

2018 WL 4958856

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United States Court of Appeals, First Circuit.

IN RE: ASACOL ANTITRUST LITIGATION.
United Food & Commercial Workers Unions
and [Employers Midwest Health Benefits Fund](#), on behalf of itself and all others
similarly situated; Mark Adorney, Plaintiffs,
Teamsters Union 25 Health Services & Insurance
Plan, on behalf of themselves and all others
similarly situated; NECA-IBEW Welfare Trust
Fund, on behalf of themselves and all others
similarly situated; [Wisconsin Masons' Health Care Fund](#), on behalf of itself and all others
similarly situated; [Minnesota Laborers Health and Welfare Fund](#), on behalf of itself and all others
similarly situated; AFSCME Health and Welfare
Fund; Pennsylvania Employees Benefit Trust
Fund; Ahold U.S.A., Inc.; [Rochester Drug Co-Operative, Inc.](#); Value Drug Company; Meijer, Inc.;
Meijer Distribution, Inc., Plaintiffs, Appellees,
v.
Warner Chilcott Limited; Allergan, Inc., f/k/
a Actavis, PLC; Allergan USA, Inc.; Allergan
Sales, LLC; Allergan, PLC, Formerly known
as Actavis, PLC, Defendants, Appellants,
Zydus Pharmaceuticals USA Inc.; Cadila
Healthcare Limited; [Warner Chilcott \(US\), LLC](#); Warner Chilcott Sales (US), LLC;
Warner Chilcott Company, LLC, Defendants.

No. 18-1065

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October 15, 2018**Synopsis**

Background: Union-sponsored benefit plans, the buyers of brand name ulcerative colitis drugs, brought putative class action against drug manufacturers under state antitrust laws, alleging the manufacturers suppressed generic entry for drug by pulling it from market at same time a new drug was introduced. The United States District Court for the District of Massachusetts, [Denise J. Casper, J., 323 F.R.D. 451](#), certified class of buyers. Manufacturers were granted leave to pursue interlocutory appeal.

Holdings: The Court of Appeals, [Kayatta](#), Circuit Judge, held that:

[1] plan possessed Article III standing to bring action, but

[2] District Court abused its discretion by determining proposed class of plans met predominance requirement for certification of class.

Reversed and remanded.

[Barron](#), Circuit Judge, issued concurring opinion.

Procedural Posture(s): Interlocutory Appeal; Motion to Certify Class.

West Headnotes (8)

[1] **Federal Courts**

🔑 Standing

The Court of Appeals reviews de novo the existence of Article III standing required to invoke the jurisdiction of a federal court. [U.S. Const. art. 3, § 2, cl. 1.](#)

[Cases that cite this headnote](#)

[2] **Federal Civil Procedure**

🔑 Rights of third parties or public

In deciding whether a fiduciary, a parent, a personal representative, or a partner may prosecute a claim on behalf of another person, courts generally focus not on whether the putative representative independently satisfies Article III standing, but rather on whether that party qualifies under the applicable law as a representative of the one who does have standing. [U.S. Const. art. 3, § 2, cl. 1.](#)

[Cases that cite this headnote](#)

[3] **Federal Civil Procedure**

🔑 Representation of class;typicality; standing in general

In class actions, a court determines whether named plaintiffs possess Article III standing by focusing on the incentives of the named plaintiffs to adequately litigate issues of importance to them; this focus is in many respects simply an application to aggregate litigation of the basic Article III requirement that a plaintiff possess such a personal stake in the outcome of the controversy as to assure concrete adverseness. *U.S. Const. art. 3, § 2, cl. 1.*

[Cases that cite this headnote](#)

[4] **Antitrust and Trade Regulation**

🔑 [Right of Action;Persons Entitled to Sue; Standing;Parties](#)

Federal Civil Procedure

🔑 [Antitrust plaintiffs](#)

Union-sponsored benefit plan, the buyer of brand name ulcerative colitis drugs, possessed Article III standing to bring putative class action against drug manufacturers under state antitrust laws, alleging the manufacturers suppressed generic entry for drug by pulling it from market at same time a new drug was introduced, despite contention that no named plaintiff had either resided or purchased relevant products during class period in 22 of the 26 states at issue; claims of named plans paralleled those of putative class members in sense that success on claim under state law would more or less dictate success under another state law, as plans' liability theories as to monopolization were limited to construction of state antitrust laws that paralleled federal antitrust law, and fact that judgments for some class members would nevertheless enter under laws of states other than states under which any class representatives' judgments would enter, where those laws were materially the same, had no relevant bearing on the personal stake of the named plaintiffs in litigating action to secure such judgments. *U.S. Const. art. 3, § 2, cl. 1.*

[Cases that cite this headnote](#)

[5] **Federal Courts**

🔑 [Class actions](#)

The Court of Appeals reviews a District Court's decision that plaintiffs' proposed class meets the requirement that questions of law or fact common to class members predominate over questions affecting only individual members for abuse of discretion; within this ambit, the Court of Appeals reviews pure issues of law de novo and fact-dominated issues for clear error. *Fed. R. Civ. P. 23(b)(3).*

[Cases that cite this headnote](#)

[6] **Federal Civil Procedure**

🔑 [Common interest in subject matter, questions and relief;damages issues](#)

The aim of the predominance inquiry, as part of class certification, is to test whether any dissimilarity among the claims of class members can be dealt with in a manner that is not inefficient or unfair. *Fed. R. Civ. P. 23(b)(3).*

[Cases that cite this headnote](#)

[7] **Federal Civil Procedure**

🔑 [Antitrust plaintiffs](#)

District Court abused its discretion by determining proposed class of union-sponsored benefit plans, the buyers of brand name ulcerative colitis drugs, met predominance requirement for certification of class in action against drug manufacturers under state antitrust laws, alleging the manufacturers suppressed generic entry for drug by pulling it from market at same time a new drug was introduced; proposed class included consumers who did not sustain injury in fact for Article III standing purposes and who would have continued to purchase a brand drug for various reasons even if a cheaper, generic version had been available, determining injuries in fact would be individual issue, the resolution of which would vary among class members, and proposed mechanism of gathering testimony

from class members via affidavit would be challenged by manufacturer and could not secure favorable ruling disposing of issue of liability. U.S. Const. art. 3, § 2, cl. 1; Fed. R. Civ. P. 23(b)(3).

Cases that cite this headnote

[8] Federal Civil Procedure

🔑 Factors, grounds, objections, and considerations in general

A class cannot be certified on the premise that the defendant will not be entitled to litigate its statutory defenses to individual claims. Fed. R. Civ. P. 23.

Cases that cite this headnote

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS, [Hon. [Denise J. Casper](#), U.S. District Judge]

Attorneys and Law Firms

[J. Mark Gidley](#), with whom [Peter J. Carney](#), [Dana Foster](#), [Matthew S. Leddicotte](#), [Jaclyn Phillips](#), Washington, DC, [Maxwell J. Hyman](#), [Robert A. Milne](#), [Jack E. Pace III](#), [Bryan D. Gant](#), [Kelly Newman](#), and White & Case LLP New York, NY, were on brief, for appellants.

[Richard A. Samp](#) and Marc B. Robertson on brief for Washington Legal Foundation, amicus curiae.

[Justin N. Boley](#), with whom [Kenneth A. Wexler](#), [Tyler J. Story](#), Wexler Wallace LLP, Chicago, IL, [Tyler W. Hudson](#), [Eric D. Barton](#), [David Barclay](#), Wagstaff & Cartmell, LLP, Kansas City, MO, [Nathaniel L. Orenstein](#), Boston, MA, [Todd A. Seaver](#), San Francisco, CA, Berman Tabacco, [Daniel E. Gustafson](#), [Karla M. Gluek](#), [Michelle J. Looby](#), Minneapolis, MN, [Joshua J. Rissman](#), Gustafson Gluek PLLC, [Jeffrey L. Kodroff](#), [William G. Caldes](#), [John A. Macoretta](#), Spector Roseman Kodroff & Willis, P.C., Philadelphia, PA, [Peter J. Mougey](#), Levin, Papantonio, Thomas, Mitchell, Rafferty & Proctor, P.A., Pensacola, FL, [Jonathan D. Karmel](#), and Karmel Law Firm, Chicago, IL, were on brief, for appellees.

