No. 17-1337

In the Supreme Court of the United States

ALCON LABORATORIES, 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 Alcon Laboratories, Inc.; Akorn, 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.; Pfizer Inc.; Prasco, LLC; Sandoz Inc.; and Valeant Pharmaceuticals International, Inc.

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 Akorn, Inc., 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 Pfizer 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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Alcon Laboratories, Inc.; Akorn, 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.; Pfizer Inc.; 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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