 U.S. at 414. What those hypothetical decisions would be, and how they would have affected the market for respondents' preferred smaller drops, is pure speculation that does not suffice to support standing. *Ibid.*; see *DaimlerChrysler*, 547 U.S. at 344.

3. The court of appeals reached a different conclusion. It focused at great length on whether respondents had identified a legally protected interest. App., *infra*, 20a-28a. But it gave short shrift to the question of whether an injury in fact actually existed. As to that "irreducible constitutional minimum," *Spokeo*, 136 S. Ct. at 1547 (citation omitted), the court emphasized the scientific studies that had noted that smaller tipped bottles would result in patients using less medication over a course of treatment. App., *infra*, 31a-32a. Because the

smaller dropper size was "the *only* change from the status quo," and the literature respondents cited claimed that a smaller dropper size would lead to lower costs, the court determined that respondents' theory of injury did "not depend on a * * * presumption essential to their allegations of financial harm." *Id.* at 32a.

The articles respondents cited, however, cannot bear the weight the court of appeals placed on them. The authors of those articles—who are scientists, not economists—did not perform an economic analysis of petitioners' pricing practices, or indeed of the pricing practices of any pharmaceutical company. See App., *infra*, 55a-57a. Rather, they merely made the facile observation that a bottle dispensing smaller drops would produce more drops and thus a cost savings. But the assumption that reducing drop volume necessarily results in reducing the cost of treatment ignores the considerations set out above—*i.e.*, that pharmaceutical companies could, for example, charge based on the number of *doses*, not on the amount of liquid dispensed; that doctors and patients may prefer the larger drops; and that there would be substantial costs associated with redesigning the bottles and obtaining FDA approval, which is itself by no means assured. *Cf. DaimlerChrysler*, 547 U.S. at 344 (noting the speculation involved in the assumption that tax breaks would result in aggregate lower tax revenues).

In any event, just like the legislators who have discretion over whether to lower the taxes of one group of taxpayers because of greater revenue from another group, see *DaimlerChrysler*, 547 U.S. at 344, any manufacturer of eye drops that did see a cost saving from producing smaller drops would also have discretion over whether to charge a lower price (or instead, for example, to invest the funds in research and development, pay employees higher

salaries, or distribute the larger profit margin to shareholders). There is simply no escaping the conclusion that respondents' theory of injury "depends on premises as to which there remains considerable doubt." *Winn*, 563 U.S. at 138.

To state the obvious, the mere fact that respondents have cited *scientific* articles does not suddenly transform speculation into a coherent theory of *economic* injury. See *Dominguez*, 666 F.3d at 1364. Because those authors' uncritical hypotheses cannot function as "clearly allege[d] facts demonstrating" Article III standing, the court of appeals' holding that respondents had sufficiently pleaded injury in fact cannot stand. *Spokeo*, 136 S. Ct. at 1547 (citation omitted).

C. The Question Presented Is An Important And Recurring One That Warrants The Court's Review In This Case

1. While the conflict between the courts of appeals arises in a specific factual context, the question presented in this case is of substantial legal importance. As Chief Judge Smith noted in his dissent from the denial of rehearing en banc, the court of appeals' opinion "play[s] mischief with * * * standing jurisprudence" in a way that would open up federal courts to any party who complains about "everyday business decisions." App., *infra*, 8a.

Even limiting those business decisions to those related to packaging design, the court of appeals' approach could, for example, allow a consumer to represent a class of toothpaste users whose tubes of toothpaste did not allow every bit of toothpaste to be used. Or a consumer could sue a hairspray manufacturer based on its spray pump directing product so that a portion is dispersed into the air, rather than all landing on the consumer's head. Or an enterprising plaintiff could take on peanut-butter producers that sell their wares in traditional jars, rather than jars

that unscrew at both ends (thus leading to less wasted peanut butter). See 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.

In each of those cases, a "creative plaintiff[]" could "theoriz[e] a way that [the defendant's] business decisions could have been made to serve plaintiffs more efficiently." App., *infra*, 8a (Smith, C.J., dissenting from denial of rehearing en banc). Yet in none of these cases should a plaintiff be deemed to have constitutional standing merely to air "dissatisfaction with [the] product * * * or with its price." *Eike*, 850 F.3d at 317.

2. Allowing such dissatisfaction to be the basis for standing would unduly broaden the reach of the federal courts. See, *e.g.*, *Spokeo*, 136 S. Ct. at 1547. Respondents are 24 individuals who seek to challenge through litigation the type of pharmaceutical eye drops consumers use in six of the largest States in the Nation (and potentially nationwide). But the market has not itself created the product respondents are seeking. Rather, respondents ask "judges—rather than industry experts [or] market forces * * * —to second-guess the efficacy of product design even in the most opaque of industries." App., *infra*, 45a (Roth, J., dissenting).

In the specific factual context presented here, moreover, the court of appeals' decision raises a particular risk that the federal courts will be "used to usurp the powers of the political branches." *Spokeo*, 136 S. Ct. at 1547 (citation omitted). Here, there is a politically accountable federal agency with expertise in the area—FDA—which is charged by Congress with approving the contents and labeling of any pharmaceutical product before it is sold to consumers. See 21 U.S.C. 355. And that agency has already approved petitioners' eye drops. See App., *infra*, 11a-12a. With this lawsuit, however, respondents seek to

have a federal court "bypass the agency" and independently evaluate "the safety and efficacy of an unconventionally sized eye drop" that respondents propose. *Id.* at 7a (Smith, C.J., dissenting from denial of rehearing en banc) (quoting *Eike*, 850 F.3d at 318); see *id.* at 45a (Roth, J., dissenting). That is obviously improper.

3. This case is an excellent vehicle in which to consider and resolve the question presented. The conflict between the courts of appeals arises in the context of "materially identical allegations," as the court of appeals in this case expressly acknowledged. App., *infra*, 23a. And, as the opinions below reflect, there is no underlying factual complexity that would interfere with the Court's review.

In short, the court of appeals' reasoning was badly flawed. And if that reasoning is allowed to stand, it will open the door to claims based only on speculative injuries attributable to hypothetical products. In light of the clear circuit conflict, and for the reasons given by the four dissenting judges below, this Court should grant review and bring the court of appeals' decision into line with the Court's standing jurisprudence.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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MARCH 2018

APPENDIX

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 16-2015

LEONARD COTTRELL; SANDRA HENON; WILLIAM REEVES; GEORGE HERMAN; SIMON NAZZAL; CAROL FREBURGER; JACK LIGGETT; PATRICIA BOUGH; MACK BROWN; DOLORES GILLESPIE; DEBORAH HARRINGTON; ROBERT INGINO; EDWARD ROGERS, JR.; DEBORAH RUSIGNULOLO; DOROTHY STOKES; JOSEPHINE TROCCOLI; HURIE WHITFIELD; THOMAS LAYLOFF; CAROLYN TANNER; PATSY TATE; JOHN SUTTON; JESUS RENTERIA; GLENDELIA FRANCO; NADINE LAMPKIN, on behalf of themselves and all others similarly situated,

Appellants

v.

ALCON LABORATORIES; ALCON RESEARCH LTD; FALCON PHARMACEUTICALS LTD; SANDOZ INC.; ALLERGAN INC, RP; ALLERGAN USA INC; ALLERGAN SALES LLC; PFIZER INC; VALEANT PHARMACEUTICALS INTERNATIONAL; BAUSCH & LOMB INC; ATON PHARMA INC; MERCK & CO INC; MERCK SHARP & DOHME CORP; PRASCO LLC; AKORN INC

(D.C. Civil Action No. 14-cv-5859)

SUR PETITION FOR REHEARING

Present: SMITH, Chief Judge, AMBRO, CHAGARES, JORDAN, SHWARTZ, RESTREPO, and ROTH*, Circuit Judges**

RESTREPO, Circuit Judge.

The petition for rehearing filed by Appellees in the above-entitled case having been submitted to the judges who participated in the decision of this Court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the judges of the circuit in regular service not having voted for rehearing, the petition for rehearing by the panel and the Court en banc, is denied.

By the Court,

s/ L. Felipe Restrepo
Circuit Judge

Date: December 22, 2017
MB/cc: All Counsel of Record

*Judge Roth's vote is limited to panel rehearing only.

**Chief Judge Smith, Judge Ambro and Judge Jordan would grant rehearing en banc.

No. 16-2015 *COTTRELL v. ALCON LABORATORIES*

OPINION DISSENTING SUR DENIAL OF PETITION OF REHEARING EN BANC

SMITH, Chief Judge, with whom AMBRO and JORDAN, Circuit Judges, join.

Plaintiffs would prefer that the eye drops prescribed for them be sold in a different type of packaging. The wisdom of their preference, however, is better left tested in the marketplace, not in this Court. Creating a disparity with one of our sister circuits, the Majority's opinion reasons otherwise. Because I believe Plaintiffs' unfulfilled preferences do not constitute an "injury" that this Court can evaluate in light of Article III of the Constitution, I respectfully file this opinion dissenting sur denial of rehearing *en banc*.

I.

Plaintiffs are consumers of prescription eye drop medications manufactured and distributed by Defendants. The medication is sold in bottles designed with dropper tips that dispense more liquid than the relevant portion of the human eye can hold at any one time. Since the entire amount of each drop cannot be contained within the eye—where it is pharmaceutically beneficial—the bottle's design necessarily results in a portion of each drop being wasted. Arguing that this waste constitutes an unfair or unconscionable practice under state consumer protection statutes, Plaintiffs filed a putative class action complaint.

Of course, Plaintiffs must have standing to bring their claim in federal court. To establish standing, Plaintiffs must show that they 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." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). The Majority notes that the case at hand "centers on the '[f]irst and foremost' of the three standing elements, injury in fact." Maj. Op. at 1547 (quoting *Spokeo*, 136 S. Ct. at 1547).

To establish injury in fact, "a plaintiff must show that he or she suffered 'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.' " *Spokeo*, 136 S. Ct. at 1548 (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). Ultimately holding that Plaintiffs successfully alleged an injury in fact sufficient to confer Article III standing, the Majority was first required to "acknowledge that the Seventh Circuit held otherwise in a recent case concerning materially identical allegations against many of the same defendants." *Cottrell v. Alcon Laboratories*, 874 F.3d 154, 165 (3rd Cir. 2017). In that case, the Seventh Circuit concluded that "[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." *Eike v. Allergan, Inc.*, 850 F.3d 315 (7th Cir. 2017). The Seventh Circuit instead characterized such a claim as merely expressing "regret or disappointment." *Id.* For reasons similar to those expressed by the Seventh Circuit in *Eike*, as well as those expressed by Judge Roth in her dissenting opinion in the case at hand, I would not hold Plaintiffs to have successfully established standing.

II.

In her dissenting opinion, Judge Roth concludes that the Majority "ignores clear law cautioning against recognizing Article III standing based on the types of conjectural allegations" advanced by Plaintiffs. *Cottrell*, 874 F.3d at 172 (Roth, J., dissenting). One precedent that the Majority's approach conflicts with is *Finkelman v. National Football League*, 810 F.3d 187 (3d Cir. 2016). Like Judge Roth, I am of the opinion that *Finkelman* "all but decides this case." *Cottrell*, 874 F.3d at 172 (Roth, J., dissenting).

In *Finkelman*, this Court held that a plaintiff did not have standing to sue under the theory that the National Football League's (NFL's) ticketing policy artificially inflated the price of Super Bowl tickets. *Finkelman*, 810 F.3d at 197. Like Plaintiffs in the case at hand, Finkelman brought a class action lawsuit arguing that he had suffered an economic harm. Specifically, Finkelman argued that if the NFL had offered more tickets to the general public—rather than "league insiders"—then Finkelman and other similarly situated individuals would have been able to purchase Super Bowl tickets at a lower price. *Id.* This Court concluded that Finkelman's theory rested on "pure conjecture about what the ticket resale market might have looked like if the NFL had sold its tickets differently. Article III injuries require a firmer foundation." *Id.* at 201.

Similar to the theory presented in *Finkelman*, Plaintiffs' theory rests on "pure conjecture" as to what the eye drop market might have looked like if Defendants had

sold their product in different packaging.[1] Attempting to distinguish its holding from *Finkelman*, the Majority notes that Plaintiffs' hypothetical marketplace only requires theorizing "the reduced size of the bottle dropper tip [a]s the *only* change from the status quo." *Cottrell*, 874 F.3d at 169 (emphasis in original). In attempting to distinguish this case from *Finkelman*, however, the Majority draws attention to the very reason why the two cases conflict. As Judge Roth writes, "contrary to the Majority's assertion, the [P]laintiffs' pricing theory does in fact depend on exactly the sort of presumption rejected by us and by other courts—namely, the presumption that no other aspects of the market would change once the defendants' conduct did." *Cottrell*, 874 F.3d at 173-74 (Roth, J., dissenting).

To put it differently, Plaintiffs' theory requires this Court to imagine a hypothetical marketplace in which Defendants are hamstrung from adapting to any new market conditions that might arise from the emergence of innovative bottle designs. This theory requires us to assume, for example, that a Defendant would decide to internalize the

[1] On remand, Finkelman amended his complaint to add detailed information describing how the secondary ticket market specifically functioned. In reviewing his amended complaint, this Court held Finkelman to only then have standing because the amended complaint did more than just allege higher prices—it "alleged a causal chain justifying *why*" ticket prices were higher. *Finkelman v. Nat'l Football League*, 877 F.3d 504, 511 (3d Cir. 2017) (emphasis in original). Unlike the detailed information in Finkelman's amended complaint, Plaintiffs in the instant case provide only conclusory allegations to support their theory. Finkelman's amended complaint is therefore distinguishable from the instant case, and does not change the import of this Court's original holding in *Finkelman v. National Football League*, 810 F.3d 187 (3d Cir. 2016).

costs associated with designing, manufacturing, and marketing new packaging instead of raising the price it offers to consumers. Further, even if a Defendant were to internalize those costs, Plaintiffs' theory also requires us to assume that a Defendant would not charge more for a bottle capable of delivering more doses. It might just as easily be the case, however, that new packaging would result in Plaintiffs paying higher prices for their treatment. Therefore, to paraphrase *Finkelman*, "while it *might* be the case that the [Defendants' bottle design] increased . . . prices . . . it might *also* be the case that it had no effect on the . . . market." *Finkelman*, 810 F.3d at 200 (emphasis in original). Similar to *Finkelman*, where this Court had "no way of knowing whether the NFL's withholding of tickets would have had the effect of increasing or decreasing prices," Plaintiffs' theory requires us to speculate as to the effects of new packaging. *Id.* Doing so conflicts with *Finkelman*, which made clear that "speculation is not enough to sustain Article III standing." *Id.*

III.

I am also concerned that the Majority's opinion could encourage courts to ignore the expert conclusions of administrative agencies. As the Seventh Circuit wrote in *Eike*, "[t]he defendants' large eye drops have been approved by the Food and Drug Administration (FDA)—in other words have been determined to be safe and effective for treatment of glaucoma." *Eike*, 850 F.3d at 318. If Plaintiffs believe that smaller drops will be "even more effective, and also cheaper," these are matters that plaintiffs must take up with the FDA, since a court "cannot bypass the agency and make its own evaluation of the safety and efficacy of an unconventionally sized eye drop." *Id.* 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.

IV.

