United States Court of Appeals
For the First Circuit

Nos. 14-1521, 14-1522

IN RE NEXIUM ANTITRUST LITIGATION

ASTRAZENECA AB, et al.,

Defendants-Appellants,

v.

UNITED FOOD AND COMMERCIAL WORKERS UNIONS AND EMPLOYERS MIDWEST HEALTH BENEFITS FUND, et al.,

Plaintiffs-Appellees.

APPEALS FROM THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

[Hon. William G. Young, U.S. District Judge]

Before

Torruella, Dyk,[*] and Kayatta,
Circuit Judges.

Kannon K. Shanmugam, with whom Dane H. Butswinkas, Paul B. Gaffney, John E. Schmidtlein, Williams & Connolly LLP, Laurence A. Schoen, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., Jay P. Lefkowitz, Karen N. Walker, Kirkland & Ellis LLP, Kevin D. McDonald, Jonathan Berman, Jones Day, Timothy C. Hester, Covington & Burling LLP, Michael P. Kelly, William A. Zucker, McCarter & English, LLP, Leslie F. Su, Minerva Law, P.C., J. Douglas Baldridge, Lisa Jose Fales, Danielle R. Foley, Sarah Choi, and Venable LLP were on brief, for defendants-appellants.

Kenneth A. Wexler, with whom Wexler Wallace LLP, Steve D.

[*]Of the Federal Circuit, sitting by designation.

Shadowen, Hillard & Shadowen LLC, J. Douglas Richards, Cohen Milstein Sellers & Toll, PLLC, Jayne A. Goldstein, Pomerantz Grossman Hufford, Dahlstrom & Gross LLP, Glen DeValerio, and Berman DeValerio were on brief, for plaintiffs-appellees.

Kathryn Comerfold Todd, Tyler R. Green, National Chamber Litigation Center, Inc., Jeffrey S. Bucholtz, Ashley C. Parrish, Karen F. Grohman, and King & Spaulding LLP, on brief for Chamber of Commerce of the United States of America, as amicus curiae in support of defendants-appellants.

Daniel E. Gustafson, Gustafson Gluek PLLC, Prof. Joshua P. Davis, Albert A. Foer, Richard Brunell, and Randy M. Stutz, on brief for American Antitrust Institute, as amicus curiae in support of plaintiffs-appellees.

Ellen Meriwether, Cafferty Clobes Meriwether & Sprengel, LLP, and David A. Balto, on brief for Community Catalyst, Inc., National Legislative Association for Prescription Drug Prices, United States Public Interest Research Group, and American Independent Business Alliance, as amici curiae in support of plaintiffs-appellees.

Scott L. Nelson and Julie A. Murray, on brief for Public Citizen Litigation Group, as amicus curiae in support of plaintiffs-appellees.

January 21, 2015

DYK, Circuit Judge.

AstraZeneca[1] sells a heartburn drug called Nexium and owns several patents related to the Nexium compound, a method of using Nexium, and the process for manufacturing Nexium ("the Nexium patents"). Nexium is a proton-pump inhibitor, a type of drug that decreases the symptoms of heartburn by reducing gastric acid production.

Three generic drug companies, Ranbaxy,[2] Teva,[3] and DRL[4] (collectively, the "generic defendants"), sought to market generic forms of Nexium. AstraZeneca sued these generic companies for infringement of some of the Nexium patents. AstraZeneca eventually settled with each generic manufacturer. Under the settlement agreements, AstraZeneca paid the generic defendants significant sums in the form of cash or debt forgiveness (so-called "reverse payments") in exchange for not challenging the validity of the Nexium patents and for delaying the launch of their respective generic products until the two main patents covering the drug

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[1] AstraZeneca AB, Aktiebolaget Hassle, and AstraZeneca LP.

[2] Ranbaxy Pharmaceuticals, Inc., Ranbaxy Inc., and Ranbaxy Laboratories Ltd.

[3] Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA Inc.

[4] Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.

product itself expired on May 27, 2014.[5] As of the date of this opinion, no generic substitute has been launched.