Before [Lynch](#), [Kayatta](#), and [Barron](#), Circuit Judges.

Opinion

[KAYATTA](#), Circuit Judge.

*1 Drug manufacturer Warner Chilcott Limited pulled one of its products—Asacol—from the market just months before the drug's patent protection expired. Warner simultaneously introduced a similar but not exactly identical substitute drug called Delzicol, the patent protection for which ran years longer. This coordinated withdrawal and entry of the two drugs allegedly precluded generic manufacturers from introducing a generic version of Asacol, which would have provided a lower-cost alternative to Warner's drugs Delzicol and Asacol HD, a version of Asacol that was also still under patent protection. Crying foul, the named plaintiffs in this case filed a class action alleging a violation of the consumer protection and antitrust laws of twenty-five states and the District of Columbia. On plaintiffs' motion, the district court certified a class of all Asacol purchasers who subsequently purchased Delzicol or Asacol HD in one of those twenty-six jurisdictions. In so doing, the court found that approximately ten percent of the class had not suffered any injury attributable to defendants' allegedly anticompetitive behavior. Nevertheless, the district court determined that those uninjured class members could be removed in a proceeding conducted by a claims administrator. We find this approach to certifying a class at odds with both Supreme Court precedent and the law of our circuit. We therefore reverse.

I.

Asacol is a pharmaceutical drug that treats mild to moderate ulcerative colitis, a chronic inflammatory bowel disorder. Developed and first manufactured by Procter and Gamble Pharmaceuticals, Asacol debuted on the market in 1992 and received the protection of two patents. Those patents expired on July 30, 2013. In 2008, Procter and Gamble brought a new variation of Asacol to market, dubbed Asacol HD, which treated moderate, but not mild, ulcerative colitis. This new drug differed from Asacol in two key ways: it included twice the dosage, and it replaced Asacol's single-layer coating with a dual-layer coating. Asacol HD's patent protection extended years beyond that of Asacol. In 2009, Warner Chilcott purchased Procter

and Gamble's pharmaceutical portfolio, which included both [Asacol](#) and [Asacol HD](#).

On March 18, 2013, only a few months shy of the end of [Asacol's](#) patent protection, Warner stopped selling and marketing [Asacol](#). On the same day, Warner introduced a new drug: Delzicol. Delzicol, like [Asacol](#), treats [ulcerative colitis](#). The two drugs contain the same active ingredient and dosage, and sold for the same price. Unlike [Asacol](#), Delzicol comes in a capsule that does not contain dibutyl phthalate (“DBP”). DBP is a plasticizer, the safety of which appears to have been the subject of a dialogue between the FDA and [Asacol's](#) manufacturers.

On June 22, 2015, several plaintiffs (collectively “plaintiffs,” “named plaintiffs,” or “class representatives”) filed suit on their own behalf and on behalf of a putative class. These plaintiffs are all union-sponsored benefit plans that paid for the purchases of [Asacol](#) HD and Delzicol. In their operative complaint, plaintiffs allege that Warner harbored an anticompetitive motivation for its conduct. According to the complaint, Warner's aim in pulling [Asacol](#) from the market and introducing Delzicol was to preclude the possibility of market entry of generic drugs, which would have cut into Warner's profits. State law provides the mechanism for this preclusion. Under most state substitution laws, pharmacists can fill a prescription by substituting a generic drug for the prescribed brand drug, but only if the brand drug is listed as a “reference” drug for the generic. This automatic substitution, plaintiffs say, provides the “only viable cost-efficient means” for new generics to “compet[e] with brand drugs.” But even a small alteration to the brand drug, such as substituting a tablet form for a capsule form, can prevent a generic equivalent from using the discontinued form as a reference drug. Thus, by pulling [Asacol](#), Warner effectively prevented generic drugs that would have used [Asacol](#) as a reference drug from entering the market after the expiration of [Asacol's](#) patents.¹ And the introduction of a similar, but not wholly equivalent, drug—Delzicol—with the potential for longer-lasting patent protection, allowed Warner to substantially retain its market share. Thus, plaintiffs contend, Warner forced consumers into a “hard switch” and maintained its monopoly power unencumbered by competition from generic entry. Plaintiffs' theory of liability rests on a Second Circuit decision that condemns similar such conduct. See [New York ex rel. Schneiderman v. Actavis PLC](#), 787 F.3d 638 (2d Cir. 2015).

*2 The named plaintiffs and the putative class members purchased Warner's products not from Warner directly, but from third party intermediaries. That means that they cannot sue Warner for damages under the federal antitrust law. [Illinois Brick Co. v. Illinois](#), 431 U.S. 720, 736, 97 S.Ct. 2061, 52 L.Ed.2d 707 (1977). Plaintiffs therefore seek recovery under the laws of twenty-five states and the District of Columbia that allow indirect purchasers to challenge anticompetitive conduct by manufacturers whose products consumers acquire through intermediaries.² All twenty-six jurisdictions, according to plaintiffs, generally interpret state law restraints on anticompetitive activity consistently with federal courts' interpretation of federal antitrust law, but have “[Illinois Brick](#) repealer” laws allowing antitrust damage actions by indirect purchasers against manufacturers.

Plaintiffs moved for class certification on behalf of a class of all similarly situated indirect purchasers, including any individual consumers who purchased the relevant Warner products from drug retailers in the twenty-six jurisdictions. Plaintiffs designed the class to include only those persons or entities that both purchased [Asacol](#) prior to July 31, 2013—the approximate date on which [Asacol's](#) patent protection expired—and also purchased either [Asacol](#) HD or Delzicol after July 31, 2013. Both sides introduced expert evidence regarding the propriety of class certification.

The district court granted plaintiffs' motion for class certification. Rejecting Warner's argument to the contrary, the district court concluded that the named plaintiffs had standing to prosecute claims on behalf of class members under various state laws even if the named plaintiffs themselves had not made purchases in all those states. Any difference between the claims of the named plaintiffs and those of unnamed class members was a matter for consideration under Rule 23, and not a matter of Article III standing, the court ruled.

Moving to the Rule 23 analysis, the district court first found that plaintiffs' proposed class satisfied the four elements of Rule 23(a): numerosity, commonality, typicality, and adequacy. See [Fed. R. Civ. P. 23\(a\)](#). The district court also concluded that the proposed class passed muster under [Rule 23\(b\)\(3\)](#) because common questions predominated over individual questions and a

class action presented a superior method for resolving plaintiffs' claims.

In making those determinations, the district court grappled with a problem that has been the source of much debate among the circuits: the presence of uninjured class members. The district court presumed that approximately ten percent of class members had not been injured by Warner's allegedly anticompetitive conduct because, even had a lower-priced generic alternative been available, these consumers would not have switched to it.³ The court based this conclusion on the reports of both sides' experts. Those experts used the experiences of similar pharmaceutical products as benchmarks from which to infer likely market dynamics had a lower-priced generic form of *Asacol* been introduced. Defendants' expert, Dr. Bruce Strombom, pointed to a benchmark product in which the prevalence of consumers who stuck with the higher-priced brand decreased to 10.6% within approximately three years after generic entry. Dr. Rena Conti, plaintiffs' expert, looked to different benchmark products, from which she concluded that the market share of generic *Asacol* would have grown to approximately 88.8% within a year of generic entry, and would then have risen to about 91.4% thirty-one months after generic entry. From these two reports, the district court presumed that "by the end of the relevant period, somewhere around 10% of the class members would have opted for *Asacol* HD or *Delzicol* even in the presence of generic *Asacol*." [In re Asacol Antitrust Litig.](#), 323 F.R.D. 451, 482 (D. Mass. 2017).

