

No. 18-1065

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**IN THE UNITED STATES COURT OF APPEALS  
FOR THE FIRST CIRCUIT**

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IN RE ASACOL ANTITRUST LITIGATION

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UNITED FOOD & COMMERCIAL WORKERS UNION AND EMPLOYERS  
MIDWEST HEALTH BENEFITS FUND, ET AL., *Plaintiffs*,  
TEAMSTERS UNION 25 HEALTH SERVICES & INSURANCE  
PLAN, ET AL., *Plaintiffs-Appellees*,

v.

WARNER CHILCOTT LIMITED, ET AL., *Defendants-Appellees*,  
ZYDUS PHARMACEUTICALS USA, INC., ET AL., *Defendants*.

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On Appeal from the United States District Court  
for the District of Massachusetts (No. 1:15-cv-12730)

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**BRIEF FOR THE AMERICAN ANTITRUST INSTITUTE  
AS AMICUS CURIAE IN SUPPORT OF  
PANEL REHEARING AND REHEARING EN BANC**

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## **CORPORATE DISCLOSURE STATEMENT**

Pursuant to Fed. R. App. P. 26.1, the American Antitrust Institute states that it is a nonprofit corporation and, as such, no entity has any ownership interest in it.

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## INTEREST OF AMICUS CURIAE<sup>1</sup>

The American Antitrust Institute (“AAI”) is an independent nonprofit organization devoted to promoting competition that protects consumers, businesses, and society. It serves the public through research, education, and advocacy on the benefits of competition and the use of antitrust enforcement as a vital component of national and international competition policy. It submits this brief, under Fed. R. App. P. 29(b)(2), because the panel’s opinion will seriously undermine the enforcement of the antitrust laws.

### ARGUMENT

#### **I. THE PANEL’S OPINION ON CLASS CERTIFICATION IS INCONSISTENT WITH *NEXIUM* AND COMMON SENSE**

The panel’s opinion and *Nexium* are starkly inconsistent. This case and *Nexium* both involve anticompetitive conduct by a pharmaceutical company to hinder generic entry. Both raise the issue that some small percentage of consumer class members do not suffer damages because they are “brand loyalists,” a phenomenon whereby a consumer does not switch to a generic version of a drug even though it is cheaper. *Nexium* held that class certification “is permissible even if the

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<sup>1</sup> No counsel for a party has authored this brief in whole or in part, and no party, party’s counsel, or any other person—other than amici or their counsel—has contributed money that was intended to fund preparing or submitting this brief. Individual views of members of the American Antitrust Institute’s Board of Directors or its 130-member Advisory Board may differ from its positions. One member of the Advisory Board and the law firm of one of the directors represent plaintiffs, but they played no role in the preparation or submission of this brief.

class includes a de minimis number of uninjured parties,” and that consumer affidavits are an acceptable mechanism to ensure that only injured class members recover. *In re Nexium Antitrust Litig.*, 777 F.3d 9, 14, 20, 30-31 (1st Cir. 2015).

Here, the panel denied certification without regard to whether the percentage of uninjured class members was *de minimis* because “any class member may be uninjured” and “thousands . . . in fact suffered no injury.” Op. 25 (emphasis added). And the panel held that affidavits are not a permissible culling mechanism because affidavits would be inadmissible hearsay at trial and defendants stated their intention to challenge them. *Id.* at 23-24 (emphasis added).

The panel adopted the reasoning of the dissent in *Nexium*, which had criticized the majority on the grounds that the “percentage [of brand loyalists] tells one almost nothing,” the absolute number of uninjured class members was likely to be high,<sup>2</sup> and since “nobody knows who [they] are,” “the culling process may need to review individually *all* the affidavits.” *Nexium*, 777 F.3d at 35 (Kayatta, J., dissenting) (emphasis added). Most significantly, the dissent in *Nexium* criticized the majority for unreasonably assuming “that the affidavits will be ‘unrefuted’” and for “affirm[ing] a certification order based entirely on a fiction” because the district court did not in fact consider affidavits at the liability trial. *Id.* at 35-36.