The named plaintiffs are union health and welfare funds that reimburse plan members for prescription drugs including Nexium. Plaintiffs alleged that the Nexium patents are invalid because they would have been obvious in light of earlier AstraZeneca patents and other references. The European Patent Office and the Canadian courts have held that the European and Canadian Nexium patents are invalid.

Plaintiffs alleged that the settlement agreements between AstraZeneca and the generic defendants (collectively, the "defendants") constituted unlawful agreements not to compete because of the likely invalidity of the Nexium patents, the size of AstraZeneca's payments to the generic defendants, and the fact that generic defendants provided nothing to AstraZeneca other than an agreement not to compete. Plaintiffs contend that but for defendants' anti-competitive conduct, a generic version of Nexium would have been available as early as April 2008, thereby lowering the price through competition. They asserted that AstraZeneca overcharged for Nexium from April 14, 2008, to at least May 27, 2014 ("the class period"). They claim damages under the antitrust and consumer protection laws of 24 states and the District of

[5] Five of the Nexium patents expired on or before this date.

Columbia.[6] The plaintiffs sought class certification for a class of third-party payors ("TPPs") (i.e., insurance plans), such as the named plaintiffs, and individual consumers.[7]

On November 14, 2013, the district court certified a class consisting of:

> All persons or entities in the United States and its territories who purchased or paid for some or all of the purchase price for Nexium or its AB-rated generic equivalents . . . in capsule form, for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries, during the period April 14, 2008[,] through and until the anticompetitive effects of Defendants' unlawful conduct cease.

Add. 40a. The certified class also included certain exceptions discussed below. The defendants sought to appeal the class certification. We granted this interlocutory appeal under Federal Rule of Civil Procedure 23(f) to review the class certification.[8]

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[6] The plaintiffs did not assert federal antitrust claims. In Illinois Brick Co. v. Illinois, 431 U.S. 720, 746–48 (1977), the Supreme Court held that indirect purchasers of goods produced by firms engaged in anti-competitive conduct were too remote from that conduct to have suffered an injury under the Clayton Act. As a result, plaintiffs bring their suits under state law in states with "Illinois Brick" repealer laws which have granted indirect purchasers the right to sue for antitrust violations.

[7] Plaintiffs filed this suit on August 24, 2012, in the Eastern District of Pennsylvania. The United States Judicial Panel on Multidistrict Litigation transferred the case to the District of Massachusetts in December 2012.

[8] The district court has since granted various summary judgment motions that narrow the claims against certain generic defendants. In particular, the district court granted summary judgment to Teva and DRL finding that plaintiffs have not shown the existence of a "large, unjustified reverse payment" to these

We conclude that class certification is permissible even if the class includes a de minimis number of uninjured parties. We hold that the district court did not abuse its discretion by certifying the class here and determining that at the certification stage, it had not been shown that future proceedings would not be manageable consistent with defendants' Seventh Amendment and due process rights.

I.

A.

Both the Supreme Court in FTC v. Actavis, 133 S.Ct. 2223, 2227–29 (2013), and the district court below, In re Nexium (Esomeprazole) Antitrust Litigation, 968 F. Supp. 2d 367 (D. Mass. 2013), have discussed extensively the regulatory and patent framework of this suit. We discuss it briefly here.

The Food, Drug, and Cosmetic Act ("FDCA") requires drug manufacturers to secure approval from the Food and Drug Administration ("FDA") to market a new drug. 21 U.S.C. § 355(b)(1), (d). To obtain approval, a new drug application

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defendants. However, the district court found that there was "sufficient circumstantial evidence" to "infer a conspiracy among the Defendants." J.A. 636 ¶ 3. The district court also concluded that Ranbaxy was not likely to launch "at-risk." However, the defendants make no contention that these various rulings affect the proper composition of the class. In the interim after trial, the jury returned a verdict in favor of defendants. See In re Nexium Antitrust Litig., No. 12-md-02409 (D. Mass. Dec. 8, 2014), ECF No. 1374. This, of course, does not moot the case here given the possibility of further proceedings.

("NDA") must include scientific data showing that the drug is safe and effective for its proposed purpose, requiring that the manufacturer conduct long and costly clinical trials. Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S.Ct. 1670, 1676 (2012).