^{*3} The district court nevertheless concluded that the number of these uninjured class members was "de minimis." The district court also accepted plaintiffs' contention that they could remove these uninjured persons from the class with the assistance of a so-called claims administrator. Our opinion in [Nexium](#), plaintiffs argue, permitted such a process. See [In re Nexium Antitrust Litig.](#), 777 F.3d 9 (1st Cir. 2015).

The district court's order certifying the class raises issues on which circuits are split and that are likely to arise in other cases in this circuit before an appeal from a final judgment would—if ever—ripen in this case. A panel of this court therefore found "special circumstances" justifying the grant of leave to pursue an interlocutory appeal under [Rule 23\(f\)](#). See [Fed. R. Civ. P. 23\(f\)](#); [Waste Mgmt. Holdings, Inc. v. Mowbray](#), 208 F.3d 288, 293-94

(1st Cir. 2000). In accord with this grant, Warner presents two primary challenges. First, it argues that, because the named plaintiffs only made purchases in four states, they lack Article III standing to assert claims under the laws of states in which they did not make purchases. Second, Warner takes issue with the district court's decision to certify a class containing uninjured class members.

II.

[1] We review de novo the existence of Article III standing required to invoke the jurisdiction of a federal court. See [Anderson ex rel. Dowd v. City of Boston](#), 375 F.3d 71, 92 (1st Cir. 2004). The named plaintiffs in this case indisputably have standing to litigate their own claims against Warner. They plausibly allege an injury in the form of lost money fairly traceable to an allegedly unlawful supra-competitive price, and seek classic redress in the form of a damage award. See generally [Lujan v. Defs. of Wildlife](#), 504 U.S. 555, 560-61, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992). Nor does the standing requirement of Article III erect any impediment to the named plaintiffs' ability to litigate as class representatives materially identical claims by other persons under the same laws under which the named plaintiffs' claims arise. [Gratz v. Bollinger](#), 539 U.S. 244, 267, 123 S.Ct. 2411, 156 L.Ed.2d 257 (2003).

Warner challenges, instead, the named plaintiffs' standing to bring claims on behalf of class members whose claims arise under the laws of the twenty-two states within which no named plaintiff has either resided or purchased the relevant Warner products during the class period. These states, apparently, apply their relevant law only to claims that arise out of purchases made within the state or by state residents. Therefore, says Warner, because no named plaintiff can successfully bring a claim under the laws of any of those twenty-two states, they necessarily lack standing to bring such claims as representatives of persons who might sue successfully in those states.

[2] One might think that we could reject this argument merely by observing that whether a plaintiff may represent persons who themselves have standing to bring the claims alleged is a question to be addressed under [Rule 23](#), rather than a question of standing. After all, that is how one would presumably proceed in seemingly analogous situations outside of [Rule 23](#). For example, in deciding

whether a fiduciary, a parent, a personal representative, or a partner may prosecute a claim on behalf of another person, courts generally focus not on whether the putative representative independently satisfies Article III standing, but rather on whether that party qualifies under the applicable law as a representative of the one who does have standing. See, e.g., [Sam M. ex rel. Elliott v. Carcieri](#), 608 F.3d 77, 83 n.5 (1st Cir. 2010); [Goodwin v. C.N.J., Inc.](#), 436 F.3d 44, 49 (1st Cir. 2006); [Pérez v. Clínica Dr. Perea](#), 915 F.2d 1556, 1990 WL 151307, at *3 (1st Cir. July 9, 1990) (unpublished); [Levin v. Berley](#), 728 F.2d 551, 555-56 (1st Cir. 1984). And sometimes the authority for such a person to bring a suit as a representative of another resides in the Federal Rules of Civil Procedure. See, e.g., [Fed. R. Civ. P. 17\(c\)\(2\)](#) (allowing a “next friend” to sue on behalf of a minor with no requirement that the next friend possess standing to bring such a claim on behalf of herself or himself).

*4 Precedent, though, forecloses such a simple and quick answer. See [Warth v. Seldin](#), 422 U.S. 490, 502, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975); [Blum v. Yaretsky](#), 457 U.S. 991, 1000-01, 102 S.Ct. 2777, 73 L.Ed.2d 534 (1982); see also 1 [William B. Rubenstein, Newberg on Class Actions](#) § 2:5 (5th ed. 2012) (“In a class action suit with multiple claims, at least one named class representative must have standing with respect to each claim.”). In [Blum](#), the Supreme Court confronted an effort by two plaintiffs to represent a class of Medicaid patients challenging the decisions of a state committee to transfer them to different levels of nursing home care, allegedly without sufficient procedural safeguards. The two named plaintiffs, who had been threatened with transfers to lower levels of nursing care, also sought to press the claims of persons who might object to being transferred to facilities providing higher levels of care. 457 U.S. at 1000-02, 102 S.Ct. 2777. The named plaintiffs had not been transferred or threatened with transfers to facilities providing higher levels of care. Furthermore, the conditions under which transfers to such facilities occurred were sufficiently different from transfers to facilities providing lesser care “that any judicial assessment of their procedural adequacy would be wholly gratuitous and advisory.” [Id.](#) at 1001, 102 S.Ct. 2777. For that reason, the plaintiffs lacked “the necessary stake in litigating conduct ... to which [the plaintiffs] ha[d] not been subject.” [Id.](#) at 999, 102 S.Ct. 2777.

[3] In keeping with this precedent, we have trained our Article III focus in class actions on “the incentives

of the named plaintiffs to adequately litigate issues of importance to them.” [Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp.](#), 632 F.3d 762, 770 (1st Cir. 2011). This focus is in many respects simply an application to aggregate litigation of the basic Article III requirement that a plaintiff possess “such a personal stake in the outcome of the controversy as to assure ... concrete adverseness.” [Baker v. Carr](#), 369 U.S. 186, 204, 82 S.Ct. 691, 7 L.Ed.2d 663 (1962).

[4] Nothing in this precedent, though, suggests that the claims of the named plaintiffs must in all respects be identical to the claims of each class member. See [Gratz](#), 539 U.S. at 262-68, 123 S.Ct. 2411. Requiring that the claims of the class representative be in all respects identical to those of each class member in order to establish standing would “confuse[] the requirements of Article III and Rule 23.” [Fallick v. Nationwide Mut. Ins. Co.](#), 162 F.3d 410, 421 (6th Cir. 1998). Indeed, such an approach would render superfluous the Rule 23 commonality and predominance requirements because any case that survived such a strict Article III analysis would by definition present only common issues. So the question of standing is not: Are there differences between the claims of the class members and those of the class representative? Rather, the pertinent question is: Are the differences that do exist the type that leave the class representative with an insufficient personal stake in the adjudication of the class members' claims? Here, with one exception, we think not.

Importantly, the claims of the named plaintiffs parallel those of the putative class members in the sense that, assuming a proper class is certified, success on the claim under one state's law will more or less dictate success under another state's law. Even while arguing that there may be a few subtle differences in the attitudes of some state courts toward such claims, Warner concedes that the “parties do agree that Plaintiffs' liability theories as to monopolization are limited to a construction of state antitrust laws that parallel the federal Sherman Act.” Under those parallel laws, all plaintiffs who were forced to pay a higher price in the absence of generic competition have a substantial and shared interest in proving that the higher price was the result of unlawful monopolizing conduct that is redressable by an award of damages. And the fact that judgments for some class members will nevertheless enter under the laws of states other than the states under which any of the class representatives'

judgments will enter, where those laws are materially the same, has no relevant bearing on the personal stake of the named plaintiffs in litigating the case to secure such judgments. See [Morrison v. YTB Int'l, Inc.](#), 649 F.3d 533, 536 (7th Cir. 2011) (holding that a state law's limit to in-state events is an “application of choice-of-law principles [that] has nothing to do with standing” (emphasis in original)). Indeed, the fact that the judgments will enter under different statutes is such a minor point of difference that in individual actions it might not even preclude a finding of issue preclusion. [B&B Hardware, Inc. v. Hargis Indus., Inc.](#), — U.S. —, 135 S.Ct. 1293, 1306, 191 L.Ed.2d 222 (2015); see also [Smith v. Bayer Corp.](#), 564 U.S. 299, 310, 131 S.Ct. 2368, 180 L.Ed.2d 341 (2011) (rejecting the proposition “that the source of law is all that matters” in determining whether two issues differ).