Finally, I am concerned that the Majority's opinion could play mischief with our standing jurisprudence beyond the class action field. By allowing plaintiffs to 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, I fear that 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. Perhaps as a way to preemptively limit its holding, the Majority repeatedly stresses that the case at hand involves consumer protection statutes prohibiting "unfair" or "unconscionable" conduct. *Cottrell*, 874 F.3d at 161, 165-67, 169-70. Although this language may signal the Majority's desire to restrict its holding to "unfairness" claims, I am concerned that the Majority provides no clear rationale to so confine its interpretation of Article III. I would hold that Article III limits this Court's ability to engage in the type of speculation that Plaintiffs' theory calls for regardless of whether a plaintiff roots its claim in unfairness, deception, or any other cause of action.

* * *

In light of the concerns cited above, I would join Judge Roth in holding that Plaintiffs have not established that they have standing to bring their claim in federal court.

APPENDIX B

PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 16-2015

LEONARD COTTRELL; SANDRA HENON; WILLIAM REEVES; GEORGE HERMAN; SIMON NAZZAL; CAROL FREBURGER; JACK LIGGETT; PATRICIA BOUGH; MACK BROWN; DOLORES GILLESPIE; DEBORAH HARRINGTON; ROBERT INGINO; EDWARD ROGERS, JR.; DEBORAH RUSIGNULOLO; DOROTHY STOKES; JOSEPHINE TROCCOLI; HURIE WHITFIELD; THOMAS LAYLOFF; CAROLYN TANNER; PATSY TATE; JOHN SUTTON; JESUS RENTERIA; GLENDELIA FRANCO; NADINE LAMPKIN, on behalf of themselves and all others similarly situated,

Appellants

v.

ALCON LABORATORIES; ALCON RESEARCH LTD; FALCON PHARMACEUTICALS LTD; SANDOZ INC.; ALLERGAN INC; RP; ALLERGAN USA INC; ALLERGAN SALES LLC; PFIZER INC; VALEANT PHARMACEUTICALS INTERNATIONAL; BAUSCH & LOMB INC.; ATON PHARMA INC; MERCK & CO INC; MERCK SHARP & DOHME CORP; PRASCO LLC; AKORN INC

October 18, 2017

Before CHAGARES, RESTREPO, and ROTH, Circuit Judges.*

OPINION

RESTREPO, Circuit Judge

In this putative class action, consumers of prescription eye medication allege that manufacturers and distributors of the medication packaged it in such a way that forced them to waste it, violating the consumer protection statutes of their home states. The District Court dismissed the entire action for lack of jurisdiction, finding the consumers' allegations of injury in fact insufficient to confer standing. For the reasons that follow, we will reverse the dismissal, and remand the case for further consideration.

I[1]

Defendants are manufacturers and distributors of generic and brand-name prescription eye drop medications that are approved by the Food and Drug Administration

*Judge Roth participated via video conference.

[1] "When reviewing an order of dismissal for lack of standing, we accept as true all material allegations of the complaint and construe them in favor of the plaintiff." *Danvers Motor Co., Inc. v. Ford Motor Co.*, 432 F.3d 286, 288 (3d Cir. 2005) (quoting *Conte Bros. Auto., Inc. v. Quaker State–Slick 50, Inc.*, 165 F.3d 221, 224 (3d Cir. 1998)). We therefore will review the facts as alleged by Plaintiffs in their operative complaint. *See id.*

("FDA") to treat serious medical conditions such as glaucoma, a leading cause of blindness.[2] Defendants sell these prescription medications in fluid form and package the fluid in plastic bottles. Bottles are pre-packaged with a fixed volume of medication (e.g., 5.0 mL) sold at set prices. Labeling on the bottles does not indicate how many doses or days of treatment a patient will be able to extract from the bottle.

Medication is dispensed from the plastic bottles into patients' eyes in drop form. The dimensions of the bottle's dropper tip dictate the size of the drop dispensed from that bottle. In effect, the larger the bottle dropper tip, the larger the drop dispensed. There is no reasonable way for a patient to instill less than one full drop into his or her eye.

A plethora of scientific research conducted over the last four decades has examined the drop size of Defendants' medications; some of the studies conducted were, in fact, sponsored and published by Defendants. According to these studies, a normal adult's inferior fornix—the area between the eye and the lower eyelid—has a capacity of approximately 7 to 10 microliters ("μLs") of fluid.[3] If a

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[2] As detailed in the District Court's opinion, the defendants in this case include both brand-name and generic pharmaceutical manufacturers and their distributors. The brand name companies include: Alcon Laboratories, Inc., Alcon Research, Ltd., Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, Pfizer Inc., Valeant Pharmaceuticals International, Inc., Bausch & Lomb, Inc., Aton Pharma, Inc., Merck & Co., Inc., and Merck, Sharpe & Dohme Corp. The generic companies are Falcon Pharmaceuticals, Ltd., Sandoz Inc., Prasco LLC, and Akorn, Inc.

[3] It can hold 20 to 30 μLs of fluid only for a moment, until the individual blinks.

drop of medication exceeding that capacity is placed into an adult patient's eye, excess medication is expelled. Expelled medication may run down a patient's cheek, providing no pharmaceutical benefit to the patient whatsoever. This medication is "entirely wasted" by the patient. App. 182. Expelled medication also may flow into a patient's tear ducts and move into his or her bloodstream. Medication entering a patient's bloodstream may increase a patient's risk of experiencing certain harmful systemic side effects.

These studies conclude that eye drops should be 5 to 15 μLs in order to maximize the amount of the medication entering the inner eye—the site of action for the medication. Drop sizes within this range minimize overflow "waste" and also minimize the risk of side effects.

Despite the scientific consensus on drop size, all of Defendants' products at issue emit drops that are considerably larger than 15 μLs. In fact, a 2008 study showed that each Defendant's drop size was more than two to three times the 15 μL maximum recommended size. Several Defendants sold products with drop sizes of 50 μL. To put these data in perspective, at least half of every drop of medication dispensed from any one of Defendants' product bottles goes to waste on a patient, and may put the patient at risk of side effects.

Plaintiffs in this litigation are individuals who paid for Defendants' eye drop medication. They allege that Defendants have control over the design and dimensions of the bottle dropper tip, and thus could reduce the size of drops emitted from their product bottles, but have chosen not to do so. Plaintiffs do not purport to have personal knowledge as to why no defendant has reduced their products' drop sizes. However, Plaintiffs include in the

Amended Complaint allegations that senior executives at Defendant Alcon explained to a consultant working with them that they were unwilling to reduce drop sizes because if they did, the company "would sell less product and make less money." App. 244.

Plaintiffs aver that Defendants' practices of selling medication in bottles that emit such large drops caused them "substantial" economic injury. App. 214. Specifically, Plaintiffs allege, "If the sizes of Defendants' prescription eye drops were limited to the maximum effective size of 15 μL . . . the medication in the bottles would last longer and [Plaintiffs] would spend substantially less on their therapy than they do with larger, substantially wasted, eye drops." App. 214. Plaintiffs illustrated this point in their Amended Complaint with an example provided in a 2008 scientific study:

> [T]he average drop size for Allergan's glaucoma drug Alphagan P . . . in a 5 mL bottle was 43 μL . . . . At the recommended dose of one drop in each affected eye three times daily, a 5 mL bottle would last a patient with bilateral glaucoma 20 days. That patient would go through 18.25 bottles in a year. In July 2013, a 5 mL bottle of Alphagan P . . . cost $104.99. A year's course of treatment would therefore cost approximately $1,915. However, approximately 65% of the medication, the amount over 15 μL, would be wasted. If the drops had been only 15 μL, the patient would have needed only 6.46 bottles a year, or 7.0 bottles if the drops had been 16 μL . . . . *The unneeded*

> *medication would cost the patient more than $1,100 a year.*

App. 215-216 (emphasis added). Plaintiffs also quantified their individual economic injuries in charts attached to the Amended Complaint.

Plaintiffs claim they could not have avoided these economic injuries; they were "compel[led] [by Defendants' practices] to spend more money on their therapy than if the drops were 15 μL." App. 214. They had no non-pharmaceutical alternative treatments for their conditions. And there were no alternative products to Defendants'; "all prescription eye drops are substantially larger than 15 μL and therefore lead to wastage." App. 217. Their only alternative was to forgo treatment and risk blindness or worsening eyesight.

II

In September 2014, Plaintiffs filed a putative class action complaint, on behalf of themselves and other similarly situated parties, in the United States District Court for the District of New Jersey. Plaintiffs asserted violations of the consumer protection laws of their respective home states: the New Jersey Consumer Fraud Act ("NJCFA"), N.J.S.A. § 56:8-1, *et seq.*; the California Unfair Competition Law ("UCL"), Cal. Bus. Prof. Code § 17200, *et seq.*; the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA"), Fla. Stat. § 501.201, *et seq.*; the Illinois Consumer Fraud Act ("ICFA"), 815 ILCS 505/1, *et seq.*; the North Carolina Unfair and Deceptive Trade Practices Act ("NCUDTPA"), N.C.G.S. § 75-1.1, *et seq.*; and the Texas Deceptive Trade Practices Act ("DTPA"), Tex. Bus. & Com. Code § 17.41, *et seq.* Plaintiffs claimed Defendants' practices in manufacturing and

selling prescription eye drop medication violated the statutes' prohibitions on unfair or unconscionable trade practices. The District Court dismissed Plaintiffs' original complaint for lack of standing, without prejudice to Plaintiffs' ability to amend the complaint and cure the standing deficiencies.

In June 2015, Plaintiffs filed an Amended Complaint, asserting claims of unfair or unconscionable practices under the same six state consumer protection statutes.[4] Plaintiffs supported their allegations of unfair or unconscionable practices with: (a) scientific literature opining on costs savings occasioned by utilizing smaller drop sizes; and (b) charts showing each Plaintiff's expenses. The charts detailed Plaintiffs' medication purchases and the out-of-pocket expenses they incurred for their purchases. Using these charts and information about each product's drop size, Plaintiffs calculated their total out-of-pocket payments on "wasted" medication. These totals ranged from a few dollars to a few hundred dollars.

In August 2015, Defendants moved to dismiss Plaintiffs' Amended Complaint for lack of standing, federal preemption, and failure to state a claim. The District Court granted Defendants' motions, finding that Plaintiffs had not pleaded an injury in fact necessary to confer standing. As a result, the court did not reach Defendants' arguments on preemption and the sufficiency of Plaintiffs'

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[4] Specifically, Plaintiffs claim that Defendants' practices were: (1) "unconscionable commercial practice[s]" under the NJCFA; (2) "unlawful" and "unfair" practices under the UCL; (3) "unfair acts or practices" under the FDUTPA; (4) "unfair acts or practices" under the ICFA; (5) "unfair . . . acts or practices" under the NCUDTPA; (6) and "unconscionable act[s]" under the DTPA. App. 266-73 (internal quotation marks and citations omitted).

claims under Federal Rule of Civil Procedure 12(b)(6). Plaintiffs then filed this timely appeal.

III

The District Court had jurisdiction pursuant to the Class Action Fairness Act ("CAFA"), 28 U.S.C. § 1332(d), because at least one member of the Plaintiff class is diverse from at least one of the Defendants, the putative class is composed of at least 100 people, and the amount in controversy exceeds five million dollars. We have jurisdiction over the District Court's dismissal of the case pursuant to 28 U.S.C. § 1291.

We exercise plenary review over a dismissal for lack of standing. *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 243 (3d Cir. 2012).

IV

Article III of the United States Constitution limits the power of the federal judiciary to "cases" and "controversies." U.S. Const. art. III. For a federal court to exercise jurisdiction under Article III, plaintiffs must allege—and eventually prove—that they having "standing" to pursue their claims. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). The doctrine of standing emerged from "the traditional understanding of a case or controversy" in order "to ensure that federal courts do not exceed their [constitutional] authority" by "unsurp[ing] the powers of the political branches." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016) (quoting *Clapper v. Amnesty Int'l USA*, 133 S. Ct. 1138, 1146 (2013)). "The doctrine limits the category of litigants empowered to maintain a lawsuit in federal court to seek redress for a legal wrong." *Id.*

The plaintiff, "as the party invoking federal jurisdiction," bears the burden of establishing the minimal requirements of Article III standing: "(1) . . . 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."[5] *Id.* In assessing whether a plaintiff has carried this burden, we separate our standing inquiry from any assessment of the merits of the plaintiff's claim. To maintain this fundamental separation between standing and merits at the dismissal stage, we assume for the purposes of our standing inquiry that a plaintiff has stated valid legal claims. *Info. Handling Servs., Inc. v. Defense Automated Printing Servs.*, 338 F.3d 1024, 1029 (D.C. Cir. 2003) (citing *Warth v. Seldin*, 422 U.S. 490, 500 (1975)). While our standing inquiry may necessarily reference the "nature and source of the claim [s] asserted," *Warth*, 422 U.S. at 500, our focus remains on whether the plaintiff is the proper party to bring those claims, *The Pitt News v. Fisher*, 215 F.3d 354, 360 (3d Cir. 2000); *White Tail Park, Inc. v. Stroube*, 413 F.3d 451, 460-61 (4th Cir. 2005).

A

This case centers on the "[f]irst and foremost" of the three standing elements, injury in fact. *Spokeo*, 136 S. Ct. at 1547 (quoting *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103 (1998)). The purpose of the injury-in-fact requirement, the Supreme Court has explained, is "to distinguish a person with a direct stake in the outcome of a litigation—even though small—from a person with a mere

[5] "In the context of class actions, Article III standing 'is determined vis-a-vis the named parties.'" *McCray v. Fidelity Nat. Title Ins. Co.*, 682 F.3d 229, 243 (3d Cir. 2012) (quoting *Krell v. Prudential Ins. Co. of Am.*, 148 F.3d 283, 306 (3d Cir. 1998)).

interest in the problem." *United States v. Students Challenging Regulatory Agency Procedures (SCRAP)*, 412 U.S. 669, 689 n.14 (1973). Put differently, the requirement serves to filter out those "with merely generalized grievances" who are "bringing suit to vindicate an interest common to the entire public." *Friends of the Earth, Inc. v. Gaston Copper Recycling Corp.*, 204 F.3d 149, 156 (4th Cir. 2000). The injury-in-fact requirement is "very generous" to claimants, demanding only that the claimant "allege[ ] some specific, 'identifiable trifle' of injury." *Bowman v. Wilson*, 672 F.2d 1145, 1151 (3d Cir. 1982) (quoting *SCRAP*, 412 U.S. at 686-90 & 689 n.14). It "is not Mount Everest." *Danvers*, 432 F.3d at 294.

To allege injury in fact sufficiently, a plaintiff must claim "that he or she suffered 'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" *Spokeo*, 136 S. Ct. at 1548 (quoting *Lujan*, 504 U.S. at 560). Typically, a plaintiff's allegations of financial harm will easily satisfy each of these components, as financial harm is a "classic" and "paradigmatic form[ ]" of injury in fact. *Danvers*, 432 F.3d at 291, 293. Indeed, we have explained that where a plaintiff alleges financial harm, standing "is often assumed without discussion." *Id.* at 293; *see also Carter v. HealthPort Techs., LLC*, 822 F.3d 47, 55 (2d Cir. 2016) ("Any monetary loss suffered by the plaintiff satisfies [the injury-in-fact] element; '[e]ven a small financial loss' suffices." (quoting *Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 710 F.3d 71, 85 (2d Cir. 2013))); *Cent. Ariz. Water Conservation Dist. v. U.S. E.P.A.*, 990 F.2d 1531, 1537 (3d Cir. 1993) ("Pecuniary injury is clearly a sufficient basis for standing." (internal quotation marks and citation omitted)).