The Hatch-Waxman Amendments[9] introduced two mechanisms to the FDCA to enable early marketing of generic substitutes. First, to market a generic drug, the manufacturer need only file an abbreviated new drug application ("ANDA") showing that the generic product has the same active ingredients as, and is biologically equivalent to, the brand name drug. Id. Second, Hatch-Waxman protects the original NDA-filer by barring FDA approval of an ANDA that is alleged to infringe a patent until the patent cases have been resolved (or 30 months have elapsed) and provides a means for early resolution of patent disputes. Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676–78 (1990).

To this end, the NDA-filer must list the number and expiration date of any patent which claims the drug that is the subject of the NDA or a method of manufacture or use of that drug in the FDA's so-called "Orange Book." 21 C.F.R. § 314.53. Upon filing, the ANDA applicant must notify the NDA-filer if it is asserting that some or all of these listed (and unexpired) patents

[9] Also known as the Drug Price Competition and Patent Term Restoration Act of 1984. 98 Stat. 1585.

are “invalid or will not be infringed by the manufacture, use or sale of the [generic] drug" (known as a paragraph IV certification). 21 U.S.C. § 355(j)(2)(A)(vii)(IV). A paragraph IV certification is treated as an act of infringement, and the branded drug manufacturer may immediately sue the generic manufacturer for infringement based on this certification. 35 U.S.C. § 271(e)(2)(A). If the branded drug manufacturer sues, the FDA may not approve the ANDA until 30 months pass or an appellate court finds the patent invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iii).

On December 3, 1999, AstraZeneca filed an NDA to market Nexium. The FDA approved AstraZeneca’s NDA in 2001, and AstraZeneca listed fourteen patents in the Orange Book. Four years later, generic manufacturer Ranbaxy filed an ANDA and filed a paragraph IV certification with its ANDA that the listed AstraZeneca patents were not infringed or were invalid. AstraZeneca sued Ranbaxy, alleging that Ranbaxy’s product would infringe six of its patents, including the patents covering the drug product itself. In the next few years, Teva and DRL also filed ANDAs and paragraph IV certifications, and were sued in separate actions by AstraZeneca for infringement of many of the same Nexium patents, including the drug product patents.

For first-filer Ranbaxy, the 30 month period triggered by AstraZeneca’s suit expired on April 14, 2008. As a result, Ranbaxy

could have begun marketing its product on April 14, 2008, if it launched "at-risk" — i.e., before the court ruled on patent invalidity or infringement. However, on the date that Ranbaxy could have launched a Nexium substitute, Ranbaxy and AstraZeneca settled their patent litigation, and the district court entered a consent judgment. Ranbaxy admitted the validity of AstraZeneca's asserted patents, admitted that its generic product infringed those patents, and agreed to delay the launch of its generic product until May 27, 2014, the date that the main drug product patents expired. In exchange, AstraZeneca agreed to pay Ranbaxy over a billion dollars. Subsequently, AstraZeneca entered into separate settlement agreements with Teva and DRL. The provisions of these agreements were similar to AstraZeneca's agreement with Ranbaxy, and both Teva and DRL also agreed to delay their respective generic product launches until May 27, 2014, in exchange for substantial monetary consideration.[10] These agreements raised antitrust concerns because they were agreements between competitors not to compete.

The agreements between AstraZeneca and the generic defendants are known as reverse payment settlements. Unlike traditional settlements, where "a party with a claim . . . for

[10] Both Teva and DRL owed AstraZeneca substantial damages from other patent infringement suits. In exchange for Teva and DRL's concessions, AstraZeneca agreed not to collect these payments.

damages receives a sum equal to or less than the value of its claim[,] [i]n reverse payment settlements . . . a party with no claim for damages . . . walks away with money simply so it will stay away from the patentee's market." Actavis, 133 S.Ct. at 2233. The Supreme Court in Actavis concluded that reverse payment settlements are properly evaluated under the antitrust laws using a rule of reason analysis. Id. at 2237. Actavis specified particular factors indicating that an agreement was an unreasonable restraint of trade, including whether the reverse payment was "large and unjustified," measured by "its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." Id. at 2237.