*5 It is true that, in order to prevail on their claims, the named plaintiffs need not prove where a class member resides, or where the class member made a purchase. But that same thing could be said of the named plaintiffs' need to prove that any class member made a purchase anywhere, even in the states under which the named plaintiffs' claims arise. As we have previously observed, “[i]n a properly certified class action, the named plaintiffs regularly litigate ... claims of other class members based on transactions in which the named plaintiffs played no part.” [Plumbers' Union](#), 632 F.3d at 769.

Warner does argue that the applicable laws in a few states actually do have added substantive elements that the named plaintiffs will have no interest in proving: First, the laws of three states require proving some effect on intrastate commerce, see [In re Flonase Antitrust Litig.](#), 610 F.Supp.2d 409, 415-16 (E.D. Pa. 2009) (Tennessee); [Sun Dun, Inc. v. Coca-Cola Co.](#), 740 F.Supp. 381, 396-97 (D. Md. 1990) (District of Columbia); [In re Microsoft Corp. Antitrust Litig.](#), 2003 WL 22070561, at *2 (D. Md. Aug. 22, 2003) (Maryland); Second, some states treble damages, compare, e.g., [Nev. Rev. Stat. § 598A.210\(2\)](#) (providing for treble damages); [Wis. Stat. § 133.18\(1\) \(a\) \(same\) with Fla. Stat. § 501.211\(2\)](#) (providing only for actual damages) and [Mass. Gen. Laws ch. 93A, § 11](#) (requiring proof of willful conduct as a predicate to trebling); and, Third, New York's consumer protection statute requires proof of deception, see [Stutman v. Chem. Bank](#), 95 N.Y.2d 24, 709 N.Y.S.2d 892, 731 N.E.2d 608 (2000).

Warner, though, makes no showing that an effect on intrastate commerce will even be a disputed issue. Trebling, in turn, seems irrelevant to our inquiry unless it is not automatically applied to the common surcharge that the named plaintiffs have ample self-interest in proving. So that leaves Warner's unopposed contentions that New York law may require proof of deception, and that trebling in Massachusetts apparently requires proof of willfulness. As to the latter, plaintiffs base their relatively novel common monopolization claim on a theory that expressly requires proof of a “specific intent to monopolize,” as “distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.” [Actavis](#), 787 F.3d at 651 (quoting [Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP](#), 540 U.S. 398, 407, 124 S.Ct. 872, 157 L.Ed.2d 823 (2004)). They expressly allege in pursuit of their own claims that Warner acted willfully. Nor does Warner claim that plaintiffs need not prove an intent to monopolize. So, whether or not such proof is ultimately required, the named plaintiffs certainly have a substantial stake in proving up a case that is, as a practical matter, unreliably distinguishable from proving willfulness.

That leaves only Warner's contention that, under [N.Y. Gen. Bus. Law § 349\(a\)](#), the named plaintiffs have an insufficient stake in the claim of New York class members because that law requires proof of deception. Plaintiffs offer no response to this argument at all. The complaint's list of common issues and its statement of its causes of action include no suggestion that they intend to prove deception (suggesting that they indeed see no stake in doing so). We therefore find that plaintiffs have waived any opposition to Warner's argument that plaintiffs lack standing to sue on behalf of those who can claim no basis for relief other than under New York law. In so doing, we put off to another day how to apply Article III standing principles to a case in which a putative class representative has a personal stake in proving most but not all of the elements of a class member's claim.

*6 Finding Article III standing otherwise satisfied in this case is in accord with the decisions of our sister circuits that have considered similar issues. See [Langan v. Johnson & Johnson Consumer Cos.](#), 897 F.3d 88, 92-96 (2d Cir. 2018); see also [Morrison](#), 649 F.3d at 536. Our conclusion is in line with our prior precedent, in which we required only that a plaintiff make a single purchase in order to satisfy standing for a claim brought under multiple state

laws. See [Nexium](#), 777 F.3d at 31-32. It also accords with direction from the Supreme Court that, once the named plaintiff establishes injury and membership in the class, the inquiry should shift “from the elements of justiciability to the ability of the named representative to ‘fairly and adequately protect the interests of the class.’ ” [Sosna v. Iowa](#), 419 U.S. 393, 403, 95 S.Ct. 553, 42 L.Ed.2d 532 (1975) (quoting Fed. R. Civ. P. 23(a)). Therefore, it is to that inquiry that we now turn our focus.

III.

[5] Satisfied that we have subject matter jurisdiction, we consider next the district court's finding that plaintiffs' proposed class meets the requirement of [Rule 23\(b\)\(3\)](#) that “questions of law or fact common to class members predominate over any questions affecting only individual members.” [Fed. R. Civ. P. 23\(b\)\(3\)](#). We review that decision for abuse of discretion. [In re New Motor Vehicles Canadian Exp. Antitrust Litig.](#), 522 F.3d 6, 17 (1st Cir. 2008). Within this ambit, we review pure issues of law de novo and “fact-dominated” issues for clear error. [Id.](#)

In considering the propriety of class certification in this case, we again deal with an issue that strikes at the heart of the competing considerations raised by some class actions: the proper treatment of uninjured class members at the class certification stage. Proof of injury, also called “injury-in-fact,” is a required element of a plaintiff's case in an action such as this one. [New Motor Vehicles](#), 522 F.3d at 19 n.18. Plaintiffs' class nevertheless includes consumers who would have continued to purchase a brand drug for various reasons, even if a cheaper, generic version had been available.

On appeal, both parties argue that the district court's estimate that approximately ten percent of the class was uninjured is wrong: Plaintiffs say it is too high and Warner says it is too low. The district court record suggests that many of these specific challenges were not preserved. See [Clauson v. Smith](#), 823 F.2d 660, 666 (1st Cir. 1987) (stating that “points which were not seasonably advanced below” are waived on appeal). In any event, having reviewed the parties' competing critiques, we find no clear material error in the district court's factual approximation. See [Nexium](#), 777 F.3d at 17 (reviewing factual findings for “clear error”). So, the question thus becomes: Can a class be certified in this case even though injury-in-fact will

be an individual issue, the resolution of which will vary among class members?

[6] To answer this question, the parties agree that we must direct our attention to the requirement of [Rule 23\(b\)\(3\)](#) that common issues must predominate over individual issues in order to certify a class. See [Amgen, Inc. v. Connecticut Ret. Plans & Tr. Funds](#), 568 U.S. 455, 469, 133 S.Ct. 1184, 185 L.Ed.2d 308 (2013). The aim of the predominance inquiry is to test whether any dissimilarity among the claims of class members can be dealt with in a manner that is not “inefficient or unfair.” [Id.](#) (citing Richard A. Nagareda, [Class Certification in the Age of Aggregate Proof](#), 84 N.Y.U. L. Rev. 97, 107 (2009)). Inefficiency can be pictured as a line of thousands of class members waiting their turn to offer testimony and evidence on individual issues. Unfairness is equally well pictured as an attempt to eliminate inefficiency by presuming to do away with the rights a party would customarily have to raise plausible individual challenges on those issues.

*7 In assessing efficiency and fairness, we have recognized that a class may be certified notwithstanding the need to adjudicate individual issues so long as the proposed adjudication will be both “administratively feasible” and “protective of defendants' Seventh Amendment and due process rights.” [Nexium](#), 777 F.3d at 19. In [Nexium](#) itself, the court found a possible mechanism available to avoid both inefficiency and unfairness. The court reasoned that, “if un rebutted,” a consumer's testimony that “given the choice, he or she would have purchased the generic” would be “sufficient to establish injury in an individual suit.” [Id.](#) at 20. It therefore concluded that “similar testimony in the form of an affidavit or declaration would be sufficient in a class action” when introduced “at the liability stage.” [Id.](#) at 20-21.