Although the District Court provided a detailed recitation of standing law in its opinion, including the components of injury in fact, it did not apply those individual components to Plaintiffs' allegations. Rather, it framed its injury-in-fact analysis around broader principles and theories of standing, as did the parties in their briefing to this Court. This approach has some persuasive appeal. But where the court or litigants cast aside the essential components of injury in fact in favor of more generalized, abstract discussion, they risk improperly, if inadvertently, crossing over in their analysis from standing to merits. So we take a different tack; we will address in turn each component of injury in fact.

1

The first component of the injury-in-fact test offered by *Spokeo*—"legally protected interests"—warrants the most discussion in this case. The Supreme Court has not defined the term "legally protected interest" as it pertains to Article III standing, nor has it clarified whether the term does any independent work in the standing analysis. The Court first introduced the term in *Lujan*, 504 U.S. at 560; *see Judicial Watch, Inc. v. U.S. Senate*, 432 F.3d 359, 363 (D.C. Cir. 2005) (Williams, J., concurring). And it appeared—without elaboration—as recently as last year in *Spokeo* in the Court's recitation of *Lujan*'s injury-in-fact test. 136 S. Ct. at 1548. Between *Lujan* and *Spokeo* though, it has not appeared with regularity in Supreme Court opinions addressing standing. A host of the Court's standing opinions have omitted the term altogether,[6] and

[6] *See, e.g.*, *Clapper*, 568 U.S. at 409 (stating "an injury must be concrete, particularized, and actual or imminent" (internal quotation marks omitted)); *Monsanto Co. v. Geertson Seed Farms*, 561 U.S.

it has rarely been applied. *See Judicial Watch*, 432 F.3d at 363 (Williams, J., concurring). This may suggest that "legally protected interest" is simply a reformulation of the other components of injury in fact. *Id.*

However, if we assume *arguendo* that the term "do[es] some work in the standing analysis," *Initiative & Referendum Inst. v. Walker*, 450 F.3d 1082, 1093 (10th Cir. 2006) (en banc), we can discern a number of guideposts from the Supreme Court's standing jurisprudence about what it may—and may not—require that bear on this case. The most important is this: in this context, whether a plaintiff has alleged an invasion of a "legally protected interest" does not hinge on whether the conduct alleged to violate a statute does, as a matter of law, violate the statute. Were we to conclude otherwise, we would effectively collapse our evaluation under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim into an Article III standing evaluation. Every losing claim would be

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139, 149 (2010) ("Standing under Article III of the Constitution requires that an injury be concrete, particularized, and actual or imminent . . . ."); *Massachusetts v. U.S. E.P.A.*, 549 U.S. 497, 517, (2007) (formulating the *Lujan* injury-in-fact test as requiring "a litigant [to] demonstrate that it has suffered a concrete and particularized injury that is either actual or imminent"); *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180 (2000) ("In *Lujan*[, 504 U.S. at 560-61], we held that, to satisfy Article III's standing requirements, a plaintiff must show (1) it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical . . . ."); *Steel Co.*, 523 U.S. at 103 (describing an injury in fact as "a harm suffered by the plaintiff that is concrete and actual or imminent, not conjectural or hypothetical" (internal quotation marks and citation omitted)).

dismissed—without prejudice[7]—for lacking standing in the first place. *Id.* at 1092; *White Tail Park*, 413 F.3d at 460-61; *Claybrook v. Slater*, 111 F.3d 904, 907 (D.C. Cir. 1997); *see also In re Special Grand Jury 89-2*, 450 F.3d 1159, 1172 (10th Cir. 2006) (observing that the Supreme Court "has made clear that a plaintiff can have standing . . . even though the interest would not be protected by the law in that case"). And we would "thwart a major function of the standing doctrine—to avoid premature judicial involvement in resolution of issues on the merits." *Judicial Watch*, 432 F.3d at 364 (Williams, J., concurring).

Second, the Supreme Court has repeatedly recognized that financial or economic interests are "legally protected interests" for purposes of the standing doctrine. *See Vermont Agency of Nat. Resources v. United States,* 529 U.S. 765, 772-77 (2000); *Clinton v. New York*, 524 U.S. 417, 432 (1998); *Sierra Club v. Morton*, 405 U.S. 727, 733-34 (1972); *see also Cent. Ariz. Water*, 990 F.2d at 1537 (stating that "pecuniary or economic injury is generally a legally protected interest," so long as that economic injury meets the remaining requirements of the injury-in-fact test); Erwin Chemerinsky, *Federal Jurisdiction* § 2.3, at 76 (7th ed. 2016) (noting that the Supreme Court has deemed economic harms sufficient injuries for standing).

Third, "legally protected interests" may arise from the Constitution, from common law, or "solely by virtue of 'statutes creating legal rights, the invasion of which creates standing.'" *Lujan*, 504 U.S. at 576-78 (quoting *Warth*,

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[7] Because the absence of standing leaves the court without subject matter jurisdiction to reach a decision on the merits, dismissals "with prejudice" for lack of standing are generally improper. *See Korvettes, Inc. v. Brous*, 617 F.2d 1021, 1024 (3d Cir. 1980).

422 U.S. at 500). Both federal law and state law—including state statutes—"can create interests that support standing in federal courts." *Cantrell v. City of Long Beach*, 241 F.3d 674, 684 (9th Cir. 2001) (citing *FMC Corp. v. Boesky*, 852 F.2d 981, 992 (7th Cir. 1988)).

Fourth, the interest asserted must be "related to the injury in fact"; it cannot be "merely a 'byproduct' of the suit itself." *Vermont Agency*, 529 U.S. at 772-73. To illustrate, a *qui tam* relator who is entitled to a portion of a recovery if his suit under the False Claims Act is successful has a legally protected interest in the outcome of the suit. *Id.* at 772. An individual who has simply placed a wager on the outcome does not. *Id.*; *see also Steel Co.*, 523 U.S. at 107 ("[A] plaintiff cannot achieve standing to litigate a substantive issue by bringing suit for the cost of bringing suit.").

With these guideposts in mind, we look to Plaintiffs' Amended Complaint. Plaintiffs claim economic interests: interests in the money they had to spend on medication that was impossible for them to use. They seek monetary compensation for Defendants' conduct that they allege caused harm to these interests. Plaintiffs' claimed interests arise from state consumer protection statutes that provide monetary relief to private individuals who are damaged by business practices that violate those statutes. These claims fit comfortably in categories of "legally protected interests" readily recognized by federal courts. *See Cantrell*, 241 F.3d at 684.

We acknowledge that the Seventh Circuit held otherwise in a recent case concerning materially identical allegations against many of the same defendants. *Eike v. Allergan, Inc.*, 850 F.3d 315 (7th Cir. 2017). In reviewing the

defendants' appeal from the district court's grant of class certification, the Seventh Circuit concluded that plaintiffs had failed to allege a "legally protected interest," and therefore, lacked standing. *Id.* at 318. The Court noted that the Plaintiffs' pleading "lack[ed] . . . any suggestion of collusion . . . or any claim" of misrepresentation or deception by defendants. *Id.* at 317. From the absence of fraud-based allegations, the court went on to reason that the plaintiffs' claims were necessarily "based simply on [their] dissatisfaction" with the defendants' products or their prices. *Id.* at 317. We decline to adopt the Court's rationale.

This reasoning fails to recognize a category of business practices entirely separate from practices that are fraudulent, deceptive, or misleading—"unfair" business practices—prohibited under the state consumer protection statutes invoked. The plaintiffs in *Eike* explicitly alleged that the defendants' practices in manufacturing and selling eye medication were "unfair" under the Illinois Consumer Fraud & Deceptive Practices Act ("ICFA") and the Missouri Merchandising Practices Act ("MMPA"). *See Eike v. Allergan, Inc.*, 2014 WL 1040728, at *1 (S.D. Ill. Mar. 18, 2014), *vacated,* 850 F.3d 315 (7th Cir. 2017).[8] The Court was obliged to take these allega-

[8] Under the ICFA, "[a] plaintiff is entitled to recovery . . . when there is unfair *or* deceptive conduct" and "may allege that conduct is unfair . . . *without alleging that the conduct is deceptive*." *Siegel v. Shell Oil Co.*, 612 F.3d 932, 935 (7th Cir. 2010) (emphasis added). Under the MMPA, "[t]he act . . . by any person of any deception, fraud, false pretense, false promise, misrepresentation, *unfair practice or* the concealment, suppression, or omission of any material fact in connection with the sale . . . of any merchandise . . . is declared to be an unlawful practice." Mo. Rev. Stat. § 407.020 (emphasis added). The

tions as true for purposes of the standing inquiry. Yet nowhere in its opinion does the term "unfair" even appear. *See generally Eike*, 850 F.3d 315.

Even setting aside the difference between "deceptive" and "unfair" practices under the state consumer protection statutes, the Court in *Eike* blended standing and merits together in a manner that the Supreme Court has exhaustively cautioned courts against. The Seventh Circuit seemed to *begin* its standing analysis with a determination that the plaintiffs had "no cause of action." *Id.* at 317-18. Because they had no cause of action, the Court reasoned, they had no injury. *Id.* at 318. Because they had no injury, they had no standing to sue. *Id.*

This logic flips the standing inquiry inside out, morphing it into a test of the legal validity of the plaintiffs' claims of unlawful conduct. But as we have already emphasized, a valid claim for relief is *not* a prerequisite for standing. *Steel Co.*, 523 U.S. at 96 (explaining that "the nonexistence of a cause of action was no proper basis for a jurisdictional dismissal" and highlighting the "fundamental distinction between arguing" that plaintiffs have no cause of action and arguing that they do not have Article III standing); *see also Bond v. United States*, 564 U.S. 211, 218-19 (2011) (noting the distinction between whether a plaintiff has a "cause of action" and whether he or she has "standing"). Indeed, the Seventh Circuit has acknowledged as much in other cases. For instance, in *Bruggeman ex rel. Bruggeman v. Blagojevich*, 324 F.3d 906 (7th Cir. 2003), it faulted the district court for finding that the plaintiffs had

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definition of "unfair" under the MMPA is "unrestricted, all-encompassing, and exceedingly broad." *Conway v. CitiMortgage, Inc.*, 438 S.W.3d 410, 416 (Mo. 2014) (citation omitted).

no standing to pursue their claims against state officials for violations of a federal statute. *Id.* at 908-09. There, it explained:

> The district judge ruled that none of [the relevant statutory provisions] entitled the plaintiffs to what they were seeking and that therefore the plaintiffs had not been injured by a violation of the statute and so lacked standing to sue. This is a misunderstanding of standing. A plaintiff has standing to sue—that is, he can invoke the jurisdiction of the court—if he is tangibly, materially, injured by the conduct of the defendant that he claims is unlawful . . . . [I]f the consequence [of his claim lacking merit] were that he lacked standing, then every decision in favor of a defendant would be a decision that the court lacked jurisdiction, entitling the plaintiff to start over in another court.

Id at 909.

The District Court here, like the Seventh Circuit, cast the Plaintiffs' allegations as mere grumblings that Defendants' products were priced too high or packaged inefficiently, because the allegations lacked notes of fraud, deception, or misrepresentation. But as in *Eike*, the absence of fraud allegations in the Amended Complaint was purposeful; Plaintiffs claim that Defendants' practices were *unfair* and unconscionable, not deceptive or fraudulent. And like the statutes at issue in *Eike,* the statutes enumerated in Plaintiffs' Amended Complaint prohibit business practices that are "unfair" or "unconscionable" *in*

addition to practices that are fraudulent, deceptive, or misleading; these terms are defined separately and differently in the text of the statutes and in relevant case law interpreting them.[9] Therefore, the District Court's characterization of Plaintiffs' claims as "sound [ing] in fraud" was inaccurate, and the conclusion that Plaintiffs were without standing due, in part, to the absence of theories of injury "normally attendant to consumer fraud claims," App. 23, misses the mark. Moreover, the District Court's

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[9] *See Rubio v. Capital One Bank*, 613 F.3d 1195, 1203 (9th Cir. 2010) ("A business act or practice may violate the [UCL] if it is either unlawful, unfair, or fraudulent. Each of these three adjectives captures a separate and distinct theory of liability." (internal quotation marks and citation omitted)); *Siegel*, 612 F.3d at 935 (7th Cir. 2010) (stating that "[a] plaintiff is entitled to recovery under [the] ICFA when there is unfair or deceptive conduct" and "may allege that conduct is unfair . . . without alleging that the conduct is deceptive"); *PNR, Inc. v. Beacon Property Mgmt., Inc.*, 842 So.2d 773, 777 (Fla. 2003) (defining an "unfair practice" under the FDUTPA as "one that offends established public policy and one that is immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers" and noting a separate definition for "deception" (internal quotation marks and citation omitted)); *Cox v. Sears Roebuck & Co.*, 138 N.J. 2, 647 A.2d 454, 462 (1994) (explaining that an unconscionable practice can qualify as unlawful under the NJCFA, "even if no person was in fact misled or deceived thereby"); *Lon Smith & Assocs., Inc. v. Key*, 527 S.W.3d 604, 623, 2017 WL 3298391, at *11 (Tex. Ct. App. Aug 3, 2017) ("The DTPA defines '[u]nconscionable action or course of action' as 'an act or practice which, to a consumer's detriment, takes advantage of the lack of knowledge, ability, experience, or capacity of the consumer to a grossly unfair degree.'" (quoting Tex. Bus. & Comm. Code Ann. § 17.45(5))); *Melton v. Family First Mortg. Corp.*, 156 N.C.App. 129, 576 S.E.2d 365, 368 (2003) ("A practice is unfair [under the NCUDTPA] when it offends established public policy as well as when the practice is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers" and offering a separate definition for "deceptive" practices (internal quotation marks and citations omitted)).

chain of reasoning—that because Plaintiffs made no allegations of fraud, they suffered no injury, and therefore had no standing to sue—blends standing with merits in the same manner as *Eike*.

For these reasons, we conclude that Plaintiffs have sufficiently alleged "legally protected interests."

2

We turn to the next component of injury in fact: concreteness. For an injury to be "concrete," it must be "real" and "actually exist"; it cannot be "abstract." *Spokeo*, 136 S. Ct. at 1548 (internal citations omitted). Bare procedural or technical violations of a statute alone will not satisfy the concreteness requirement. *Id.* at 1549; *see also Allen v. Wright*, 468 U.S. 737, 754 (1984) ("[A]n asserted right to have the Government act in accordance with law is not sufficient, standing alone, to confer jurisdiction on a federal court."), *abrogated on other grounds by Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377 (2014). Here, Plaintiffs do not simply allege that Defendants' practices violated state consumer protection statutes. They allege that those violations caused each of them tangible, economic harm. This satisfies the concreteness requirement.

3

An injury must be *both* concrete and particularized; these are distinct components of injury in fact. *Spokeo*, 136 S. Ct. at 1548. "For an injury to be 'particularized,' it 'must affect the plaintiff in a personal and individual way.'" *Id.* at 1548; *see also In re Schering Plough*, 678 F.3d at 245 (noting that the party seeking review must be "himself among the injured" (quoting *Lujan*, 504 U.S. at

560)); *The Pitt News*, 215 F.3d at 360. Although "[g]eneralized grievances" common to the public will not suffice, *Knick v. Twp. of Scott*, 862 F.3d 310, 318 (3d Cir. 2017), "[t]he fact that an injury may be suffered by a large number of people does not of itself make that injury a nonjusticiable generalized grievance," *Spokeo*, 136 S. Ct. at 1548 n.7. Requiring a plaintiff to allege facts establishing he is personally injured by a defendant's conduct places "the decision as to whether review will be sought in the hands of those who have a direct stake in the outcome." *Sierra Club v. Morton*, 405 U.S. 727, 740 (1972). Here, each Plaintiff alleges financial harm that he or she has personally incurred in purchasing medication that was impossible for him or her to use. There can be no dispute that this harm is particularized.

