PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 16-2015

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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

On Appeal from the United States District Court
for the District of New Jersey
(D.C. Civil Action No. 3-14-cv-05859)
District Judge: Honorable Freda L. Wolfson

Argued: January 24, 2017

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

Filed: October 18, 2017

LEAH M. NICHOLLS, ESQ. [ARGUED]
Public Justice, P.C.
1620 L. St. N.W., Suite 630
Washington, DC 20036

RICHARD S. CORNFELD, ESQ.
Law Office of Richard S. Cornfeld
1010 Market St., Suite 1720
St. Louis, MO 63101

JOHN G. SIMON, ESQ.
KEVIN M. CARNIE, JR., ESQ.
The Simon Law Firm, P.C.

* Judge Roth participated via video conference.

800 Market St., Suite 1700
St. Louis, MO 63101

JEFFREY W. HERRMANN, ESQ.
Cohn Lifland Pearlman Herrmann & Knopf LLP
Park 80 West-Plaza One
250 Pehle Ave., Suite 401
Saddle Brook, NJ 07663

BRIAN S. WOLFMAN, ESQ.
600 New Jersey Ave. N.W., Suite 312
Washington, DC 20001

Counsel for Appellants

ROBYN E. BLADOW, ESQ. [ARGUED]
AUSTIN C. NORRIS, ESQ.
Kirkland & Ellis LLP
333 South Hope Street, 29th Floor
Los Angeles, CA 90071

Counsel for Appellee Pfizer, Inc.

LIZA M. WALSH, ESQ.
ELEONORE OFOSU-ANTWI, ESQ.
Walsh Pizzi O'Reilly & Falanga LLP
One Riverfront Plaza
1037 Raymond Boulevard, Suite 600
Newark, NJ 07102

Counsel for Appellees Pfizer, Inc., Valeant Pharmaceuticals International, Inc., Bausch & Lomb Incorporated, and Aton Pharma, Inc.

ROGER B. KAPLAN, ESQ.
Greenberg Traurig, LLP
200 Park Avenue
Florham Park, NJ 07932

GREGORY E. OSTFELD, ESQ.
Greenberg Traurig, LLP
77 W. Wacker Drive, Suite 3100
Chicago, IL 60601

LORI G. COHEN, ESQ.
Greenberg Traurig, LLP
3333 Piemont Road NE, Suite 2500
Atlanta, GA 30305

Counsel for Appellees Alcon Laboratories, Inc., Alcon Research Ltd., Sandoz Inc. and Falcon Pharmaceuticals, Ltd.

CHARLES B. CASPER, ESQ.
Montgomery McCracken Walker & Rhoads, LLP
LibertyView, Suite 600
457 Haddonfield Road
Cherry Hill, NJ 08002

STEPHEN G. STRAUSS, ESQ.
TIMOTHY J. HASKEN, ESQ.
Bryan Cave LLP
211 N. Broadway, Suite 3600
St. Louis, MO 63102

Counsel for Appellees Merck & Co., Inc., Merck Sharp & Dohme Corp., and Prasco, LLC.

ROBERT J. MCGUIRL, ESQ.
Law Offices Of Robert J. McGuirl, LLC
295 Spring Valley Road
Park Ridge, NJ 07656

Counsel for Appellees Allergan, Inc., Allergan USA, Inc., and Allergan Sales, LLC

JAMES P. MUEHLBERGER, ESQ.
LORI A. MCGRODER, ESQ.
Shook Hardy & Bacon LLP
2555 Grand Blvd.
Kansas City, MO 64108

Counsel for Appellees Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, Valeant Pharmaceuticals International, Inc., Bausch & Lomb Incorporated, and Aton Pharma, Inc.

WALTER H. SWAYZE, III, ESQ.
MEGAN E. GROSSMAN, ESQ.
KYLE G. EVERLY, ESQ.
Segal Mccambridge Singer & Mahoney, Ltd.
15 Exchange Place, Suite 1020
Jersey City, NJ 07302

JOHN M. KILROY, JR., ESQ.
Polsinelli PC
900 W. 48th Place, Suite 900
Kansas City, MO 64112

J. STANTON HILL, ESQ.
Polsinelli PC
1355 Peachtree Street, N.E., Suite 500
Atlanta, GA 30309

Counsel for Appellee Akorn, Inc.

JULIE NEPVEU, ESQ.
AARP Foundation Litigation
Room B4-245
601 E Street, N.W.
Washington, DC 20049

Counsel for Amicus AARP & AARP Foundation, in support of Appellants

RICHARD A. DEAN, ESQ.
Tucker Ellis
950 Main Avenue
Suite 1100
Cleveland, OH 44113

Daniel J. Kelly, ESQ.
Tucker Ellis LLP
One Market Plaza, Steuart Tower Suite 700
San Francisco, CA 94105

Benjamin C. Sasse, ESQ.
Tucker Ellis LLP
950 Main Ave., Suite 1100
Cleveland, OH 44113

Counsel for Amicus Generic Pharmaceutical Association, in support of Appellees

JEFFREY S. BUCHOLTZ, ESQ.
PAUL A. MEZZINA, ESQ.
King & Spalding
1700 Pennsylvania Avenue, N.W.
Suite 200
Washington, DC 20006

Counsel for Amicus Chamber of Commerce of the United States of America, American Tort Reform Association, Pharmaceutical Research and Manufacturers of America, and National Association of Manufacturers in support of Appellees

ANITA HOTCHKISS, ESQ.
Goldberg Segalla
902 Carnegie Center
Suite 100
Princeton, NJ 08540

Counsel for Amicus Product Liability Advisory Council, in support of Appellees

Michael J. Quirk, ESQ.
Williams Cuker Berezofsky, LLC
1515 Market Street, Suite 1300
Philadelphia PA 19102-1929

National Association of Consumer Advocates

OPINION OF THE COURT

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]

[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.*

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

[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.

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 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.

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

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 ("NCUTDPA"), 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

[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).

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' 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

[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)).

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 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 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 it has rarely been applied. *See Judicial Watch*,

[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. 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

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 dismissed – without prejudice[7] – for lacking standing in the first place. *Id.* at 1092; *White Tail Park*, 413 F.3d at 460-61;

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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)).

[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).

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*, 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

[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 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).

obliged to take these allegations 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 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

[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.*, 647 A.2d 454, 462 (N.J. 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*, 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*., 576 S.E.2d 365, 368 (N.C. Ct. App. 2003) ("A practice is unfair [under the NCUDTPA] when it offends

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 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

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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)).

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 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-

[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.

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 7. It discusses in some detail Plaintiffs' theory of economic injury, which our colleague regards as unreasonable. Our learned colleague also cites to *Dominquez 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 *Dominquez*, 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

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 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

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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 7, 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.

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.

V

[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)).

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 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

[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).

[3] *Id.*

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 properly

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[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, 103 (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. 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).

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

[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).

value of the ticket.[13] We held that this 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

[13] *Id.* at 197-98.
[14] *Id.* at 200.
[15] 666 F.3d 1359 (D.C. Cir. 2012).

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 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

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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 27 (distinguishing *Finkelman* on the grounds that "Plaintiffs' pricing theory does not depend on a comparable presumption essential to their allegations of financial harm").

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* 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,

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

[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) . . ..").

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 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

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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

effectively in their briefing, noting that "patients demand treatment, not fluid volume, so demand for defendants' products is properly measured in doses, 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

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(patients). *See* Licking & Garfield, *A Road Map To Strategic Drug Pricing*, at 3.

[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.

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.

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,

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[30] JA 17.

[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).

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.