The district court in this case sought to track [Nexium](#), finding that “prior to judgment, it will be possible to establish a mechanism for distinguishing the injured from the uninjured class members.” [In re Asacol Antitrust Litig.](#), 323 F.R.D. at 481 (quoting [Nexium](#), 777 F.3d at 19). Pointing to a proposal advanced by plaintiffs, the district court described the mechanism to which it referred as follows: “[i]n a Court-approved notice, Class members will be asked to submit a claim form, along with data and documentation that may be deemed

necessary for consideration. The Claims Administrator will evaluate each claim pursuant to a formula proposed by Plaintiffs and approved by the Court.” [Id.](#) at 479. Plaintiffs' actual proposed mechanism also noted that “[i]ndividual Class members will have an opportunity to contest the calculations, and the Court will review the Claims Administrator's report, making any changes it believes are necessary.”

[7] One can only guess what data and documentation may be deemed necessary, what the formula will be, and how the claims administrator will decide who suffered no injury. Nevertheless, the district court was convinced that [Nexium](#) blesses such a scheme. We disagree.

[Nexium](#) held that “unrebutted testimony” contained in affidavits would suffice as a mechanism for identifying who was injured and who was not injured. [Id.](#) at 21 (emphasis added). If unrebutted, such testimony in an affidavit could be used prior to trial to obtain summary judgment, thereby efficiently and fairly removing the issue of injury-in-fact from the case for trial. See [Fed. R. Civ. P. 56\(c\)\(1\)\(A\), \(c\)\(4\)](#); see also, e.g., [Kuperman v. Wrenn](#), 645 F.3d 69, 80 (1st Cir. 2011) (finding that a party prevailed on an issue on summary judgment on the basis of an unrebutted affidavit). In [Nexium](#) itself, neither our court nor the district court ever learned whether the defendants would in fact rebut any affidavits. The possibility that unrebutted affidavits could be used was raised sua sponte for the first time in the majority opinion. By the time that opinion was issued, the case had been tried without the benefit of our holding and, having won, the defendants indeed chose not to challenge the inclusion of any class members, by that point presumably enjoying the breadth of their win. See generally [In re Nexium \(Esomeprazole\) Antitrust Litig.](#), 842 F.3d 34, 40-42 (1st Cir. 2016).

Here, though, the record is clear that plaintiffs do not propose to rely on unrebutted testimony to eliminate the question of injury-in-fact before trial. And, unlike in [Nexium](#), defendants have expressly stated their intention to challenge any affidavits that might be gathered. Nor do plaintiffs point to any basis in the record for deeming all such challenges to be so implausible as to warrant a finding that we can consider the issue to be uncontested. Warner has explained that some class members stopped taking (and will therefore have no record of purchasing) [Asacol](#) anywhere between 2009 and 2012, and some class members when asked will admit a preference for DBP-

free medication such as [Delzicol](#). Additionally, some class members would not have switched to a generic because they had no co-pay, and therefore were not price sensitive. So whatever one thinks of [Nexium's](#) sua sponte positing in the face of the defendants' silence that unrebutted affidavits might be both available and sufficient, see [Nexium](#), 777 F.3d at 36 (Kayatta, J., dissenting), here we have no basis for venturing such a prediction (nor did the district court do so).

*8 Our inability to fairly presume that these plaintiffs can rely on unrebutted testimony in affidavits to prove injury-in-fact is fatal to plaintiffs' motion to certify this case. Testimony that is genuinely challenged, certainly on an element of a party's affirmative case, cannot secure a favorable summary judgment ruling disposing of the issue. [Fed. R. Civ. P. 56\(a\)](#). And the affidavits would be inadmissible hearsay at trial, leaving a fatal gap in the evidence for all but the few class members who testify in person. Nor have the plaintiffs provided any basis from which we could conclude that the number of affidavits to which the defendants will be able to mount a genuine challenge is so small that it will be administratively feasible to require those challenged affiants to testify at trial.

[8] We also reject any invitation to rewrite [Nexium](#) as sanctioning the use of inadmissible hearsay to prove injury to each class member at or after trial. The fact that plaintiffs seek class certification provides no occasion for jettisoning the rules of evidence and procedure, the Seventh Amendment, or the dictate of the Rules Enabling Act, 28 U.S.C. § 2072(b). See [Tyson Foods, Inc. v. Bouaphakeo](#), — U.S. —, 136 S.Ct. 1036, 1048, 194 L.Ed.2d 124 (2016) (evidence may not be used in a class action to give “plaintiffs and defendants different rights in a class proceeding than they could have asserted in an individual action”). A “claims administrator's” review of contested forms completed by consumers concerning an element of their claims would fail to be “protective of defendants' Seventh Amendment and due process rights.” [Nexium](#), 777 F.3d at 19. Plaintiffs' proposed claims process provides defendants no meaningful opportunity to contest whether an individual would have, in fact, purchased a generic drug had one been available. A “class cannot be certified on the premise that [the defendant] will not be entitled to litigate its statutory defenses to individual claims.” [Wal-Mart Stores, Inc. v. Dukes](#), 564 U.S. 338, 367, 131 S.Ct. 2541, 180 L.Ed.2d 374 (2011). Here, we have more than a statutory defense; rather, we

have a challenge to a plaintiff's ability to prove an element of liability. And although [Halliburton](#) permitted class certification based on a proper presumption furnished by the applicable law, even if the presumption might be rebutted as to individual plaintiffs in a few instances, [Halliburton Co. v. Erica P. John Fund, Inc.](#), 573 U.S. 258, 134 S.Ct. 2398, 2412, 189 L.Ed.2d 339 (2014), here we have no such presumption.

Relatedly, this is not a case in which a very small absolute number of class members might be picked off in a manageable, individualized process at or before trial. Rather, this is a case in which any class member may be uninjured, and there are apparently thousands who in fact suffered no injury. The need to identify those individuals will predominate and render an adjudication unmanageable absent evidence such as the un rebutted affidavits assumed in [Nexium](#), or some other mechanism that can manageably remove uninjured persons from the class in a manner that protects the parties' rights. See [Nexium](#), 777 F.3d at 30 (“We thus define ‘de minimis’ in functional terms.”). And, as we have already explained, the process on which the district court relied is not such a mechanism.

Plaintiffs' fallback argument, urged most prominently on appeal, is that, at trial, they will prove “class-wide impact” with the testimony of their expert, Dr. Conti, and with defendants' own documents and admissions. But plaintiffs point to no documents or admissions that would support a finding that all class members suffered injury. So this argument on appeal comes down to their claim that they will prove class-wide impact at trial with the testimony of their expert, Dr. Conti.

To support this alternative approach, plaintiffs point to the approval in [Tyson Foods](#) of the plaintiffs' use of an expert report that calculated each individual employee's average time spent “donning and doffing” protective equipment for the purpose of establishing the employees' total hours worked in an overtime compensation case under the Fair Labor Standards Act. 136 S.Ct. at 1042-43. Here, plaintiffs contend that, “[c]onsistent with ... the guidance in [Tyson Foods](#)[], plaintiffs will prove classwide antitrust impact at trial using representative evidence.” Such evidence relies on Dr. Conti's calculation that a generic substitute drug would have achieved approximately ninety percent market penetration in a but-for world, from which, in part, the district court estimated

that about ten percent of the class was likely brand loyal and thus uninjured. For several reasons, plaintiffs' reliance on [Tyson Foods](#) falls short of the mark.

*9 To begin with, using the average time it takes a person to don and doff clothes to estimate how long it takes a given individual to do so (as in [Tyson Foods](#)) is quite different than saying, for example, that a given person wore certain clothes merely because most but not all others did so. If statistically valid, an average multiplied by the total number of individuals likely equals the actual total time spent by all. But Dr. Conti's estimate that a generic drug would achieve roughly ninety percent market penetration, if used to prove that each individual would have likely purchased the generic drug and was thus injured by defendants' conduct, leads to the demonstrably wrong conclusion that one hundred percent of individuals were injured. And that is a contention that Dr. Conti's opinion itself rejects.