4

Finally, we must determine whether Plaintiffs' alleged injuries are "actual or imminent" rather than merely "conjectural or hypothetical." *Spokeo*, 136 S. Ct. at 1548. This component of injury-in-fact is designed to separate those plaintiffs who have alleged "that [they] ha[ve] been or will in fact be perceptibly harmed by the challenged [defendants'] action" from those who claim only that they "can imagine circumstances in which [they] could be affected by the [defendant's] action." *SCRAP*, 412 U.S. at 688-89. Plaintiffs' "pleadings must be something more than an ingenious academic exercise in the conceivable." *Id.*

Plaintiffs attempt to measure their financial harm by way of two "theories" outlined in their Amended Complaint: (1) the cost differential between what they would have paid for their course of medication from smaller

tipped bottles and what they actually paid for the larger tipped bottles (the "pricing theory"); or (2) the total overflow from each drop administered that was impossible for them to use (the "reimbursement theory"). These are two ways of calculating the same thing: the cost of "wasted" medication that Plaintiffs allege they were compelled to purchase but could not use. Under both theories, the total financial harm works out to be the same. And under both theories, Plaintiffs' claimed financial harm has *already* occurred, it is not merely possible, or even probable. So there is no question of adequate imminence in this case. *See Adarand Constructors, Inc. v. Pena*, 515 U.S. 200, 210 (1995) (noting that the plaintiff "of course" had standing to seek damages for alleged *past* economic injury, as opposed to alleged risks of future injuries); *Lewert v. P.F. Chang's China Bistro, Inc.*, 819 F.3d 963, 966-97 (7th Cir. 2016); *Maya v. Centex Corp.*, 658 F.3d 1060, 1069 (9th Cir. 2011) ("Allegedly, plaintiffs spent money that, absent defendants' actions, they would not have spent . . . . This is a quintessential injury-in-fact.").

Despite this, the District Court rejected Plaintiffs' "pricing theory" of "actual" harm as too speculative to support standing in this case. The District Court interpreted Plaintiffs' pricing theory to rely on two critical presumptions: (a) Defendants would have reduced the volume of medication in each bottle to correspond with the lower volume of medication needed for a patient's course of therapy; and (b) Defendants would have reduced the price of a bottle of medication in accordance with the reduction in volume. It rejected the second premise, because it had "no way of knowing whether Defendants would price their products [based on volume], particularly since the pricing of pharmaceuticals is complex." App. 20-21.

We might be inclined to agree with the District Court that the pricing theory was too speculative if it, in fact, had depended on these presumptions. But it did not. Plaintiffs alleged under the pricing theory that smaller tipped bottles would lower the cost of their medication treatment regimen. Treatment costs could have been lowered in several ways, only one of which involved lowering the actual price of the bottle of medication. Alternatively, Plaintiffs would have paid less for their course of medication if they were able to extract more doses of medication—at least twice as many doses, according to the allegations—out of the same bottle, without any changes from the status quo in bottle pricing, physicians' prescribing practices, or the volume of medication in each bottle.

Plaintiffs illustrated in the Amended Complaint how smaller tipped bottles would reduce the number of bottles needed for a one-year therapy regimen, and the resulting cost savings, by referencing an example in a 2008 scientific study, as detailed *supra*.[10] Plaintiffs also supported this iteration of the pricing theory by citing to numerous other scientific studies in the Amended Complaint. *See, e.g.*, App. 240 (noting that "[o]bviously a smaller drop size would mean that more doses could be dispensed from each bottle of medication, providing cost savings to patients and managed care providers" (quoting Richard Fiscella *et al.*, *Efficiency of Instillation Methods for Prostaglandin*

[10] Further, Plaintiffs clearly articulated this theory in their briefing to the District Court opposing Defendants' motion to dismiss. They explained that their claims "ha[d] nothing to do with whether Defendants would ever reduce the prices of their bottles of medication. The reason patients would save money is that they would not need to buy so many bottles" at the same price, because their bottles "would have lasted longer" and ultimately "their therapy would [have] cost them less." D.N.J. Civ. Case No. 14-5859, Doc. No. 91, at 20-21.

Medications, 22 J. Ocular Pharmacology and Therapeutics 477, 478 (2006))). This alternative iteration of the pricing theory is far less speculative than the iteration of the pricing theory that the District Court understood Plaintiffs to be advancing. It is also far less speculative than the theory of financial harm we rejected in *Finkelman v. Nat'l Football League*, 810 F.3d 187 (3d Cir. 2016), the primary case on which the District Court relied here.

In *Finkelman*, one plaintiff alleged that the National Football League's ("NFL") policy on distributing Superbowl tickets forced him to pay more for his ticket in the resale market than he otherwise would have. *Id.* at 190-91, 199-200. Under the NFL Superbowl ticket policy, 99% of the game tickets were distributed to NFL insiders, rather than sold to the public at-large. The plaintiff claimed that this policy reduced the number of tickets available in the resale market. *Id.* Under the basic economic principle of supply and demand then, the policy resulted in an inflated ticket price in the resale market, according to the plaintiff. *Id.* at 199-200. We rejected plaintiff's theory, as the plaintiff pled no facts to support their assertion that the NFL's policy would *actually reduce* the number of tickets in the resale market, since League insiders had the same incentives to resell their tickets for a large profit as the public at-large. *Id.* at 200-02.

The alternative iteration of Plaintiffs' pricing theory does not depend on a comparable presumption essential to their allegations of financial harm. As explained, the reduced size of the bottle dropper tip is the *only* change from the status quo. Accordingly, we find the pricing theory sufficient to satisfy the injury-in-fact requirement.

Even if we had agreed that the pricing theory was too speculative to confer standing, the District Court did not appear to have the same concern about the reimbursement theory. Rather, the District Court rejected the reimbursement theory because it was not a theory of injury that previously had been recognized in fraud cases. Fraud cases, and the theories of injury recognized in those cases, are inapposite here for the reasons explained above. Plaintiffs' allegations concern unfairness and unconscionability. Therefore, under either theory, Plaintiffs' harm is "actual" and satisfies this final component of injury in fact.

* * *

Having found Plaintiffs to sufficiently allege in their Amended Complaint the "'invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical,'" *Spokeo*, 136 S. Ct. at 1548 (quoting *Lujan*, 504 U.S. at 560), we hold that Plaintiffs have alleged an injury in fact sufficient to confer Article III standing to challenge Defendants' allegedly unfair business practices under the enumerated state consumer protection statutes. Of course, it could be that the District Court's legal interpretation of those statutes will not protect against the complained-of business practices and thus will not provide Plaintiffs with the relief they seek. But that question goes to the merits of Plaintiffs' claims under the law, and should be tested through Defendants' motion to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6).[11]

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[11] The Dissent suggests that Plaintiffs have not established standing because their "alleged economic injury" is "overly speculative." Diss. Op. at 174. It discusses in some detail Plaintiffs' theory of economic injury, which our colleague regards as

The District Court did not reach Defendants' Rule 12(b)(6) arguments in this case. So that question is for another day. For the reasons already discussed, we will not require Plaintiffs to prove Defendants' business practices are unfair under state consumer protection statutes in order to find that they have standing to level those attacks in the first place. *La. Energy and Power Authority v. Fed. Energy Regulatory Comm'n*, 141 F.3d 364, 368 (D.C. Cir. 1998).

B

Defendants Falcon, Sandoz, and Akorn, the generic manufacturers, contend that even if we find that Plaintiffs have standing to pursue their claims, we should affirm the dismissal of their Amended Complaint on an alternative

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unreasonable. Our learned colleague also cites to *Dominguez v. UAL Corp.*, 666 F.3d 1359 (D.C. Cir. 2012), for the proposition that too-speculative economic injuries cannot confer standing.

Three years after *Dominguez*, the D.C. Circuit considered a case which a District Court had dismissed for lack of standing on the purported basis of "an attenuated, speculative chain of events that relies on numerous independent actors." *Osborn v. Visa Inc.*, 797 F.3d 1057, 1063 (D.C. Cir. 2015). In reversing the District Court, the D.C. Circuit specifically rejected the lower court "demanding proof of an economic theory that was not required in a complaint," *id.*, and differentiated between cases decided at later stages (such as summary judgment) and dismissals on the basis of lack of standing. *Id.* at 1064. "A Rule 12(b)(1) motion . . . is not the occasion for evaluating the empirical accuracy of an economic theory." *Id.* at 1065-66. In its discussion of the merits of Plaintiffs' theory of economic injury—partly by reference to out-of-record material, Diss. Op. at 174-75, fn. 24-25—the Dissent engages in just that type of evaluation. Whether Plaintiffs defeat motions to dismiss for failure to state a claim and for summary judgment, or can convince a jury, the facts alleged "pass muster for standing purposes at the pleadings stage." *Osborn*, 797 F.3d at 1066.

ground: because their claims are preempted by federal law. Specifically, these Defendants contend they cannot unilaterally make changes to their products' bottle droppers without FDA approval, because a change to the dropper would be considered "major," and all "major" changes require FDA approval to take effect. Therefore, they argue, federal impossibility preemption is appropriate, since they could not simultaneously comply with FDA requirements and with state consumer protection laws that required them to manufacturer bottles with smaller tips.[12] Further, these Defendants argue that claims against generic manufacturers should be preempted because FDA regulations require generic products to have the same bottle design as their brand name equivalents.

Plaintiffs argue in response that some manufacturers have changed their drop volumes over time without FDA approval, which suggests FDA approval is unnecessary. Plaintiffs also argue that there is no same-size-drop equivalence requirement between brand name and generic manufacturers, as reflected by the fact that drop sizes differ between these manufacturers already.

The District Court did not reach preemption in this case, having found that Plaintiffs lacked standing to pursue their claims. We decline to address it in the first instance on appeal, as the record before us is not adequately developed to evaluate the parties' arguments.

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[12] Impossibility preemption, one of several types of preemption, applies "when it is 'impossible for a private party to comply with both state and federal requirements.'" *In re Fosamax (Alendronate Sodium) Products Liability Litig.*, 852 F.3d 268, 282 (3d Cir. 2017) (quoting *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011)).

V

For the foregoing reasons, we will reverse the District Court's dismissal of this action and remand for further proceedings consistent with this opinion.

ROTH, Circuit Judge, dissenting.

Article III of our Constitution is a strict master, preserving constitutional strictures imposed on courts through the requirement that only true cases and controversies be heard. The Majority today, however, erodes these strictures by allowing the plaintiffs here to manufacture a purely speculative injury in order to invoke our jurisdiction. They assert that the defendants *could have* manufactured a more efficient product, which in turn *could have* lowered plaintiffs' overall treatment costs. Because this approach ignores both clear precedent from the Supreme Court and the complexities of pricing in the pharmaceutical industry, I respectfully dissent.

I

I begin by defining the exact nature of the harm that the plaintiffs claim to have suffered as a result of the defendants' conduct. The plaintiffs are the users of prescription eye drops for various visual ailments. The defendants manufacture and sell the eye drops used by the plaintiffs in bottles containing a fixed volume of fluid. The bottles have dropper tips, which dispense more fluid than is medically necessary to treat the plaintiffs' ailments, causing some portion of each drop to be wasted. While the plaintiffs and the Majority note that exposing one's eyes to too

much of the fluid can have negative side effects, no plaintiff in the purported class alleges to have suffered harmful medical consequences. The plaintiffs' sole injury, therefore, is the money spent on that portion of a single eye drop which exceeds the medically necessary volume.[1] The plaintiffs do not argue that they were charged more than the market price for eye drops; rather, they argue that the defendants *could* manufacture a hypothetical eye dropper that would dispense the exact amount of fluid needed to maximize efficacy without waste. Were the defendants to produce such a dropper, they continue, the effective lifespan of each bottle of medicine would increase, reducing the plaintiffs' long-term treatment costs by reducing the number of bottles each plaintiff would have to purchase. Notably, their case depends on the assumption that no other changes would occur in the market to prevent them from capturing the additional value of each bottle at no extra cost. It is the strength of this assumption that we must evaluate.

II

As the Majority recognizes, constitutional standing has three core elements: (1) an injury in fact, (2) causation, and (3) redressability.[2] A complaint must adequately

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[1] While the plaintiffs and the Majority discuss two separate theories explaining how to arrive at this figure—the "pricing theory" and the "reimbursement theory"—both depend on the critical assumption that pricing was based on volume, not on effective doses. I find this assumption untenable, and therefore I will not address the theories separately.

[2] *Hassan v. City of N.Y.*, 804 F.3d 277, 289 (3d Cir. 2015).

plead all three elements to invoke federal court jurisdiction.[3] In reviewing the adequacy of a complaint's assertion of standing, we employ the familiar standards used in evaluating motions to dismiss for failure to state a claim; we accept all of the plaintiff's factual allegations as true, reject conclusions, and assess the plausibility of the plaintiff's standing in light of the well-pleaded allegations.[4] In this evaluation, however, we may make only *reasonable* inferences in support of the plaintiff's claim to standing.[5]

This case turns on whether the plaintiffs have adequately alleged the "[f]irst and foremost"[6] of the "irreducible constitutional minimum"[7] of standing: injury in fact. Such injury must be sufficiently concrete; "that is, it must actually exist."[8] As such, the Supreme Court has repeatedly expressed "reluctance to endorse standing theories that rest on speculation about the decisions of independent actors."[9] Complaints alleging such abstract and speculative injuries have been rejected, both by our Court and by the Supreme Court for failing to give rise to a reasonable inference of injury in fact.[10] While the Majority

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[3] *Id.*

[4] *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 243 (3d Cir. 2012).

[5] *In re Horizon Healthcare Servs. Inc. Data Breach Litig.*, 846 F.3d 625, 633 (3d Cir. 2017).

[6] *Steel Co. v. Citizens for Better Env't*, 523 U.S. 83 (1998).

[7] *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016).

[8] *Id.* at 1548.

[9] *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 (2013).

[10] *See, e.g.*, *Summers v. Earth Island Inst.*, 555 U.S. 488, 495-96 (2009); *Whitmore v. Arkansas*, 495 U.S. 149, 157 (1990); *City of L.A.*

properly notes these governing principles of constitutional standing,[11] it ignores clear law cautioning against recognizing Article III standing based on the types of conjectural allegations that the plaintiffs advance here. Further, the Majority's reasoning ignores the complex nature of pharmaceutical markets as they currently operate, relying on an unreasonable set of assumptions to reach its desired outcome. I address both issues in turn.