Plaintiffs here alleged that the Nexium patents were likely invalid or not infringed by the generic defendants' products, and the payments were not made in exchange for any services performed by the generic defendants. As a result, defendants' agreements constituted an unlawful horizontal conspiracy to foreclose generic competition. Plaintiffs claimed that because drug prices fall significantly with generic entry, the prices of generic Nexium in the "but-for" market[11] would have been

[11] "[B]ut for [defendants'] [a]greements, generic versions of Nexium would have been available to [p]laintiffs and members of the Class in the United States as early as April 14, 2008." J.A.

lower than the branded Nexium prices during the class period absent generic entry. In addition, in the early period, purchasers of branded Nexium would have paid supracompetitive prices as well. As a result, the class members were injured by defendants' overcharges.

The merits of plaintiffs' antitrust challenge are not before us.[12] The issue is whether the district court properly certified plaintiffs' Rule 23(b)(3) damages class.

B.

The district court below concluded that plaintiffs "ha[d] sufficiently demonstrated a showing of adequacy of representation and predominance of common questions to the class to meet the requirements of class certification under Rules 23(a) and 23(b)(3)." Add. 2a.[13] Specifically, the district court decided that plaintiffs had adequately shown that (1) "prices for esomeprazole [during the class period] continued [to be] artificially high as a result of the Defendants' reverse payment agreements," and (2) "that all class members have been exposed to

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127 ¶ 2.

[12] In September 2013, the district court concluded that the plaintiffs had plausibly alleged antitrust injury to survive defendants' 12(b)(6) motion, i.e., that defendants' exercise of market power generated anti-competitive consequences. In re Nexium, 968 F. Supp. 2d at 393. See also n.8, supra.

[13] Plaintiffs here initially included Pharmacy Benefit Managers ("PBMs") in the class definition. PBMs bought Nexium directly from AstraZeneca and sold it to TPPs and consumers.

purchasing or paying for esomeprazole magnesium at a supracompetitive price." Add. 19a–20a. The district court determined that some members of the class did not suffer injury, perhaps "including more than a de minimis number of TPPs and consumers." Add. 20a. But despite the presence of uninjured class members, the court determined that "[defendants' expert] failed reliably to quantify the prevalence of his alleged problematic subgroups and thus fail[ed] to establish that they are sufficiently extensive to undermine [plaintiffs' expert's] conclusion[]" that the vast majority of class members were injured. Add. 22a. Finally, in keeping with the Supreme Court's admonition that "class certification ought not . . . turn into a 'free-ranging merits inquir[y]' through unnecessary demands for exact calculations of damages," the district court concluded that "[a]t this stage in class certification . . . the incidence of uninjured consumers and TPPs are insufficient to overcome a showing of common antitrust impact to the putative class, but the Court preserves the Defendants' right to challenge individual damage claims at trial." Add. 12a (citing Amgen, Inc. v. Connecticut Ret. Plans & Trust Funds, 133 S.Ct. 1184, 1194–95 (2013)); Add. 24a.

We review class certification orders for abuse of discretion. Smilow v. Sw. Bell Mobile Sys., Inc., 323 F.3d 32, 37 (1st Cir. 2003) (citing Califano v. Yamasaki, 442 U.S. 682, 703 (1979)). "An abuse of discretion also occurs if the court adopts

an incorrect legal rule." Waste Mgmt. Holdings, Inc. v. Mowbray, 208 F.3d 288, 295 (1st Cir. 2000). A "class certification appeal 'can pose pure issues of law reviewed de novo.'" In re New Motor Vehicles Canadian Export Antitrust Litig., 522 F.3d 6, 17 (citing Tardiff v. Knox County, 365 F.3d 1, 4 (1st Cir. 2004)). Factual determinations are reviewed for clear error. Id. (citing In re PolyMedica Corp. Sec. Litig., 432 F.3d 1, 4 (1st Cir. 2005)).

II.