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<sup>2</sup> The number of uninjured class members was likely to be at least 24,000 in *Nexium*, whereas the number is no more than 5,000 here. See *In re Asacol Antitrust Litig.*, 323 F.R.D. 451, 469 (D. Mass. 2017).

If ever there were a fiction, however, it is the panel’s supposition here that defendants would in fact challenge the individual injury of absent class members if given the opportunity to do so at trial. They would not.<sup>3</sup> In antitrust trials, defendants essentially never do. See Joshua P. Davis & Eric L. Cramer, *Antitrust, Class Certification, and the Politics of Procedure*, 17 Geo. Mason L. Rev. 969, 989-92 (2010). The panel identified but failed to heed the rule that “[u]nder 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.” Op. 36-37 (quoting *In re New Motor Vehicles Canadian Export Antitrust Litig.*, 522 F.3d 6, 20 (1st Cir. 2008)). Because individual injury would not be contested at trial, the predominance requirement is easily satisfied.

Defendants would not challenge individual injury at trial because it would not make economic sense for them to do so. If damages are established on a class-wide basis, as plaintiffs proposed to do here, then excluding any particular class member will not affect the amount of defendants’ damages. As the panel recognized, “In some cases, the total damage caused by the defendant is independent of the number and identity of the people harmed,” and such a case “might be tried as

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<sup>3</sup> Indeed *Nexium* confirms this, as the district court “expressly preserve[d] the Defendants’ rights to challenge individual damage claims at trial,” *Nexium*, 777 F.3d at 31 (internal quotation marks omitted), but no such challenges were made when the case was actually tried.



a class action without causing any harm to the defendant no matter how the recovered funds are allocated among the beneficiaries.” Op. 29. However, the panel believed that this was not such a case because “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 total possible damage.” *Id.* at 30.

Respectfully, the panel erred. Plaintiffs’ damages model would have to account for uninjured class members—in the aggregate—to be reliable, and the district court found that it did so. *Asacol*, 323 F.R.D. at 468-69. At trial the experts would contest the percentage of “brand loyalists,” which would directly affect the amount of damages, *see id.*, but that *aggregate* number would be determinative; removing any particular absent class member would make no difference. *Cf.* 4 William B. Rubenstein, *Newberg on Class Actions* § 12:2 & n.4 (5th ed. 2012) (citing *Nexium* direct-purchaser case as example where aggregate damages are “sufficient to prove liability”).

Another reason that defendants would not likely challenge whether any individual absent class member was injured is that, because of the operation of generic substitution laws, *see New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 644-45 (2d Cir. 2015), there is an overwhelming (at least 90%) likelihood that any individual class member would have purchased the cheaper generic. The panel

did not think that this high probability was sufficient to prove that any particular class member was injured, although there are good reasons to think it should be.<sup>4</sup> In any event, the high probability should be sufficient to *presume* injury and makes it unlikely that defendants would genuinely challenge individual affidavits, even if a successful challenge would reduce their damages exposure (which it would not).

Judge Barron seemed to recognize the challenge posed by the probability issue, Op. 44 (“I suspect that defendants might have a . . . 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.”), but not its implications for “how specific issues will play out” during the litigation. One does not bother looking through haystacks for needles when one’s liability exposure is measured by the straw.

The panel thought that a “no harm, no foul” approach would “put us on a slippery slope” because “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.” Op. 30-31. However, this

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<sup>4</sup> See Appellees’ Pet. at 14 n.2; Joshua P. Davis, *Classwide Recoveries*, 82 Geo. Wash. L. Rev. 890 (2014). The panel rejected the probability point as akin to proving that “a given person wore certain clothes merely because most but not all others did so.” Op. 27. The analogy is inapt because of the hypothetical nature of the issue here. A more realistic analogy would be proving that a given person likely would have worn a coat outdoors if the temperature dropped below freezing.

ignores that a small percentage of injured class members begets a small likelihood that any particular class member is injured, which would render aggregate damages inappropriate. *See Davis, Classwide Recoveries*, at 925-27. Moreover, the predominance inquiry already entails practical judgment. *See Gintis v. Bouchard Trans. Co.*, 596 F.3d 64, 67 (1st Cir. 2010) (Souter, J.) (discussing “trial court’s judgment call about how clearly predominant the common issues must be”). Even those courts that require injury to “all or virtually all” class members must decide what “virtually all” means.