A

Just last year, in *Finkelman v. National Football League*, we reaffirmed that "[p]laintiffs do not allege an injury-in-fact when they rely on a chain of contingencies or mere speculation."[12] I believe that *Finkelman* all but decides this case. There, a plaintiff brought suit against the NFL, alleging that the NFL's practice of withholding approximately 99% of Super Bowl tickets for certain insiders artificially inflated the price of tickets available via the resale market. The plaintiff argued that he suffered an economic injury because he was forced to buy a ticket on the secondary market for $2,000, which was $1,200 more than the face value of the ticket.[13] We held that this

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v. Lyons, 461 U.S. 95, 101 (1983) ("Abstract injury is not enough."); *Knick v. Township of Scott*, 862 F.3d 310, 319 (3d Cir. 2017); *Miller v. Nissan Motor Acceptance Corp.*, 362 F.3d 209, 225 (3d Cir. 2004).

[11] I take no issue with the Majority's conclusion that actual economic injuries are generally invasions of legally protected interests, or that the alleged injury here would be particularized to purchasers of the eye drops. I disagree, however, with the Majority's conclusion that the plaintiffs' alleged economic injuries "actually exist." *Spokeo*, 136 S. Ct. at 1547.

[12] *Finkelman v. Nat'l Football League*, 810 F.3d 187, 193 (3d Cir. 2016) (internal quotation marks omitted).

[13] *Id.* at 197-98.

allegation was insufficiently concrete, and declined to recognize his standing to sue. We properly recognized that markets operate in complex ways. First, we noted that insiders faced the same incentives to sell their tickets on the secondary market as did the general public. Second, we noted that, given the insiders' potential profit margins, insiders were more likely to sell on the secondary market at *lower* prices, suggesting that the withholding could have no effect, and potentially even a positive one, on secondary market prices. Taken together, these two propositions made clear that any potentially unlawful conduct by the NFL did not necessarily result in higher prices to the plaintiff; we concluded that "we have no way of knowing whether the NFL's withholding of tickets would have had the effect of increasing or decreasing prices on the secondary market."[14]

While *Finkelman* spoke primarily about market unpredictability in the context of third party action, it relied heavily on the Court of Appeals for the District of Columbia Circuit's opinion in *Dominguez v. UAL Corp.*,[15] which involved no intervening third parties. There, a plaintiff sought to challenge a policy by United Airlines that prevented resale of tickets, arguing that allowing a secondary market would bring down prices in the aggregate. Much like the plaintiffs here have done by attaching scientific studies to their Amended Complaint, Dominguez introduced expert evidence demonstrating that, holding all other forces being equal, a change in United Airlines's policy would result in lower overall prices for consumers. The D.C. Circuit rejected this argument, reasoning that it "assume[d] that United would continue to offer the same

[14] *Id.* at 200.

[15] 666 F.3d 1359 (D.C. Cir. 2012).

types of tickets that it does now" without accounting for the possibility that United "would need to alter its pricing strategy, which may very well result in higher average ticket prices . . . ."[16] Because this attempt to "pile[ ] speculation atop speculation" fell short of Dominguez's obligations under Article III, the D.C. Circuit held that Dominguez lacked standing to bring the action.[17]

Taken together, *Finkelman* and *Dominguez* make clear that, for purposes of analyzing economic injuries in the context of marketwide effects, we cannot do precisely what the plaintiffs here ask of us: isolate and change one variable while assuming that no downstream changes would also occur. These cases are not outliers; rather, they reflect courts' skepticism about plaintiffs' ability to satisfy the case or controversy requirement of Article III by relying on such imaginative economic theories.[18] Thus, contrary to the Majority's assertion,[19] the plaintiffs' pricing theory does in fact depend on exactly the sort of presumption rejected by us and by other courts—namely, the presumption that no other aspects of the market would change once the defendants' conduct did. It is true that we "credit allegations of injury that involve no more than application of basic economic logic."[20] However, *Finkelman*

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[16] *Id.* at 1364.

[17] *Id.*

[18] *See, e.g.*, *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 344-45, (2006) (finding an alleged injury too conjectural for failing to account for "how [other actors] respond to a reduction in revenue . . .");

[19] Maj. Op. at 169 (distinguishing *Finkelman* on the grounds that "Plaintiffs' pricing theory does not depend on a comparable presumption essential to their allegations of financial harm").

[20] *Finkelman*, 810 F.3d at 201 (internal quotation marks omitted).

makes clear that this principle distinguishes "between allegations that stand on well-pleaded facts and allegations that stand on nothing more than supposition."[21] As other courts have noted, this distinction is critical at the pleading stage for a simple reason: assumptions about basic economic logic are susceptible to proof at trial.[22] The plaintiffs here ask more: they ask us to assume certain facts about *other actors'* behavior—exactly the sort of assumption that cannot be proven at trial. Accordingly, I would reject the plaintiffs' alleged economic injury as overly speculative and untenable under existing precedent.[23]

B

Although the speculative nature of the plaintiffs' alleged injury would likely be fatal regardless of the nature of the product, it is worth noting that their theory is a particularly bad fit for the market for pharmaceuticals, undercutting the reasonableness of the assumptions they ask us to make and the inference of economic harm they ask us to draw in their favor. The plaintiffs essentially ask us to assume that the defendants price their medication by volume; thus, in the plaintiffs' view, changing the

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[21] *Id.*

[22] *Osborn v. Visa Inc.*, 797 F.3d 1057, 1064-65 (D.C. Cir. 2015) (finding basic economic assumptions sufficient to satisfy injury requirement where plaintiffs' "sorts of assumptions [we]re provable at trial").

[23] *See United Transp. Union v. I.C.C.*, 891 F.2d 908, 912 (D.C. Cir. 1989) ("When considering any chain of allegations for standing purposes, we may reject as overly speculative those links which are predictions of future events (especially future actions to be taken by third parties) . . . .").

eyedropper size would not change the price of the medicine, while extending the useful lifespan of each bottle, driving down their aggregate costs. This assumption is unreasonable, given the unique nature of markets for medical goods and services.

Pharmaceutical companies have, for some time now, recognized that "unit-based pricing[ ] is too one-dimensional for the marketplace's current needs."[24] Increasingly, throughout the United States and the world, manufacturers engage in "value-based pricing" which deemphasizes the overall volume of medicine received by the patient in favor of an assessment of the value—measured in part by effective doses—received by a patient.[25] Amici raise this point effectively in their briefing, noting that "patients demand treatment, not fluid volume, so demand for defendants' products is properly measured in doses,

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[24] Ellen Licking & Susan Garfield, *A Road Map To Strategic Drug Pricing*, IN VIVO, March 2016, at 1, 3 *available online at* http://www.ey.com/Publication/vwLUAssets/ey-in-vivo-a-road-map-to-strategic-drug-prices-subheader/$FILE/ey-in-vivo-a-road-map-to-strategic-drug-prices-subheader.pdf.

[25] DELOITTE CENTER FOR HEALTH SOLUTIONS, VALUE-BASED PRICING FOR PHARMACEUTICALS: IMPLICATIONS OF THE SHIFT FROM VOLUME TO VALUE 3 (2012), *available online at* http://deloitte.wsj.com/cfo/files/2012/09/ValueBasedPricingPharma.pdf. Pricing in the medical services sector is unique in this regard, as the standard economic forces that set prices for consumer goods do not apply to prescription drugs. This is in part due to the disjunction between the source of payment for services (insurers) and the end users of services (patients). *See* Licking & Garfield, *A Road Map To Strategic Drug Pricing*, at 3.

not in milliliters."[26] Thus, alternative pricing models have begun to take hold in pharmaceutical markets across the world.[27] Some of the plaintiffs' own studies confirm this, noting that the cost of the plaintiffs' therapy "may be based on several factors [including drop size]."[28] The net effect of this shift is to sever the link between volume and price upon which the plaintiffs' alleged injury depends. As amici argue, therefore, it is likely that the defendants "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 the plaintiffs any money."[29]

The plaintiffs, in the same breath in which they accuse the District Court of misunderstanding their pricing theory, misunderstand the importance of such countervailing market forces. As the District Court observed, the studies provided by the plaintiffs all tend to "assume[ ] as true that manufacturers of eye drops would price their medication solely based on the volume of the fluid contained in the bottled."[30] The reason for this observation is not to suggest that the defendants would *lower* their prices in response to a new dropper design; rather, it is to suggest that the price of each bottle could actually *increase* if each bottle provided more doses.

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[26] Amicus Br. of the Am. Tort Reform Assoc., U.S. Chamber of Commerce, Nat'l Assoc. of Mfrs., & Pharma. Research & Mfrs. of Am. (hereafter, "ATRA Br.") at 11.

[27] Licking & Garfield, *A Road Map to Strategic Drug Pricing*, at 7.

[28] Am. Compl. ¶ 192.

[29] ATRA Br. at 9.

[30] JA 17.

At its core, therefore, the plaintiffs' Amended Complaint asks us to make an assumption about the effects of changing the size of the defendants' eye droppers which does not reflect market conditions and pressures in the pharmaceutical industry. As such, the plaintiffs ask us to speculate about a theoretical eye dropper design, then draw an unreasonable inference about the downstream consequences of such an innovation. Because the realities of the pharmaceutical industry make such inferences unreasonable, the Majority errs by accepting them at face value. The plaintiffs have failed to plausibly allege standing.

III

I am sympathetic to the difficulties in demonstrating marketwide injuries in class action litigation. The difficulty of such a showing, however, is not an excuse to treat jurisdiction lightly; "jurisdiction is a strict master."[31] Today's ruling flouts this principle, allowing class action plaintiffs to ignore "the exacting federal standing requirements"[32] by offering nothing more than speculation about complex and industry-specific pricing models. On a practical level, the Majority also invites judges—rather than industry experts, market forces, or agency heads—to second-guess the efficacy of product design even in the most opaque of industries. Because I am troubled by both the legal and practical ramifications of the Majority's decision, I respectfully dissent.

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[31] *State Nat'l Ins. Co. v. Cty. of Camden*, 824 F.3d 399, 411 (3d Cir. 2016) (internal quotation marks omitted).

[32] *Goode v. City of Phila.*, 539 F.3d 311, 318 (3d Cir. 2008).

APPENDIX C

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Civ. Action No. 14-5859 (FLW)

Lenoard Cottrell, *et al.*,
Plaintiffs,

v.

Alcon Laboratories, Inc., *et al.*,
Defendants.

March 24, 2016

OPINION

WOLFSON, District Judge.

For lack of standing, the Court previously dismissed this putative consumer class action, comprised of in– and out-of-state plaintiffs[1] accusing defendant pharmaceutical

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[1] These plaintiffs include: Leonard Cottrell, Sandra Henon, William Reeves, George Herman, Simon Nazzal, Carol Freburger, Jack Liggett, Patricia Bough, Mack Brown, Dolores Gillespie, Deborah Harrington, Robert Ingino, Edward Rogers, Jr., Deborah Rusignulolo, Dorothy Stokes, Josephine Troccoli, Hurie Whitfield, Thomas Layloff, Carolyn Tanner, Patsy Tate, John Sutton, Jesus Renteria, Glendelia Franco and Nadine Lampkin (collectively, "Plaintiffs").

manufacturers and distributors[2] of engaging in unfair and illegal business practices. *See Cottrell v. Alcon Labs, Inc.*, No. 14-5859, 2015 U.S Dist. LEXIS 81830 (D.N.J. Jun. 24, 2015). However, the Court provided Plaintiffs an opportunity to amend their Complaint to cure the deficiencies as to standing. In the instant matter, the Generic and Brand Name Defendants separately move once again to dismiss the Amended Complaint, challenging, *inter alia*, Plaintiffs' new theory of Article III standing. Because the Court finds that Plaintiffs' amendments fare no better than their original allegations, for the reasons set forth here, Plaintiffs' Amended Complaint is dismissed for want of standing.

BACKGROUND AND PROCEDURAL HISTORY

Because the relevant facts of this case were recounted in this Court's previous Opinion, to promote economy, they will be incorporated here. To summarize the alleged facts, Defendants are makers and distributors of various FDA-approved prescription eye drop medications. *See* Am. Compl., ¶ 1. These medications are sold as fluid, in a given volume, in plastic bottles. *Id.* at ¶ 4. Plaintiffs allege

[2] Plaintiffs name as defendants both brand-name and generic pharmaceutical manufacturers and their distributors. The brand name companies include: Alcon Laboratories, Inc., Alcon Research, Ltd., Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, Pfizer Inc., Valeant Pharmaceuticals International, Inc., Bausch & Lomb, Inc., Aton Pharma, Inc., Merck & Co., Inc., and Merck, Sharpe & Dohme Corp. (collectively, the "Brand Name Defendants"). The generic companies are Falcon Pharmaceuticals, Ltd., Sandoz Inc., Prasco LLC, Akorn, Inc. (collectively, the "Generic Defendants"). All defendants will be collectively referred to as "Defendants."

that Defendants set the price for these medications without "stating how many doses are contained in the bottles or how many days they will last." *Id.*

As a part of the alleged illegal and unfair business practices, Plaintiffs aver that Defendants have deliberately designed and manufactured the tips of the bottles to dispense larger than necessary drops of medication, in an effort to compel consumers, like Plaintiffs, "to pay for much more medication than the users of those medications needed." *Id.* at ¶ 1. In that connection, Plaintiffs allege that the large tips lead to dispensing excess fluid from the bottle that "cannot be used, is entirely wasted, provides no pharmaceutical benefit, and is often harmful." *Id.* at ¶ 5.

Previously, the Court dismissed Plaintiff's original complaint based on a lack of standing. In that Opinion, I rejected Plaintiffs' theory that they were injured when Plaintiffs were precluded from using the wasted eye drops, because, absent any allegation that consumers were promised a specific number of doses or drops and that they failed to receive those amounts, Plaintiffs' theory of loss was too conjectural.

In their Amended Complaint, to be clear, Plaintiffs are not complaining of physical injuries from the use of these eye drops, but rather, Plaintiffs theorize that if the tips were made smaller, Plaintiffs would necessarily be able to use the wasted drops, and that would produce a cost savings to Plaintiffs. In that regard, Plaintiffs premise their standing on the "invasion of [a] legally protected interest," that is, "the practice of Defendants in selling their products in a form that compelled Plaintiffs to waste large quantities of medication that were not useful for treatment of their disease." *Id.* at ¶ 175. Plaintiffs aver that

they would personally benefit from a court order "requiring that Defendants reimburse them for the amount they spent on the not-useful amounts of medication." *Id.* "Alternatively, as to standing, Plaintiffs allege that their therapy would have cost less if their eye drops had been smaller." *Id.* at ¶ 178.

In support of their theories of standing, Plaintiffs included various scientific literature opining that 1) a smaller drop volume would provide patients with the maximum therapeutic result; and correspondingly, 2) smaller drop sizes would lead to economic benefits, i.e., cost savings. *See* Am. Compl., ¶¶ 179, 183, 185, 188, 196, 200. For example, one article stated "smaller drops would be preferable to minimize systemic exposure and spilled or wasted medication. Obviously, a smaller drop size would mean that more doses could be dispensed form each bottle of medication, providing cost savings to patients and managed care providers." *Id.* at ¶ 200.

Plaintiffs also included charts that set forth the amount that each of the named Plaintiffs spent on purchasing the medication, the amount of medication in milliliter, the alleged wasted portion of the drop, and, allegedly, the amount of money spent on the wasted portion. *See Id.* at ¶¶ 225-231. To calculate the money spent on the wasted portion, it appears from the charts that Plaintiffs simply divided the purchase price by the amount of medication, and then multiplied that number by the amount of the alleged wasted portion of the drop.