In [Tyson Foods](#), the Court pointed out that under the controlling substantive law, the proffered representative evidence would be admissible and sufficient to prove injury in any individual class member's individual trial. See [Tyson Foods](#), 136 S.Ct. at 1047 (quoting [Anderson v. Mt. Clemens Pottery Co.](#), 328 U.S. 680, 687, 66 S.Ct. 1187, 90 L.Ed. 1515 (1946), for the proposition that, under the Fair Labor Standards Act, “an employee has carried out his burden” if he produces evidence demonstrating the amount of improperly compensated work “as a matter of just and reasonable inference”). Here, plaintiffs point to no such substantive law that would make an opinion that ninety percent of class members were injured both admissible and sufficient to prove that any given individual class member was injured. And whether such evidence would actually be “sufficient to sustain a jury finding,” [id.](#) at 1048, is far from self-evident. See, e.g., [Guenther v. Armstrong Rubber Co.](#), 406 F.2d 1315, 1318 (3d Cir. 1969) (“[A]s we see it there was no justification for allowing plaintiff's case on that so-called probability hypothesis to go to a jury.”); see also [United States v. Veysey](#), 334 F.3d 600, 604-06 (7th Cir. 2003) (reviewing the academic literature and case law surrounding the use of statistical evidence); [United States v. Hannigan](#), 27 F.3d 890, 896-901 (3d Cir. 1994) (Becker, J., concurring in the judgment) (similar); Laurence H. Tribe, [Trial by Mathematics: Precision and Ritual in the Legal Process](#), 84 Harv. L. Rev. 1329 (1971) (discussing the use of statistical evidence in litigation). Indeed, plaintiffs do not

even grapple with the question of whether federal or state law provides the relevant rule of decision. And without making such showings, plaintiffs cannot meet their burden to “ ‘affirmatively demonstrate ... compliance’ with [Rule 23](#).” [Comcast Corp. v. Behrend](#), 569 U.S. 27, 33, 133 S.Ct. 1426, 185 L.Ed.2d 515 (2013) (quoting [Wal-Mart Stores, Inc.](#), 564 U.S. at 350, 131 S.Ct. 2541).

Plaintiffs argue that we should nevertheless approve of their proposed approach because it protects Warner from any practical harm that might otherwise be caused by removing questions of individual injury-in-fact from the jury. Warner would only be found liable and forced to pay damages if the jury found that Warner's actions unlawfully raised the price paid by consumers by a specified amount, and if the jury also determined the percentage of sales for which that price surcharge would not have been paid but for the illegal conduct. The total aggregate damages award would therefore in theory net out all purchases by brand loyal consumers as a group. The fact that some of that money might then be paid to uninjured people should be of no concern to Warner, say plaintiffs.

This argument confuses different types of aggregate damages scenarios. See 4 [William B. Rubenstein, Newberg on Class Actions § 12:2](#) (5th ed. 2012). In some cases, the total damage caused by the defendant is independent of the number and identity of people harmed. Newberg gives as an example a trustee's theft of money from a pension fund. *Id.* Such a case perhaps might be tried as a class action without causing any harm to the defendant no matter how the recovered funds are allocated among the beneficiaries (although there would still be the question whether Article III nevertheless precludes per se the knowing use of a civil suit to make an award to an uninjured person, see [Tyson Foods](#), 136 S.Ct. at 1053 (Roberts, C.J., concurring)). In many other instances, as here, the aggregate damage amount is the sum of damages suffered by a number of individuals, such that proving that the defendant is not liable to a particular individual because that individual suffered no injury reduces the amount of the possible total damage. Furthermore, here the district court has reasonably presumed that determining whether any given individual was injured (and therefore has a claim) turns on an assessment of the individual facts concerning that person. In such a case, the defendant must be offered the opportunity to challenge each class member's proof that the defendant is liable to that class member. See [Wal-Mart](#)

[Stores, Inc.](#), 564 U.S. at 366-67, 131 S.Ct. 2541. Whether that opportunity precludes class certification turns on whether such challenges are reasonably plausible in a given case and whether the plaintiff cannot demonstrate that allowing for such challenges in a manner that protects the defendant's rights will be manageable and superior to the alternatives. See [Fed. R. Civ. P. 23\(b\)\(3\)](#).

*10 Accepting plaintiffs' proposed procedure for class litigation would also put us on a slippery slope, at risk of an escalating disregard of the difference between representative civil litigation and statistical observations of tendencies and distributions. Once one accepts plaintiffs' “no harm, no foul” position there would be no logical reason to prevent a named plaintiff from bringing suit on behalf of a large class of people, forty-nine percent or even ninety-nine percent of whom were not injured, so long as aggregate damages on behalf of “the class” were reduced proportionately. Such a result would fly in the face of the core principle that class actions are the aggregation of individual claims, and do not create a class entity or re-apportion substantive claims. See 1 [William B. Rubenstein, Newberg on Class Actions § 1:1](#) (5th ed. 2012) (stating that [Rule 23](#) is “fundamentally a procedural device” that allows a representative to “litigate on behalf of many absent class members” but cannot “abridge, modify, or enlarge any substantive right” (emphasis in original)); see also [Tyson Foods](#), 136 S.Ct. at 1048 (noting that a class action cannot enlarge class members' substantive rights and thus basing the availability of evidence in a class action on what would be available “in an individual action”); [In re Deepwater Horizon](#), 739 F.3d 790, 828 (5th Cir. 2014) (Garza, J., dissenting) (“[Rule 23](#)'s aggregation function cannot be used to create new rights and then settle claims brought under them.” (internal quotation marks omitted)).

We recognize that there remains the problem of how to deal with conduct that inflicts small amounts of damage on large numbers of people. Certainly [Rule 23](#) serves as an important tool to address many such situations. See [Mace v. Van Ru Credit Corp.](#), 109 F.3d 338, 344 (7th Cir. 1997) (“The policy at the very core of the class action mechanism is to overcome the problem that small recoveries do not provide the incentive for any individual to bring a solo action.”); [Castano v. Am. Tobacco Co.](#), 84 F.3d 734, 748 (5th Cir. 1996) (noting that “negative value” suits provide the “most compelling rationale for finding superiority in a class action”). But that fact grants us no license to create

a [Rule 23\(b\)\(3\)](#) class in every negative value case by either altering or reallocating substantive claims or departing from the rules of evidence. Moreover, there are other tools available to address the problem of low-value, high-volume claims that pose individual issues of causation. Regulators may sue, *see, e.g.,* [FTC v. Actavis, Inc.](#), 570 U.S. 136, 141, 133 S.Ct. 2223, 186 L.Ed.2d 343 (2013); governments may bring *parens patriae* claims, *see, e.g.,* [New Hampshire v. Purdue Pharma, No. 17-cv-427, 2018 WL 333824, at *1](#) (D.N.H. Jan. 9, 2018); substantive laws may provide presumptions available to all class members, *see, e.g.,* [Halliburton](#), 134 S.Ct. at 2411-12; and private lawyers may marshal the threats of *res judicata* and fee shifting to induce aggregate settlements when liability is clear.

In reaching our conclusion, we acknowledge the divergence evident in the manner in which our sister circuits have addressed the treatment of uninjured putative class members. Framing the issue of uninjured class members through the lens of Article III, the Second Circuit opined that “no class may be certified that contains members lacking Article III standing,” and required that the class “be defined in such a way that anyone within it would have standing.” [Denney v. Deutsche Bank AG](#), 443 F.3d 253, 264 (2d Cir. 2006).⁴

In [Halvorson v. Auto-Owners Insurance Co.](#), 718 F.3d 773 (8th Cir. 2013), the Eighth Circuit announced the same standing requirement articulated by the Second Circuit, but also seemed to ground its analysis in the predominance requirement of [Rule 23\(b\)\(3\)](#). It thus denied class certification because the “individual inquiries” necessary to determine which class members were uninjured would “overwhelm questions common to the class.” *Id.* at 779 (quoting [Comcast Corp.](#), 569 U.S. at 34, 133 S.Ct. 1426); *see* [Neale v. Volvo Cars of N. Am., LLC](#), 794 F.3d 353, 366 (3d Cir. 2015) (“[I]t is ... not clear to us whether the Eighth Circuit’s standing analysis rests on Article III or [Rule 23](#).”).