The panel also ignores the other side of the slippery slope. In a class of a million consumers, where 1% of the class is uninjured, the panel’s rule would deny certification (because 10,000 is a large number) and leave the 99% with nothing—all in the name of protecting a “right” of the defendants that has no economic significance to them and which, accordingly, they would not pursue at trial. *Cf. Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009) (“[D]eprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing”).

The panel gave short shrift to the “core purpose of Rule 23(b)(3) [which] is to vindicate the claims of consumers and other groups of people whose individual claims would be too small to warrant litigation.” *Smilow v. Sw. Bell Mobile Systems, Inc.*, 323 F.3d 32, 41 (1st Cir. 2003). The panel opined that this purpose

“grants us no license to create a Rule 23(b)(3) class in every negative value case,” Op. 32, which of course is true, as superiority alone is insufficient for certification. But this court’s precedents consistently counsel that the “class certification prerequisites should be construed in light of the underlying objectives of class actions.” *Smilow*, 323 F.3d at 41; *see Gintis*, 596 F.3d at 67.

## **II. THE PANEL’S OPINION SERIOUSLY IMPAIRS ANTITRUST ENFORCEMENT**

The panel’s opinion calls into question the viability of both direct- and indirect-purchaser antitrust class actions in this Circuit when a class likely includes uninjured members, even though this is typical and “almost inevitable because at the outset of the case many of the members of the class may be unknown, or if they are known still the facts bearing on their claims may be unknown.” *Kohen v. PIMCO*, 571 F.3d 672, 677 (7th Cir. 2009) (Posner, J.).

In particular, the opinion threatens to create a liability shield in the pharmaceutical industry, not just for product-hopping actions but for a large swath of critically important generic-drug exclusion cases, where the “brand loyalist” phenomenon is common. The difficulty of identifying uninjured “brand-loyal” class members is especially acute (and perverse) when, as here, defendants’ alleged wrongdoing has prevented generics from coming to market and thereby revealing customer purchasing preferences. But lawsuits involving delayed generic entry

(like *Nexium*) raise the same issue because they are often brought absent actual generic entry.

Accordingly, one of the most troubling effects of the majority's rule may be to destroy class actions targeting pay-for-delay settlements, which are estimated to "cost American consumers \$3.5 billion per year." FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions 2* (Jan. 2010), <https://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff>. The panel's opinion may also enable drug manufacturers to preempt private liability for the next wave of devious, exclusionary gambits that suppress generic entry, which will only induce more (and more egregious forms) of such conduct. See FTC Statement on Antitrust Concerns and the FDA Approval Process 6-12 (July 27, 2017), <https://www.ftc.gov/public-statements/2017/07/prepared-statement-federal-trade-commission-antitrust-concerns-fda> (exclusionary abuse of "REMS" programs estimated to cost Americans \$5.4 billion); see also FTC, *Overview of FTC Actions in Pharmaceutical Products and Distribution 3-73* (Aug. 2018), [https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview\\_pharma\\_august\\_2018.pdf](https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_august_2018.pdf) (cataloging other cases).

The panel acknowledged the "problem of low-value, high-volume claims that pose individual issues of causation," which would be precluded by its opinion,

but suggested that “other tools”—primarily government enforcement<sup>5</sup>—could address the problem. Op. 32. The panel misapprehends the design of the antitrust laws and modern enforcement realities. Public and private antitrust enforcement are complements, not substitutes.

The Supreme Court has consistently emphasized the importance of private actions in enforcing the U.S. antitrust laws. *See, e.g., California v. American Stores Co.*, 495 U.S. 271, 284 (1990) (describing private enforcement as “an integral part of the congressional plan for protecting competition”); *Oneok, Inc. v. Learjet, Inc.*, 135 S. Ct. 1591, 1601 (2015) (noting States’ “long history of providing ‘common-law and statutory remedies against monopolies and unfair business practices’” (quoting *California v. ARC America Corp.*, 490 U.S. 93, 101 (1989))). And class actions are central to this enforcement regime. *See Hawaii v. Standard Oil*, 405 U.S. 251, 266 (1972) (class actions “may enhance the efficacy of private [antitrust] actions by permitting citizens to combine their limited resources to achieve a more powerful litigation posture”).