In their Amended Complaint, Plaintiffs assert twenty-three causes of action against Defendants. Plaintiffs seek to bring these claims individually, and on behalf of classes of consumers and third-party payors who have paid all or

part of the purchase prices of prescription eye drops manufactured and sold by Defendants. More specifically, each of the named plaintiffs asserts consumer fraud related claims applicable in the state in which he/she resides. Those state laws include: New Jersey Consumer Fraud Act, California Unfair Competition Law, Florida Deceptive and Unfair Trade Practices Act, Illinois Consumer Fraud Act, North Carolina Unfair and Deceptive Trade Practices Act and Texas Deceptive Trade Practices Act.

On these current motions, the Brand Name and Generic Defendants move separately to dismiss all of Plaintiffs' claims based on standing, preemption and failure to state a claim.[3] Because I find that Plaintiffs have failed to cure their standing requirements, I will confine my discussion only to that issue. And, because standing is dispositive of this case, I am deprived of jurisdiction to hear the case on its merits. *See Finkelman v. National Football League*, 810 F.3d 187, 193 (3d Cir. 2016) ("[a] federal court's obligation to assure itself that it has subject matter jurisdiction over a claim is antecedent to its power to reach the merits of that claim.")(citations omitted).

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[3] As I have stated in my previous Opinion, to date, similar claims against Defendants have been brought in three other federal jurisdictions: Florida, Missouri, and Illinois. In the Florida action, *Freburger v. Alcon Labs.*, No. 13-24446 (S.D. Fla.), plaintiffs voluntarily dismissed the lawsuit before oral argument on a pending motion to dismiss. In the Illinois case, *Eike v. Allergan, Inc.*, No. 12-1141 (S.D. Ill.), the court there denied defendants' motion to dismiss based on similar grounds to those asserted here. However, the district court in the Eastern District of Missouri dismissed Plaintiffs' claims on identical arguments raised by Defendants in this matter. *See Thompson v. Allergan USA, Inc.*, 993 F. Supp. 2d 1007 (E.D. Mo. 2014).

DISCUSSION

I. Standing

I will reiterate my previous recitation of the law with regard to standing. Article III of the Constitution limits the scope of the federal judicial power to the adjudication of "cases" or "controversies." U. S. Const. art. III, § 2. This "bedrock requirement," *see Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 471 (1982), protects the system of separation of powers and respect for the coequal branches by restricting the province of the judiciary to "decid[ing] on the rights of individuals." *Marbury v. Madison*, 5 U.S. 137 (1803). Indeed, "'[n]o principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies.'" *Raines v. Byrd*, 521 U.S. 811, 818 (1997) (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 37 (1976)).

Courts have developed several justicability doctrines to enforce the case-or-controversy requirement, and "perhaps the most important of these doctrines" is the requirement that "a litigant have 'standing' to invoke the power of a federal court." *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 244 (3d Cir. 2012) (quoting *Allen v. Wright*, 468 U.S. 737, 750 (1984)). The seminal standing question is "whether the plaintiff has alleged such a personal stake in the outcome of the controversy as to warrant his [or her] invocation of federal-court jurisdiction and to justify exercise of the court's remedial powers on his [or her] behalf." *Id.* (internal quotations and citations omitted).

To establish Article III standing, a plaintiff bears the burden of sufficiently alleging three elements: 1) an injury-in-fact; (2) a sufficient causal connection between the injury and the conduct complained of; and 3) a likelihood that the injury will be redressed by a favorable decision. *Finkelman*, 810 F.3d at 193.

First, the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992) (internal quotations, alterations, and citations omitted). In addressing this element, the Third Circuit recently stressed that "to be concrete, an injury must be real, or distinct and palpable, as opposed to merely abstract." *Finkelman*, 810 F.3d at 193 (citations and quotations omitted). To be particularized, "an injury must affect the plaintiff in a personal and individual way." *Id.* In that regard, "Plaintiffs do not allege an injury-in-fact when they rely on a chain of contingencies or mere speculation." *Id.*

Second, there must be a causal connection between the injury and the conduct complained of — the injury has to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court. *Lujan*, 504 U.S. at 560-61. This requirement is "akin to but-for causation in tort and may be satisfied even where the conduct in question might not have been a proximate cause of the harm, i.e., indirect causal relationship." *Finkelman*, 810 F.3d at 193. Finally, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision. *Lujan*, 504 U.S. at 561.

Of these three elements, the Third Circuit has advised that "the injury-in-fact element is often determinative." *Toll Bros., Inc. v. Twp. of Readington*, 555 F.3d 131, 138 (3d Cir. 2009). Hence, it bears repeating that the complained-of injury must not be abstract or subjective. *See Id.*; *Laird v. Tatum*, 408 U.S. 1, 13-14 (1972). Allegations of a potential future injury, or the mere possibility of a future injury, will not establish standing. *See Whitmore v. Arkansas,* 495 U.S. 149, 158 (1990); *Employer's Ass'n of New Jersey v. New Jersey*, 601 F. Supp. 232, 238 (D.N.J. 2003), *aff'd* 774 F.2d 1151 (3d Cir. 1985). While economic injury is one of the paradigmatic forms of standing, *see Danvers Motor Co., Inc. v. Ford Motor Co.*, 432 F.3d 286, 291 (3d Cir. 2005), a demand for damages, by itself, will not establish an injury-in-fact. *See Rivera v. Wyeth-Ayerst*, 283 F.3d 315, 320 (5th Cir. 2002); *Koronthaly v. L'Oreal USA, Inc.*, No. 07-5588, 2008 U.S. Dist. LEXIS 59024, at *13 (D.N.J. Jul. 29, 2008).

Moreover, "the 'injury-in-fact' test requires more than an injury to a cognizable interest. It requires that the party seeking review be himself [or herself] among the injured." *Id.* at 563 (quoting *Sierra Club v. Morton*, 405 U.S. 727, 734-35 (1972)). The injury must also be "an invasion of a legally protected interest." *Id.* at 560. In other words, the injury-in-fact requirement exists to assure that litigants have a "personal stake" in the litigation. *See The Pitt News v. Fisher*, 215 F.3d 354, 360 (3d Cir. 2000). By ensuring that litigants present actual cases and controversies, courts can keep the judicial branch from encroaching on legislative prerogatives, thereby preserving the separation of powers. *See Valley Forge v. Americans United for Separation of Church and State*, 454 U.S. 464, 473-74 (1982).

"[T]he standing inquiry requires careful judicial examination of a complaint's allegations to ascertain whether the particular plaintiff is entitled to an adjudication of the particular claims asserted." *Allen*, 468 U.S. at 752. In that regard, at the pleading stage, "[a]lthough general factual allegations of injury resulting from the defendant's conduct may suffice, the complaint must still 'clearly and specifically set forth facts sufficient to satisfy' Article III." *Reilly v. Ceridian Corp.*, 664 F.3d 38, 41 (3d Cir. 2011) (quoting *Lujan*, 504 U.S. at 561); *Whitmore*, 495 U.S. at 155; *see, e.g.*, *Anjelino v. N.Y. Times Co.*, 200 F.3d 73, 88 (3d Cir. 2000) ("Standing is established at the pleading stage by setting forth specific facts that indicate that the party has been injured in fact or that injury is imminent, that the challenged action is causally connected to the actual or imminent injury, and that the injury may be redressed by the cause of action.").

In assessing the sufficiency of the plaintiff's allegations related to standing, the Third Circuit has summed up the process:

> First, we "tak[e] note of the elements a plaintiff must plead to state a claim"—here, the three elements of Article III standing. Second, we eliminate from consideration any allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth." Third, "where there are well-pleaded factual allegations, [we] assume their veracity and then determine whether they plausibly" establish the prerequisites of standing. In conducting this analysis, we are mindful of the Su-

> preme Court's teaching that all aspects factual of a complaint must rest on "well-pleaded allegations" and not "mere conclusory statements." Thus, to survive lack of standing, a plaintiff a motion to dismiss for "must allege facts that affirmatively and plausibly suggest that it has standing to sue."

Finkelman, 810 F.3d at 194 (citations omitted). To be sure, the plaintiff cannot rely on assertions that are merely "speculative or conjectural." *Id.*

A. Plaintiffs' Pricing Theory

In Plaintiffs' original complaint, they allege that if Defendants made the tips of the dispensers smaller, the cost of the medications would decrease, thereby producing a cost savings to consumers. I rejected this theory as hypothetical and conjectural, because Plaintiffs failed to allege any bases for their assertion that Defendants would price "smaller-tipped" bottles less expensively than their current version.

On their second attempt to establish standing, Plaintiffs did not abandon this theory, but rather, they devote multiple pages of their Amended Complaint to citing various articles and studies that express those authors' opinions regarding the size of the drop volume. *See* Am. Compl., ¶¶ 178-216. Indeed, according to those articles, from a therapeutic stand point, smaller drop sizes would be more beneficial to the patients. But, it appears these articles go on to opine on the economic effects of the decreased drop sizes; that is, lower costs. However, reliance on these articles does not cure the speculative nature of Plaintiffs' pricing theory.

While it is difficult — from the allegations — for the Court to discern the methodology from which these articles base their conclusion regarding pricing, one of the articles Plaintiffs cite, however, provides some insight:

> The economic impact of using a smaller drop may be illustrated by Propine 0.1%. An average bottle labeled 15.0 ml actually contained an average of 15.5 ml with a drop volume determined to be 39.8 µl. The average bottle yielded 389 eyedrops, sufficient for 13.9 weeks of therapy (both eyes, twice eyedrops could be reduced bottle would yield 1,0333 daily use) . . . . If the to 15 µl . . . the average drops, sufficient for 36.9 weeks of therapy . . . . systems and alteration Alteration of eyedrop of the medication's delivery physical greatly properties to produce smaller drops could diminish the cost of topical glaucoma therapy . . . .

Am. Compl., ¶ 185. It appears, simply, that the author assumes as true that manufacturers of eye drops would price their medication solely based on the volume of the fluid contained in the bottles. That same assumption underlies Plaintiff's own theory, which is reflected in Plaintiffs' charts.

On the other hand, some articles are not as unequivocal; for example, in ¶ 192 of the Amended Complaint, Plaintiff relies on an article entitled, *Cost Consideration of the New Fixed Combinations for Glaucoma Medical Therapy*, which only suggests that the "[f]inal cost of therapy may be based on ***several*** factors beyond that of the retail price and include the drop size and the amount of

drops per bottle." Am. Compl, ¶ 192 (emphasis added); *see also* § 199 ("[m]any factors influence the daily cost of therapy for eyedrops.").

Additionally, the remaining articles to which Plaintiff cite, state in passing and conclusory terms that smaller drop volume would likely produce lower costs. *See, e.g.*, *Id.* at ¶ 179 ("[a]n important benefit of using a smaller instilled volume, in addition to improved drug activity and lower cost, is a potential decrease in side effects from ophthalmic drugs."); ¶ 183 ("Drop size and method of delivery are also important from an economic standpoint since tips that deliver large or multiple drops increase costs."); ¶ 188 ("From a biopharmaceutical and economic point of view, however, smaller volumes . . . should be instilled."); ¶ 194 ("it has been suggested that the decrease in drop size . . . would reduce the rate of drug loss . . . and, in addition, the cost of therapy."); ¶ 196 (same); and ¶ 200 (same).

Putting aside the fact that some of these articles conflict as to how they arrive at their opinions on costs, the main point to take away from Plaintiffs' allegations based on the articles is that the authors assume — just as Plaintiffs do — that if Defendants replace their bottles with smaller tips, the medications would somehow cost less. The flaw in relying on these opinions is that they do not specifically address or discuss Defendants' pricing model as to the ophthalmic medications at issue. Rather, Plaintiffs and these authors resort to hypothesizing what manufactures would do if tip dispensers were made smaller. Indeed, Plaintiffs concede as much: Plaintiff's theory of pricing is based on "a comparison to a hypothetical world in which Defendants might have produced smaller drops." Am. Compl., ¶ 176. Plaintiffs have not pled any basis for alleging that the way Defendants price their products will

take into account the drop sizes. This is the very type of speculative pleading that the Third Circuit has recently cautioned against.

In *Finkelman*, one of the plaintiffs purchased a Super Bowl ticket for an allegedly inflated price on the ticket resale market. *Finkelman*, 810 F.3d at 190-91. As a result, that plaintiff sued the National Football League ("NFL") under New Jersey's Consumer Fraud Act for a refund of the cost in excess of the printed ticket price. *Id.* at 190. Plaintiff's cause of action was premised on the NFL's practice of withholding tickets. In that connection, as to standing, Plaintiff reasoned that such a practice reduced the supply of tickets and inflated ticket resale price, thereby causing him injury.

The Third Circuit, in the context of a motion to dismiss, found that the plaintiff's allegations were not sufficient to meet standing requirements. First, the Third Circuit found that the alleged increased price that the plaintiff paid on the resale market was based on the plaintiff's "basic" assumption that a "reduction in supply will cause prices to rise." *Id.* at 199 (citations omitted). However, the court explained that there may be other factors that have caused the prices to inflate: "while it *might* be the case that the NFL's withholding increased ticket prices on the resale market, it might also be the case that it had no effect on the resale market." *Id.* at 200. To state the problem succinctly, courts "have no way of knowing whether the NFL's withholding of tickets would have had the effect of increasing or decreasing prices on the secondary market. [Courts] can only speculate — and speculation is not enough to sustain Article III standing." *Id.* The Third Circuit further commented that, although the plaintiff's the-

ory of standing is based on an application of a "basic economic logic," that logic, however, is premised on his supposition. *Id.* at 201. In fact, the Third Circuit concluded that "[i]t [was] pure conjecture about what the ticket resale market might have looked like if the NFL had sold its tickets differently." *Id.*

The Third Circuit's advisement is well taken by this Court. Like their original complaint, Plaintiffs' newly revised pleadings have not offered any facts — other than their speculation — that the pricing of a hypothetical bottle design with smaller dispensing tips would be based on the volume of fluids. And, indeed, just like the type of allegations made by the plaintiff in *Finkelman*, Plaintiffs, here, premise their theory on the "basic principle" that pricing is solely based on volume. The articles that Plaintiffs cite rely on that same principle, and there is no indication in those articles that any of the defendants would manufacture products that dispense fewer eye drops at a less expensive price. Importantly, it appears that all the studies on which Plaintiffs rely examine the medical aspect of the drop volume relating to ophthalmic medicines, not on any economic aspects of how manufacturers of those medicines price their products. Indeed, Plaintiffs have not identified any of these authors to be experts on such economic issues. Thus, while volume may be a pricing factor — just as some of the articles opined — this Court has no way of knowing whether Defendants would price their products in such a way, particularly since the pricing of pharmaceuticals is complex and multi-factored. *Cf. Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 585 (6th Cir. 2013); *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 115 (2011). Therefore, the Court cannot not credit Plaintiffs' bald assertions that Defendants would base the

prices of their products on the volume of fluids as the determinative factor, or a factor at all.[4] Indeed, "Article III injuries require a firmer foundation." *Finkelman*, 810 F.3d at 201; *Dominguez v. UAL Corp.*, 666 F.3d 1359, 1364 (D.C. Cir. 2012)(finding that the plaintiffs had no Article III standing when their theory concerning airline tickets required "pil[ing] speculation atop speculation" as to how the tickets would be priced in the future); *Carter v. Alcon Labs, Inc.*, No. 13-997, 2014 U.S. Dist. LEXIS 32381, at *12-13 (E.D. Mo. Mar. 13, 2014)("even if Defendants sold bottles with less medication, Plaintiff has not suggested there is anything to preclude them from charging what they now charge for the bottles currently available for purchase.").[5]

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[4] Finally, in an effort to support their pricing theory, specifically with respect to defendant Alcon, Plaintiffs included allegations regarding conversations Alcon's expert, Dr. Alan Robin allegedly had with other Alcon marketing executives in the 1990s. Am. Compl., ¶¶ 210-216. While Plaintiffs alleged the same conversations in the original complaint, and the Court rejected as conclusory, Plaintiffs included additional facts that these executives told the expert that Alcon was unwilling to reduce drop size because it would make less money. *Id.* As the Court held previously, these allegations do not address "how it would impact Alcon's discretion, much less the discretion of the thirteen other Defendants, in setting the prices of redesigned products." *Cottrell*, 2015 U.S Dist. LEXIS 81830 at *18-19 n.5. Plaintiffs' additional allegations, again, do not explain how these 20-year old conversations with former executives have any impact on Alcon's discretion now — or any other defendants in this case — to set the prices of certain hypothetically redesigned bottles in the Alcon's set the future.