*11 More clearly viewing the issue of uninjured class members through the prism of [Rule 23\(b\)\(3\)](#) predominance, the D.C. Circuit vacated the certification of a class because the plaintiffs had failed to “show that they can prove, through common evidence, that all class members were in fact injured by the alleged conspiracy.” *See* [In re Rail Freight Fuel Surcharge Antitrust Litig.-MDL No. 1869](#), 725 F.3d 244, 252 (D.C. Cir. 2013)

(emphasis added); *see also* [Nexium](#), 777 F.3d at 24 n.20 (characterizing [Rail Freight](#) as requiring that plaintiffs “‘show that they can prove’—not that they have proved”—that all class members were in fact injured (emphasis in original)).

The Fifth Circuit has similarly held that “where fact of damage cannot be established for every class member through proof common to the class, the need to establish antitrust liability for individual class members defeats [Rule 23\(b\)\(3\)](#) predominance.” [Bell Atl. Corp. v. AT&T Corp.](#), 339 F.3d 294, 302 (5th Cir. 2003). And the Third Circuit, expressly and closely following [New Motor Vehicles](#), has joined this majority view. *See* [In re Hydrogen Peroxide Antitrust Litig.](#), 552 F.3d 305, 311 (3d Cir. 2008).⁵

The Seventh Circuit does appear to have signaled a willingness to allow a district court to certify a damages class containing not “a great many” uninjured members without requiring that there be a mechanism for eventually culling out the uninjured. [Messner v. Northshore Univ. HealthSystem](#), 669 F.3d 802, 825 (7th Cir. 2012); [Kohen v. Pac. Inv. Mgmt. Co. LLC](#), 571 F.3d 672, 677-78 (7th Cir. 2009). The Ninth Circuit recently arguably adopted a similar rule, although to some uncertain extent it seems to rely in great part on a notion that being “exposed to” injurious conduct can serve a proxy for common injury. *See* [Torres v. Mercer Canyons Inc.](#), 835 F.3d 1125, 1137 (9th Cir. 2016). Neither circuit, though, has explained what not “a great many” means. *See, e.g.,* [Messner](#), 669 F.3d at 825 (“There is no precise measure for ‘a great many.’ ”). And if it means only that there can be a few unusual class members who can be picked off by the defendant, then neither case rests too far outside the mainstream. *See* [Halliburton](#), 134 S.Ct. at 2412.

In any event, in no case cited above, nor in any case to which plaintiffs have directed our attention, has a federal court affirmed a damages judgment in a class action against a defendant who was precluded from raising genuine challenges at trial to the assertion of liability by individual members of a class that was known to have members who could not be presumed to be injured. Nor has either party drawn to our attention any federal court allowing, under [Rule 23](#), a trial in which thousands of class members testify. We see no reason to think that this case should be the first such case.

IV.

The rule we reiterate today, consistent with our prior holding in [Nexium](#), strikes a balance that is faithful to the requirements of Article III and [Rule 23](#), while remaining cognizant of the practical realities of class actions. We have not previously required every class member to demonstrate standing when a class is certified, nor do we do so today. See [Nexium](#), 777 F.3d at 32; see also [Neale](#), 794 F.3d at 362; [DG ex rel. Stricklin v. Devaughn](#), 594 F.3d 1188, 1197 (10th Cir. 2010); [Kohen](#), 571 F.3d at 676-77. We also agree that it would “put the cart before the horse,” [Kohen](#), 571 F.3d at 676, to read [Rule 23](#) to require that a plaintiff demonstrate prior to class certification that each class member is injured. But certainly where injury-in-fact is a required element of a claim, as it is in an antitrust action, see [New Motor Vehicles](#), 522 F.3d at 19 n.18, a class cannot be certified based on an expectation that the defendant will have no opportunity to press at trial genuine challenges to allegations of injury-in-fact. Cf. [Wal-Mart Stores, Inc.](#), 564 U.S. at 367, 131 S.Ct. 2541. And to determine whether a class certified for litigation will be manageable, the district court must at the time of certification offer a reasonable and workable plan for how that opportunity will be provided in a manner that is protective of the defendant's constitutional rights and does not cause individual inquiries to overwhelm common issues. These plaintiffs have plainly not enabled the district court to articulate such a plan. See [New Motor Vehicles](#), 522 F.3d at 20 (“Under the predominance inquiry, ‘a district court must formulate some prediction as to how specific issues will play out in order to determine whether common or individual issues predominate in a given case.’” (quoting [Mowbray](#), 208 F.3d at 298)).

*12 For the foregoing reasons, we reverse the decision of the district court granting class certification, and remand for further proceedings in accord with this opinion.

BARRON, Circuit Judge (Concurring).

The issues that courts must address in deciding whether to certify a proposed class action in a case like this are potentially vexing. The class is large. It contains a non-trivial number of uninjured class members. The nature of the injury is not easily proved through common evidence. And the prospect of individualized recovery is unlikely,

even though the aggregate wrong may be great, given the costs of litigation and the relatively minimal amount of loss each plaintiff incurred. Should, then, such a class be certified?

On the one hand, [Rule 23](#) was clearly written to facilitate large consumer class actions. See, e.g., [Amchem Prod., Inc. v. Windsor](#), 521 U.S. 591, 617, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997) (“While the text of [Rule 23\(b\)\(3\)](#) does not exclude from certification cases in which individual damages run high, the Advisory Committee had dominantly in mind vindication of ‘the rights of groups of people who individually would be without effective strength to bring their opponents into court at all.’ ”); [In re New Motor Vehicles Canadian Exp. Antitrust Litig.](#), 522 F.3d 6, 8 (1st Cir. 2008) (“[A]n erroneous failure to certify a class where individual claims are small may deprive plaintiffs of the only realistic mechanism to vindicate meritorious claims.”). On the other hand, [Rule 23](#) sets forth requirements—most particularly, the requirement that common rather than individual issues predominate—that raise serious questions about whether a class of the sort I have just described can be certified. See [Fed. R. Civ. P. 23\(b\)\(3\)](#).

Not surprisingly, appellate courts throughout the country have struggled to develop a uniform mode of analyzing such cases. In fact, our own precedent reflects a similar struggle, given our holding rejecting certification of a consumer antitrust class in [New Motor](#), 522 F.3d at 9, and our holding affirming the certification of one in [In re Nexium Antitrust Litig.](#), 777 F.3d 9, 14 (1st Cir. 2015).

Of course, because [Nexium](#) is our last word on the subject, we are bound, as a panel, to follow it if it controls. But, here, I agree with the majority that it does not, even though, in my view, one could be forgiven for concluding—as the District Court did—that [Nexium](#) does require certification of the class proposed here.

In [Nexium](#), we upheld the certification of a class where, like here, the anticipated means by which plaintiffs would cull uninjured class members would include the use of individual affidavits attesting to the affiant's injury. See [id.](#) at 20-21. Moreover, in [Nexium](#), like here, the affidavits would be used to resolve an inquiry into injury turning on whether the plaintiffs would have hypothetically purchased a cheaper generic had one been available rather than on any representations as to past purchases. See

id. at 20 n.17. And, finally, in [Nexium](#), like here, the overwhelming bulk of the class is purported to be injured, as only a relatively small percentage of the class members in each case are conceded to be uninjured. *See id.* at 27.

*13 Nonetheless, I join our opinion reversing the order certifying this class. As our opinion explains, the culling process on which the plaintiffs rely—and which the District Court found to be sufficient—is not one that [Nexium](#) blessed or that we may bless, at least on this record. I do, however, want to say more about my reasons for reaching that conclusion. In particular, I wish to highlight two grounds for distinguishing this case from [Nexium](#).