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<sup>5</sup> The panel also opined that “private lawyers may marshal the threats of res judicata and fee shifting to induce aggregate settlements when liability is clear.” Op. 32. However, most antitrust claims, including pharmaceutical-exclusion claims, are brought under the “rule of reason,” rather than the “per se rule,” which by definition means liability is unclear. *See Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018). Moreover, a private lawyer’s threat to pursue to judgment an antitrust claim for, say, \$10, at an upfront cost of millions of dollars in expert and other fees, would not be credible.

The government “cannot be expected to do all of the necessary enforcement for a number of reasons, including budgetary constraints.” Robert H. Lande, *Class Warfare: Why Antitrust Class Actions Are Essential for Compensation and Deterrence*, *Antitrust*, Spring 2016, at 81, 83. Moreover, public enforcement institutions do not have the tools to play “the crucial role that antitrust class action recoveries play in compensating victims of illegal activity and deterring anticompetitive behavior.” *Id.* at 84. The FTC, which is the primary antitrust enforcement agency in the pharmaceutical industry, normally seeks only injunctive relief. While it has the authority to pursue monetary equitable remedies such as disgorgement or restitution, historically it has used this authority sparingly. See Maureen K. Ohlhausen, *Dollars, Doctrine and Damage Control: How Disgorgement Affects the FTC’s Antitrust Mission* 3-5 (Apr. 20, 2016), <https://www.ftc.gov/public-statements/2016/04/dollars-doctrine-damage-control-how-disgorgement-affects-ftcs-antitrust> (remarks of former commissioner and acting chair of the FTC).<sup>6</sup> The Department of Justice almost never pursues civil monetary relief.

State *parens patriae* actions, which must be brought by notoriously under-resourced State attorneys’ general offices, also cannot be expected to take up the

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<sup>6</sup> In recent years, the Commission has more actively pursued disgorgement in pharmaceutical cases. However, its authority to do so has been challenged. See, e.g., M. Sean Royall et al., *Are Disgorgement’s Days Numbered?* *Kokesh v. SEC May Foreshadow Curtailment of the FTC’s Authority to Obtain Monetary Relief*, *Antitrust*, Spring 2018, at 94. Moreover, intra-agency support for the remedy has been mixed. See Ohlhausen, *supra*.

slack. *Parens* actions are typically brought in conjunction with private class actions. See Kevin J.L. O’Connor et al., *Interaction of Public and Private Enforcement* § 4.02.3, at 293-94, in *Private Enforcement of Antitrust Law in the United States: A Handbook* (Albert A. Foer & Randy M. Stutz eds., 2012). Moreover, *parens* actions have little utility under federal law because they are simultaneously limited to claims on behalf of “natural persons” yet subject to *Illinois Brick*’s ban on indirect-purchaser suits under the Sherman Act. See *id.* at 293.

In short, government agencies cannot fill the needless gap in antitrust enforcement that the panel’s opinion creates.

## CONCLUSION

For the foregoing reasons, appellees’ petition for panel rehearing and rehearing en banc should be granted.

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g), I certify:

1 This brief complies with the type-volume limitation of Fed. R. App. 29(b)(4) because the brief contains 2600 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

2. This brief complies with the typeface and type style requirements of Fed. R. App. P. 32(a)(5) because it has been prepared in a proportionally spaced typeface using Microsoft Word, in 14 point Times New Roman font.

*s/ Richard M. Brunell*  
Richard M. Brunell

Dated: Nov. 20, 2018

## **CERTIFICATE OF SERVICE**

I hereby certify that I served a copy of the foregoing document on all registered counsel on Nov. 20, 2018 by electronic means through the Court's CM/ECF system.

*s/ Richard M. Brunell*  
Richard M. Brunell

Dated: Nov. 20, 2018