[5] I cited a plethora of cases in my previous opinion that I found supported my conclusion in this regard. I will not repeat them here. *See Cottrell*, 2015 U.S. Dist. LEXIS 81830 at *19-20.

B. Reimbursement of Costs

The reimbursement theory that Plaintiffs propose was previously rejected by this Court. In the Amended Complaint, Plaintiffs reiterate that they have suffered a concrete injury because they "did not receive the full use and therapeutic benefit of the medication they purchased as a result of Defendants' actions" and that they were compelled "to purchase amounts of medication that were not useful and therefore wasted." Am. Compl., ¶¶ 175-176. In that regard, Plaintiffs claim that they are entitled to receive reimbursement from Defendants for those wasted drops. But, these allegations do not assuage any of the Court's concerns.

First and foremost, Plaintiffs' causes of action sound in fraud. Yet, Plaintiffs do not allege that they were promised by Defendants a specific number of doses or drops and that the consumers failed to receive those amounts. Nor are there any allegations that Plaintiffs were forced to purchase additional prescriptions because the medications were depleted prematurely. Indeed, Plaintiffs do not allege that the eye medications failed to perform as intended such that Plaintiffs did not receive the benefit of their bargain. Moreover, there are no allegations that Plaintiffs were induced by any deception on the part of the defendants to purchase the medications. And, importantly, there are no allegations that any Plaintiffs would have purchased comparable cheaper products that dispense smaller drops, in lieu of Defendants' products.

What I have just outlined above are theories of injuries normally attendant to consumer fraud claims. In fact, I advised Plaintiffs that there are, generally, two theories of economic harm associated with consumer fraud actions:

benefit-of-the-bargain and out-of-pocket expenses. The former relates to economic damages caused by a product failing to perform as advertised, and therefore, the consumer would not have received the benefit of his/her bargain. *See, e.g., Koronthaly v. L'Oreal USA, Inc.*, 374 Fed. Appx. 257, 259 (3d Cir. 2010) ("[a]bsent any allegation that [plaintiff] received a product that failed to work for its intended purpose or was worth objectively less than what one could reasonably expect, [plaintiff] has not demonstrated a concrete injury-in-fact."). The latter encompasses any expenses that a plaintiff incurred as a result of purchasing the defective product, *e.g.*, replacement costs. *See, e.g.*, *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 606 (3d Cir. 2012); *Dicuio v. Brother Intern. Corp.*, No. 11-1447, 2012 U.S. Dist. LEXIS 112047, at *7 (D.N.J. Aug. 9, 2012) ("The out-of-pocket rule applies when a plaintiff can demonstrate that he paid money, and is now, out-of-pocket."). I further advised Plaintiffs that they must allege sufficiently to establish a viable economic harm such that they have standing to sue. However, none of the new pleadings asserted by Plaintiffs demonstrate such a harm.

Rather, Plaintiffs' reimbursement theory rests on their disagreement with how Defendants designed their bottles — a design that has been specifically approved by the FDA in a medical context — and their insistence that they should be reimbursed for drops that were wasted as a result of the design, although Plaintiffs were never promised a certain number of doses. This is not sufficient. Suppose Plaintiffs' claims were based on allegations that the packaging of Defendants' products were excessive such that they had overpaid for the products. Further suppose that if Defendants changed such packaging, con-

sumers would pay less for the medications. Clearly, however, Plaintiffs would not have standing to sue Defendants for consumer fraud based on the packaging allegations because Plaintiffs would have suffered no injuries since no deception by Defendants was made in that regard. In sum, such a hypothetical example and Plaintiffs' reimbursement theory alike, merely rely on an "unsupported conclusion regarding [an] alleged loss." *See Lieberson v. Johnson & Johnson Consumer Cos.*, 865 F. Supp. 2d 529, 541 (D.N.J. 2011).

In conclusion, the Court holds that Plaintiffs have failed to sufficiently allege Article III standing. Therefore, it deprives this Court of subject matter jurisdiction. *See Ballentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007). Absent jurisdiction, the Court is without authority to address the parties' remaining merit-based arguments. *See Adams v. Ford Motor Co.*, 653 F.3d 299, 304 (3d Cir. 2010) ("[i]f plaintiffs do not possess Article III standing, both the District Court and this Court lack subject matter jurisdiction to address the merits of plaintiff's case.").

CONCLUSION

For the reasons set forth above, Defendants' motions to dismiss are **GRANTED** as Plaintiffs lack standing to bring suit. As a result, Plaintiffs' motion for leave to file supplemental exhibits relating to issues involving the merits of this Case is denied as **MOOT.**

APPENDIX D

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Civ. Action. No. 14–5859 (FLW)

Lenoard COTTRELL, et al.,
Plaintiffs,

v.

ALCON LABORATORIES, INC., et al.,
Defendants.

June 24, 2015

OPINION

WOLFSON, District Judge.

In this putative consumer class action, in- and out-of-state plaintiffs[1] accuse defendant pharmaceutical manufacturers and distributors[2] of engaging in unfair and illegal business practices by marketing prescription eye medications that allegedly deliver unnecessarily large eye drops, which results in consumers purchasing more medication than they require. These Plaintiffs have brought various state law consumer fraud-related claims against Defendants. The Generic and Brand Name Defendants move separately to dismiss Plaintiffs' Complaint on the following grounds: (1) lack of standing; (2) preemption; and (3) failure to state a claim. For the reasons set forth herein, the Court **GRANTS** Defendants' motions on the basis that Plaintiffs lack standing to bring suit, and therefore, all of Plaintiffs' claims are dismissed without prejudice. However, Plaintiffs are given leave to amend their Complaint within thirty-days (30) from the date of the Order accompanying this Opinion.

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[1] These plaintiffs include: Leonard Cottrell, Sandra Henon, William Reeves, George Herman, Simon Nazzal, Carol Freburger, Jack Liggett, Patricia Bough, Mack Brown, Dolores Gillespie, Deborah Harrington, Robert Ingino, Edward Rogers, Jr., Deborah Rusignulolo, Dorothy Stokes, Josephine Troccoli, Hurie Whitfield, Thomas Layloff, Carolyn Tanner, Patsy Tate, John Sutton, Jesus Renteria, Glendelia Franco and Nadine Lampkin (collectively, "Plaintiffs").

[2] Plaintiffs name as defendants both brand-name and generic pharmaceutical manufacturers and their distributors. The brand name companies include: Alcon Laboratories, Inc., Alcon Research, Ltd., Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, Pfizer Inc., Valeant Pharmaceuticals International, Inc., Bausch & Lomb, Inc., Aton Pharma, Inc., Merck & Co., Inc., and Merck, Sharpe & Dohme Corp. (collectively, the "Brand Name Defendants"). The generic companies are Falcon Pharmaceuticals, Ltd., Sandoz Inc., Prasco LLC, Akorn, Inc. (collectively, the "Generic Defendants"). All defendants will be collectively referred to as "Defendants."

BACKGROUND

For the purposes of these motions, I will only recount relevant facts from Plaintiffs' Complaint and take them as true. Defendants are brand name and generic pharmaceutical companies that "perform selling, marketing and distribution activities . . . for [various] prescription eye drop products." Compl., ¶ 43. These eye drops, also known as "topical ophthalmic pharmaceuticals," are prescribed for serious diseases and conditions such as glaucoma, allergies, infections, inflammations, [and] pre-and post-operative conditions . . . ." *Id.* at ¶ 2. Defendants "sell their prescription eye drop products as fluid in plastic bottles. They sell a given volume of medication (*e.g.,* 2.5 or 5.0 mL) for a certain price." *Id.* at ¶ 3.

According to Plaintiffs, scientific literature from the past decades "establishes that these bottles, which also serve as dispensers, emit drops so large that they exceed the capacity of the fornix, the area between the eye and the lower eyelid." *Id.* at ¶ 5. Consequently, the excess fluid "can cause allergy or pigmentation, or drains into their nasolacrimal drainage systems and from there into the bloodstream where it can create a risk of toxic side effects." *Id.* Plaintiffs submit that, according to certain scientific studies, "[s]maller size drops on the order of 15 μL have an efficacy and bioavailability equivalent to larger drops." *Id.* at ¶ 8. "Yet Defendants' eye drops are uniformly much larger than 15 L. Some are more than three times that size." *Id.* at ¶ 9. Plaintiffs allege that as a result of Defendants' design, "the excess product cannot be used, is entirely wasted, [and] provides no pharmaceutical benefit." *Id.* at ¶ 5.

Indeed, the gravamen of Plaintiffs' Complaint is that "Defendants have persisted in their unfair, unethical, un-

conscionable, and unlawful practices of selling prescription ophthalmic medicine in dispensers that emit much larger eye drops. As a result, consumers use more medication than they should, run out of medicine before they should, and have to buy additional bottles at great expense, providing increased . . . profits for Defendants." *Id.* at ¶ 11. In that regard, Plaintiffs complain that "there is no legitimate reason why Defendants have not supplied smaller eye drops. As they have long known, the size of the drop is determined by a factor under their control, the dimensions of the plastic dropper tip." *Id.* at ¶ 10. Instead, Plaintiffs claim that Defendants "would not reduce the drop size of [their] products because it would mean that patients would be able to use the bottles longer and [Defendants] would therefore sell less product." *Id.* at ¶ 6. Importantly, as to damages, Plaintiffs base their claims on the allegation that "patients are entitled to receive full use and therapeutic benefit of the entire product they purchase. Yet because of the Defendants' illegal schemes to increase their profits at consumers' expense, patients are compelled to purchase larger quantities that, through no fault of their own, go to waste, and as a result they and their third-party payor pay much more than they should for the treatment they need." *Id.* at ¶ 3.

Plaintiffs further allege certain facts regarding the role of the Food and Drug Administration ("FDA") in approving the size of eye drops. Plaintiffs aver that "a reduction in eye drop size to 15 µl would not have a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product." *Id.* at ¶ 153. Therefore, Plaintiffs, in their Complaint, claim that a reduction in eye drop size

would not be a "major change" requiring prior FDA approval. *See Id.* Moreover, Plaintiffs explain that because the FDA does not "regulate the economics of drug use . . . the FDA does not require or specifically permit Defendants [ ] to make their eye drops so large that it leads to waste of medication." *Id.* at ¶ 155. In further support of their position that the FDA plays no role in this respect, Plaintiffs cite to certain anecdotal evidence. For example, Plaintiffs point out that defendant Alcon's drug, Travatan Z, had a 25 μL when the FDA conducted its initial approval review. *Id.* at ¶ 156. Nevertheless, Plaintiffs allege that just a few years later, a scientific study determined that "the size of Travatan Z drops [was] 30 μL." *Id.* at ¶ 157. And, according to Plaintiffs, "the FDA's website contains no applications for, or approvals of, the above changes in drop size . . . . Thus, [the] FDA approval of those changes was apparently not required." *Id.* at ¶ 158.

In the Complaint, twenty-five causes of action are asserted against Defendants. Plaintiffs seek to bring these claims individually, and on behalf of classes of consumers and third-party payors who have paid all or part of the purchase prices of prescription eye drops manufactured and sold by Defendants. More specifically, each of the named plaintiffs asserts consumer fraud related claims applicable in the state in which he/she resides. Those state laws include: New Jersey Consumer Fraud Act, California Unfair Competition Law, Florida Deceptive and Unfair Trade Practices Act, Illinois Consumer Fraud Act, North Carolina Unfair and Deceptive Trade Practices Act and Texas Deceptive Trade Practices Act.

On these current motions, the Brand Name and Generic Defendants move separately to dismiss all of Plaintiffs' claims based on standing, preemption and failure to

state a claim.[3] Because standing is a threshold question of jurisdiction, I turn to that issue first. *See Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 109–10 (1998) (finding that a plaintiff's Article III standing is a prerequisite for the federal courts to decide the merits of a suit); *Ballentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007).

DISCUSSION

I. Standing

Article III of the Constitution limits the scope of the federal judicial power to the adjudication of "cases" or "controversies." U.S. Const. art. III, § 2. This "bedrock requirement," *see Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 471 (1982), protects the system of separation of powers and respect for the coequal branches by restricting the province of the judiciary to "decid[ing] on the rights of individuals." *Marbury v. Madison*, 1 Cranch 137, 5 U.S. 137 (1803). Indeed, "'[n]o principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies.'" *Raines v. Byrd*, 521

[3] To date, similar claims against Defendants have been brought in three other federal jurisdictions: Florida, Missouri, and Illinois. In the Florida action, *Freburger v. Alcon Labs.*, No. 13–24446 (S.D.Fla.), plaintiffs voluntarily dismissed the lawsuit before oral argument on a pending motion to dismiss. In the Illinois case, *Eike v. Allergan, Inc.*, No. 12–1141 (S.D.Ill.), the court there denied defendants' motion to dismiss based on similar grounds to those asserted here. However, the district court in the Eastern District of Missouri dismissed plaintiffs' claims on identical arguments raised by Defendants in this matter. *See Thompson v. Allergan USA, Inc.*, 993 F. Supp. 2d 1007 (E.D.Mo.2014).

U.S. 811, 818 (1997) (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 37 (1976)).

Courts have developed several justicability doctrines to enforce the case-or-controversy requirement, and "perhaps the most important of these doctrines" is the requirement that "a litigant have 'standing' to invoke the power of a federal court." *In re Schering–Plough Corp. Intron/Temodar Consumer Class Action,* 678 F.3d 235, 244 (3d Cir. 2012) (quoting *Allen v. Wright,* 468 U.S. 737, 750 (1984)). The seminal standing question is "whether the plaintiff has alleged such a personal stake in the outcome of the controversy as to warrant his [or her] invocation of federal-court jurisdiction and to justify exercise of the court's remedial powers on his [or her] behalf." *Id.* (internal quotations and citations omitted).

Of course, a plaintiff bears the burden of meeting the "irreducible constitutional minimum" of Article III standing by establishing three well-settled elements:

> First, the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical.
>
> Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court.

> Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Lujan v. Defenders of Wildlife, 504 U.S. 555, 560–61, (1992) (internal quotations, alterations, and citations omitted).