First, in [Nexium](#), it was perfectly clear that the defendants would be able to challenge—prior to a liability finding—the sufficiency of testimony to prove injury (whether that testimony was offered at trial or pre-trial by affidavit) by any class member that she would have purchased a generic version of the drug had one been available. For that reason, we were confident that “a mechanism would exist for establishing injury at the liability stage of this case, compliant with the requirements of the Seventh Amendment and due process.” *Id.* at 21.

Here, in contrast, it is hard for me to see how the plaintiffs' proposed claims processing mechanism for culling uninjured class members could be deployed before there were any claims to process. In fact, by the plaintiffs' own account, that culling mechanism will be deployed only “post-judgment.” Thus, the reason that we gave in [Nexium](#) for concluding that there was no Seventh Amendment problem with the culling mechanism that we identified there does not appear to be one that we may rely on here.

Second, insofar as the plaintiffs here, as in [Nexium](#), do propose to submit affidavits concerning class members' hypothetical purchasing preferences prior to completion of the liability phase, there is still another ground for distinguishing this case from that one. In [Nexium](#), unlike here, the defendants presented a categorical challenge. They contended that the presence, at the certification stage, of any uninjured class members itself defeated predominance because the plaintiffs had no possible means to prove injury at all. The defendants based that contention on the hypothetical nature of the inquiry into injury presented in that case, given that the inquiry turned

on what was necessarily speculation about a plaintiff's hypothetical purchasing preference. *See id.* at 20 (noting the defendants' argument that “the [brand-loyalist issue] presents problems that plaintiffs cannot overcome, for plaintiffs have no methodology to identify [at a later stage of litigation] those consumers who would have switched to a generic version” (emphasis added)).

[Nexium](#) rejected that categorical challenge. It did so by explaining that, in an individual action, a plaintiff could prove the injury claimed through “testimony by the consumer that, given the choice, he or she would have purchased the generic.” *Id.* at 20. And [Nexium](#) then went on to explain that because “[t]here cannot be a more stringent burden of proof in class actions than in individual actions,” it followed that “similar testimony in the form of an affidavit or declaration would be sufficient in a class action.” *Id.* For that reason, [Nexium](#) concluded that the defendants had failed to show that the plaintiffs could not meet their burden at the certification stage to demonstrate a viable means of identifying injured class members.

To be sure, [Nexium](#) did not stop there. [Nexium](#) also acknowledged that proof of injury in the form of personal testimony may “require[] determination of the individual circumstances of class members” and thus may cause individual rather than common issues to predominate. *Id.* at 21. But, having identified that additional potential obstacle to establishing predominance, [Nexium](#) dispensed with that concern by explaining that the predominance requirement does not categorically preclude a class from relying on individualized proof of injury, at least where the number of uninjured class members is de minimis. *See id.* (refusing to find that “the need for individual determinations or inquiry for a de minimis number of uninjured members at later stages of the litigation defeats class certification”).

*14 Unfortunately, [Nexium's](#) holding that the predominance requirement does not impose a categorical bar against plaintiffs relying on individualized means of proving injury only gets us so far here. And that is because I do not read [Nexium](#) to have addressed the distinct issue of when, even where the number of uninjured class members is de minimis, plaintiffs' reliance on individualized means of proving injury is so great that it can no longer comport with the predominance requirement. Yet, that is the question that we must

confront here, because the defendants make precisely that contention in this case.

In considering that question, I would not rule out the possibility that plaintiffs who seek to prove injury in such a case by relying on affidavits might be able to satisfy the predominance requirement just as the plaintiffs were found to have satisfied it in [Halliburton Co. v. Erica P. John Fund, Inc.](#), 573 U.S. 258, 134 S.Ct. 2398, 2412, 189 L.Ed.2d 339 (2014) (upholding certification on the basis of a presumption of reliance even where “the defendant might attempt to pick off the occasional class member here or there through individualized rebuttal”). I note, in that regard, that one reason that the [Halliburton](#) Court assumed that the defendants would only be able to engage in “individualized rebuttal” against the “occasional class member” may have been that proof of reliance in that case involved resolution of a “ ‘speculative state of facts, *i.e.*, how [the plaintiff] would have acted ... if the misrepresentation had not been made.’ ” [Id.](#) at 2407 (quoting [Basic Inc. v. Levinson](#), 485 U.S. 224, 245, 108 S.Ct. 978, 99 L.Ed.2d 194 (1988)). I suspect that defendants might have a similarly hard time making more than a speculative case that they would be able effectively to contest an affiant’s representation that, if presented with a cheaper generic alternative, she would have spent less rather than more to get the same drug. [See Nexium](#), 777 F.3d at 31 (“The defendants’ speculation cannot defeat the plaintiffs’ showing.”). Moreover, I could imagine that plaintiffs in a case not unlike this one might be able to establish—perhaps through undisputed evidence from, say, health plan purchasing records—that only a small identifiable subset of the class’s members would actually need to rely on individualized testimony concerning their hypothetical purchasing preferences to show injury.

In the event that plaintiffs made those showings, I could see how, in light of [Nexium](#), a court might be able to conclude that the plaintiffs, at the certification stage, could succeed in showing that resolution of the injury issue would not require an impermissibly large number of

individualized determinations. [See id.](#) at 21 (noting that [Rule 23\(b\)\(3\)](#) “does not require a plaintiff seeking class certification to prove that each element of her claim is susceptible to classwide proof” but only to show that there is no “reason to think that [individualized] questions will overwhelm common ones and render class certification inappropriate”). But, even if that is the case, the plaintiffs before us make no showing that would permit us to so find.

As our opinion explains, the plaintiffs do not argue that the defendants would be incapable of mounting effective challenges to any, let alone to most, of the plaintiffs’ affidavits at summary judgment. Nor may we conclude that the plaintiffs would only need to rely on individualized proof of injury for a small identifiable subset of the class, such that their reliance on individual adjudications could be deemed both efficient and fair.

The plaintiffs have not shown that the number of potentially uninjured class members could be winnowed down through common means of proof, even when that evidence is considered in combination with evidence gleaned from health plan purchasing records. And we may not assume that only the plaintiffs within the small subset of the class conceded to be uninjured will need to offer an affidavit to prove what hypothetical choice they would have made if given the option to purchase a generic. Class members do not come pre-identified as brand loyal or price sensitive, after all, and one does not ordinarily set out to find a needle in a haystack by examining only ten percent of the straw.

***15** I thus see no basis for affirming the certification order on this record, because the plaintiffs have not yet shown that common rather than individual issues would predominate if this class were certified. Accordingly, I join our opinion in full.

All Citations

--- F.3d ----, 2018 WL 4958856

Footnotes

- 1 A number of our recent opinions provide comprehensive overviews of the regulatory framework that governs the introduction of generic drugs. [See In re Nexium \(Esomeprazole\) Antitrust Litig.](#), 842 F.3d 34, 40-42 (1st Cir. 2016); [In re Loestrin 24 Fe Antitrust Litig.](#), 814 F.3d 538, 542-43 (1st Cir. 2016); [In re Nexium Antitrust Litig.](#), 777 F.3d 9, 15-16 (1st Cir. 2015).

- 2 Like the district court and the parties, we will use “states” informally in the remainder of this opinion to refer to both states and the District of Columbia.
- 3 Plaintiffs make no explicit claim that the price of Delzicol and [Asacol](#) HD would have been lower had generic versions of [Asacol](#) been available.
- 4 In [Denney](#), the Second Circuit found that each member of the class had suffered an injury-in-fact, and thus held that the class satisfied Article III standing. [443 F.3d at 265](#).
- 5 Because our circuit precedent clearly requires that there exist “some means of determining that each member of the class was in fact injured,” [New Motor Vehicles](#), [522 F.3d at 28](#), we have been able to finesse the question whether Article III's standing requirement imposes any barrier to the certification of a class that will at judgment have uninjured members. See [Nexium](#), [777 F.3d at 32](#) (“To the extent that it is necessary that each and every member of the class who secures a recovery also has standing, the requirement will be satisfied—only injured class members will recover.”).

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