The Third Circuit has stressed that of the three required elements of constitutional standing, "the injury-in-fact element is often determinative." *Toll Bros., Inc. v. Twp. of Readington,* 555 F.3d 131, 138 (3d Cir. 2009). To satisfy this requirement, the alleged injury must be "particularized," such that it "must affect the plaintiff in a personal and individual way." *Lujan,* 504 U.S. at 560 n.1. Indeed, an injury-in-fact also "must be concrete in both a qualitative and temporal sense. The complainant must allege an injury to himself that is distinct and palpable." *Whitmore v. Arkansas,* 495 U.S. 149, 155 (1990). And, the injury must not be abstract or subjective. *See Id.; Laird v. Tatum,* 408 U.S. 1, 13–14 (1972). Allegations of a potential future injury, or the mere possibility of a future injury, will not establish standing. *See Whitmore,* 495 U.S. at 158; *Employer's Ass'n of New Jersey v. New Jersey,* 601 F. Supp. 232, 238 (D.N.J. 2003), *aff'd* 774 F.2d 1151 (3d Cir. 1985). While economic injury is one of the paradigmatic forms of standing, *see Danvers Motor Co., Inc. v. Ford Motor Co.,* 432 F.3d 286, 291 (3d Cir. 2005), a demand for damages, by itself, will not establish an injury-in-fact. *See Rivera v. Wyeth–Ayerst,* 283 F.3d 315, 320 (5th Cir. 2002); *Koronthaly v. L'Oreal USA, Inc.,* No. 07–5588, 2008 U.S. Dist. LEXIS 59024, at *13 (D.N.J. Jul. 29, 2008).

Moreover, "the 'injury-in-fact' test requires more than an injury to a cognizable interest. It requires that the party seeking review be himself [or herself] among the injured." *Id.* at 563 (quoting *Sierra Club v. Morton,* 405 U.S. 727, 734–35 (1972)). The injury must also be "an invasion of a legally protected interest." *Id.* at 560. In other words, the injury-in-fact requirement exists to assure that litigants have a "personal stake" in the litigation. *See The Pitt News v. Fisher,* 215 F.3d 354, 360 (3d Cir. 2000). By ensuring that litigants present actual cases and controversies, courts can keep the judicial branch from encroaching on legislative prerogatives, thereby preserving the separation of powers. *See Valley Forge v. Americans United for Separation of Church and State,* 454 U.S. 464, 473–74 (1982).

"[T]he standing inquiry requires careful judicial examination of a complaint's allegations to ascertain whether the particular plaintiff is entitled to an adjudication of the particular claims asserted." *Allen,* 468 U.S. at 752. In that regard, at the pleading stage, "[a]lthough general factual allegations of injury resulting from the defendant's conduct may suffice, the complaint must still 'clearly and specifically set forth facts sufficient to satisfy' Article III." *Reilly v. Ceridian Corp.,* 664 F.3d 38, 41 (3d Cir. 2011) (quoting *Lujan,* 504 U.S. at 561); *Whitmore,* 495 U.S. at 155; *see, e.g., Anjelino v. N.Y. Times Co.,* 200 F.3d 73, 88 (3d Cir. 2000) ("Standing is established at the pleading stage by setting forth specific facts that indicate that the party has been injured in fact or that injury is imminent, that the challenged action is causally connected to the actual or imminent injury, and that the injury may be redressed by the cause of action.").

In this case, although Plaintiffs assert numerous claims and allege a variety of scientific studies relating to the designs of Defendants' eye drop bottles, their only theory of economic harm is relatively straightforward: Plaintiffs were injured because they did not receive the full use and therapeutic benefit of the entire product they purchased due to Defendants' design of their bottles to dispense larger than necessary eye drops, which led to waste. Simply stated, Plaintiffs maintain that their losses resulted from overpaying for wasted drops that they were not able to use. Moreover, while Plaintiffs allege that physical harm can result from an excessive dose of the medications, none of the named Plaintiffs have alleged that they suffered any side effects from the use of the eye drops. Thus, Plaintiffs, themselves, may not premise standing on a theory of physical injury.

Defendants posit that Plaintiffs have not shown a concrete injury-in-fact because Plaintiffs received the benefit of their bargain; that is, Plaintiffs were able to use the prescribed eye medications that they purchased. Plaintiffs, in response, contend that standing is easily established in this case based on the standards set forth by § 5(a) of the Federal Trade Commission ("FTC") Act. Plaintiffs' argument relies on a FTC statement, entitled "Policy Statement on Unfairness" ("Policy Statement"). Pursuant to the Policy Statement, "[a]n act or practice [in the context of consumer fairness] is 'unfair' . . . if it causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or competition." *See* FTC Policy Statement on Unfairness (Dec.

17, 1980).[4] Substantial injury, according to the Policy Statement, may involve "monetary harm . . . when sellers coerce consumers into purchasing unwanted goods and services." *Id.* Based on these standards, Plaintiffs allege, in part, that "Defendants' practices cause substantial consumer injury because Defendants have . . . [compelled] consumers into purchasing unwanted amounts of prescription eye drops." Compl., ¶ 189. The Court does not find Plaintiffs' theory of economic damages sufficient to confer standing.

At the outset, while Plaintiffs rely on standards set forth in the Policy Statement, an alleged violation of the Policy Statement, by itself, is not sufficient to show an injury-in-fact for standing purposes. *See Polanco v. Omnicell, Inc.,* 988 F. Supp. 2d 451, 469 (D.N.J. 2013) ("merely asserting violations of certain statutes is not sufficient to demonstrate an injury-in-fact for purposes of establishing standing under Article III . . . ."); *Doe v. Nat'l Bd. of Med. Exam'rs,* 199 F.3d 146, 153 (3d Cir. 1999) (observing that it is "incorrect" to "equate[ ] a violation of a statute with an injury sufficient to confer standing" and explaining that "[t]he proper analysis of standing focuses on whether the plaintiff suffered an actual injury, not on whether a statute was violated."); *see also Rivera v. Wyeth–Ayerst Laboratories,* 283 F.3d 315, 319–20 (5th Cir. 2002) (finding that plaintiffs could not prevail by establishing that Wyeth violated a legal duty owed to consumers; instead, the

[4] Plaintiffs argue that the Policy Statement is critical to the standing analysis because they have based their claims in large part on the standards set forth in the Policy Statement, which certain states—namely, Florida, Illinois and North Carolina—have adopted as a part of their consumer fraud statutes. *See* Compl., ¶¶ 210, 216, 220 (citing Fla. Stat. § 501.204(2); 815 ILCS 505/2; N.C.G.S. § 75–1.1(a)).

injury must be personal). Rather, each Plaintiff must allege that he or she personally suffered some actual economic damage as a result of using Defendants' medications.

There are typically two theories of economic harm associated with consumer fraud actions: benefit-of-the-bargain and out-of-pocket expenses. The former relates to economic damages caused by a product failing to perform as advertised, and therefore, the consumer would not have received the benefit of his/her bargain. *See, e.g., Koronthaly v. L'Oreal USA, Inc.*, 374 Fed. Appx. 257, 259 (3d Cir. 2010) ("[a]bsent any allegation that [plaintiff] received a product that failed to work for its intended purpose or was worth objectively less than what one could reasonably expect, [plaintiff] has not demonstrated a concrete injury-in-fact."). The latter encompasses any expenses that a plaintiff incurred as a result of purchasing the defective product, *e.g.,* replacement costs. *See, e.g., Marcus v. BMW of N. Am., LLC,* 687 F.3d 583, 606 (3d Cir. 2012); *Dicuio v. Brother Intern. Corp.,* No. 11–1447, 2012 U.S. Dist. LEXIS 112047, at *7 (D.N.J. Aug. 9, 2012) ("The out-of-pocket rule applies when a plaintiff can demonstrate that he paid money, and is now, out-of-pocket."). It is important to point out that Plaintiffs do not premise their standing on either of these two theories; indeed, Plaintiffs have neither alleged that Defendants somehow induced Plaintiffs to purchase the medications by misrepresenting or concealing any information, nor do Plaintiffs claim that the medications were ineffective for their prescribed use and that they paid a premium for the medications.

Instead, Plaintiffs claim that they were precluded from using the wasted eye drops because of Defendants'

design of the bottle tip. But, what Plaintiffs do not allege, is that they were promised a specific number of doses or drops of the medications by Defendants and that they failed to receive those amounts. Absent any promises, Plaintiffs' theory of damages is merely "an unsupported conclusion concerning [their] alleged loss," *see Lieberson v. Johnson & Johnson Consumer Cos.*, 865 F. Supp. 2d 529, 541 (D.N.J. 2011); Plaintiffs do not allege what specific economic loss they have suffered. First, Plaintiffs do not allege any of the costs associated with the products at issue, and while Plaintiffs claim that the wasted drops have some economic value, they have failed to quantify that value. Put differently, Plaintiffs theorize that if the bottles were designed to dispense with smaller doses of eye drops, that fact would somehow produce a savings to them. Plaintiff's injury-related allegations amount to nothing more than conjecture since Plaintiffs have neither alleged any comparable cheaper products that they would have purchased, nor have they alleged that Defendants would manufacture, or have manufactured, less expensive products based on a different design.

Notwithstanding those deficiencies, as to costs, Plaintiffs aver that "evidence" exists to establish that the medications at issue would be less expensive if the eye drops were made smaller. Plaintiffs cite to a 2006 article co-authored by an Allergan employee, which states that "smaller drops would be preferable to minimize systemic exposure and spilled or wasted medication" and reducing eye drop size would "provid[e] cost savings to patients and managed care providers." Compl., ¶ 7. Aside from the fact that this article presumably only pertains to Allergan's products, it is also cited out of context. The article discusses the possibility that patients might be able to dis-

pense smaller drops from their ***existing*** bottles of medication by holding the bottle at a different angle. Crucially, there is no indication in the article that any of the defendants would manufacture products that produce smaller eye drops at a less expensive price.[5] Hence, allegations based on this article are not sufficient to establish an injury-in-fact.

In sum, absent sufficient allegations as to injury, Plaintiffs are left with their bald assertion that they overpaid for effective eye medications that would have been less expensive if they were designed according to Plaintiffs' specifications. Such a conclusory theory is simply too remote and abstract to qualify as a concrete and particularized injury under Article III standing. *See, e.g., Koronthaly,* 374 Fed. Appx. at 259 ("[a]bsent any allegation that [plaintiff] received a product that failed to work for its intended purposes or was worth objectively less than what one could reasonably expect," the plaintiff had not suffered Article III injury-in-fact); *Medley v. Johnson & Johnson Consumer Cos.,* No. 10–2291, 2011 U.S. Dist. LEXIS 4627, at *5–7 (D.N.J. Jan. 18, 2011) (plaintiffs lacked Article III standing because "the product worked as intended."); *Thompson,* 993 F. Supp. 2d at 1009 (rejecting claims similar to those raised here on the basis that plaintiffs failed to allege that the eye drop products are

[5] Nor can Plaintiffs base their injury-in-fact on a statement that reducing drop size would result in Alcon selling fewer bottles of medication. Compl. ¶¶ 6, 79. Plaintiffs allege that such a statement was made by an unidentified Alcon marketing executive at an unspecified time for an unknown reason. But, this allegation does not meet the Rule 12(b)(6) standard as it is conclusory in nature. More importantly, this statement alone does not allege how it would impact Alcon's discretion, much less the discretion of the thirteen other Defendants, in setting the prices of redesigned products.

"anything other than what [they have] always purported to be" and received the "benefit of the bargain."); *Carter v. Alcon Labs, Inc.,* No. 13–997, 2014 U.S. Dist. LEXIS 32381, at *12–13 (E.D. Mo. Mar. 13, 2014) ("even if Defendants sold bottles with less medication, Plaintiff has not suggested there is anything to preclude them from charging what they now charge for the bottles currently available for purchase."); *Dominguez v. UAL Corp.,* 666 F.3d 1359, 1364 (D.C. Cir. 2012) (finding no Article III standing when plaintiffs' theory regarding United Airlines ticket prices required "pil[ing] speculation atop speculation" as to how United would price its tickets in the future); *Bowman v. RAM Med., Inc.,* 10–4403, 2012 U.S. Dist. LEXIS 75218, at *7–10 (D.N.J. May 31, 2012); *Waldron v. Jos. A. Bank Clothiers, Inc.,* No. 12–2060, 2013 U.S. Dist. LEXIS 189191, at *15 (D.N.J. Jan. 18, 2013); *Coghlan v. Wellcraft Marine Corp.,* 240 F.3d 449, 455 n.3 (5th Cir. 2001); *Medley v. Johnson & Johnson Consumer Cos.,* No. 10–2991, 2011 U.S. Dist. LEXIS 4627, at *4–6 (D.N.J. Jan. 18, 2011).[6]

[6] To be fair, I recognize that the court in *Eike v. Allergan, Inc.,* found that plaintiffs there, who brought claims similar to those asserted in this case, have sufficiently alleged an actual injury. 2014 U.S. Dist. LEXIS 34894, at *10–11 (S.D.Ill. Mar. 18, 2014). But, the *Eike* Court's analysis in that regard was confined to violations of the Illinois Consumer Fraud & Deceptive Business Practice Act, not Article III standing. More fundamentally, however, for the reasons expressed here, I am not persuaded by that court's conclusion. In fact, although I need not address the merits of Plaintiffs' claims, I note that the lack of Article III standing may be fatal to Plaintiffs establishing an ascertainable loss or injury in each of their state-law based consumer fraud claims.

Because Plaintiffs lack standing to bring suit, it deprives this Court of subject matter jurisdiction. *See Ballentine,* 486 F.3d at 810. Absent jurisdiction, it is well-settled that the Court is without authority to address the parties' remaining merit-based arguments. *See Adams v. Ford Motor Co.,* 653 F.3d 299, 304 (3d Cir. 2010) ("[i]f plaintiffs do not possess Article III standing, both the District Court and this Court lack subject matter jurisdiction to address the merits of plaintiff's case."). Nevertheless, because the Court finds that Plaintiffs have not sufficiently alleged standing, they are given leave to amend their Complaint to cure the deficiencies consistent with the dictates of this Opinion. Thus, I am not addressing the parties' arguments on the merits of Plaintiffs' case.[7]

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[7] I will nonetheless take this opportunity to highlight the issue of preemption should this litigation proceed farther—in the event the Complaint is amended and motion practice follows. Both Generic and Brand Name Defendants contend that Plaintiffs brought state law consumer fraud related claims in order to "force" the manufacturers to redesign their federally approved droppers to dispense smaller drops; doing so, Defendants submit, conflicts with federal law regulating manufacturers of prescription drugs. In the context of pharmaceutical regulations and specifically labeling, the Supreme Court in *Wyeth v. Levine,* 555 U.S. 555 (2009), held that the plaintiffs' labeling claims under state tort laws against ***brand name*** drug companies are not preempted by the FDCA. *Id.* at 578. However, in both *PLIVA, Inc. v. Mensing,* 131 S. Ct. 2567 (2011) and *Mutual Pharmaceutical Co. v. Bartlett,* 133 S. Ct. 2466, (2013), the Supreme Court held that state tort claims against ***generic*** companies—including labeling and design claims—are preempted because of the doctrine of "sameness." *See Mensing,* 131 S. Ct. 2574–75; *Bartlett,* 133 S. Ct. at 2474–76. In so doing, the Supreme Court in these decisions made clear the distinction between generic and brand name products. It is, thus, incumbent upon the parties, here, to address any distinctions in future motion practice regarding preemption.

CONCLUSION

For the reasons set forth above, Defendants' motions to dismiss are **GRANTED** as Plaintiffs lack standing to bring suit. Plaintiffs are given leave to amend their Complaint within 30 days from the date of the Order accompanying this Opinion.

DATE: June 24, 2015 /s/ Freda L. Wolfson
United State District Judge