Defendants contend that the class certification is improper because the class includes members who were not injured by generic foreclosure – for example, individual consumers who would have continued to purchase branded Nexium for the same price after generic entry. Understanding the defendants' challenge requires description of the standards for class certification, only one of which is at issue on appeal.

To certify a 23(b)(3) class, the district court must undertake a "rigorous analysis" to determine whether plaintiffs met the four threshold requirements of Rule 23(a) (numerosity, commonality, typicality, and adequacy of representation) and Rule 23(b)(3)'s two additional prerequisites. Comcast Corp. v. Behrend, 133 S.Ct. 1426, 1432 (2013); Wal-Mart Stores, Inc. v. Dukes, 131 S.Ct. 2541, 2551 (2011); see also Gen. Tel. Co. of Sw. v. Falcon, 457 U.S. 147, 161 (1982). Defendants do not dispute that the four

Rule 23(a) requirements were met here. In addition, Rule 23(b)(3) permits certification only if

> the court finds that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.[14]

Fed. R. Civ. P. 23(b)(3).

To meet the predominance requirement, the party seeking certification must show that "the fact of antitrust impact can[] be established through common proof" and that "any resulting damages would likewise be established by sufficiently common proof." New Motor Vehicles, 522 F.3d at 20 (emphasis added). The party also bears the burden of "affirmatively demonstrat[ing] his compliance" with the Rule 23 requirements. Comcast, 133 S.Ct. at 1432. The district court concluded that plaintiffs had done so here, despite finding that the certified class included some number of uninjured class members.

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[14] The matters pertinent to these findings include:

(A) the class members' interests in individually controlling the prosecution or defense of separate actions;

(B) the extent and nature of any litigation concerning the controversy already begun by or against class members;

(C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and

(D) the likely difficulties in managing a class action.

On appeal, defendants ask us to reverse the class-certification decision, relying on two related arguments. First, defendants contend that the presence of any uninjured class members (even a de minimis number) defeats the 23(b)(3) predominance requirement because the existence of uninjured class members precludes the use of common proof at trial. Second, defendants contend that even if a de minimis number of potentially uninjured class members would not defeat class certification, more than a de minimis number of class members were uninjured here.

III.

A.

Relevant to the question of whether a class can include uninjured members, three principles are established. First, a class action is improper unless the theory of liability is limited to the injury caused by the defendants. In other words, the defendants cannot be held liable for damages beyond the injury they caused. The Supreme Court emphasized this principle in Comcast. The plaintiffs in that case had initially relied on four theories of liability and had calculated aggregate damages based on all four theories. 133 S.Ct. at 1434. But the district court certified the class based on only one theory, and plaintiffs did not provide a damages calculation for that one theory standing alone. Id. Because the plaintiffs relied on "a methodology that identifies damages that are not the result of the wrong[,]" they did not

establish that "damages are capable of measurement on a classwide basis," failing to meet the Rule 23(b)(3) requirement. Id. at 1434, 1433.[15] Here, in contrast, the plaintiffs' theory of liability is appropriately limited. As defendants concede, the plaintiffs' theory and model for damages would only require that the defendants pay aggregate damages equivalent to the injury that they caused.

Second, the definition of the class must be "definite," that is, the standards must allow the class members to be ascertainable. See William B. Rubenstein, Newberg on Class Actions §§ 3:1, 3:3 (5th ed. 2013) (explaining that an "implied" requirement for certification is that "a putative class [is] ascertainable with reference to objective criteria"); Matamoros v. Starbucks Corp., 699 F.3d 129, 139 (1st Cir. 2012) (holding that a class was not "unascertainable and overbroad" where it was defined

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[15] Other circuits have also adopted this understanding of Comcast. See In re Urethane Antitrust Litig., 768 F.3d 1245, 1258–59 (10th Cir. 2014) (explaining the expert's benchmarks in Comcast became "useless" upon a ruling that three of the liability theories could not be used); In re Deepwater Horizon, 739 F.3d 790, 815 (5th Cir. 2014) (explaining that Comcast stands for the proposition that formulas for classwide measurement of damages should not be "incompatible" with liability theories); Butler v. Sears, 727 F.3d 796, 799 (7th Cir. 2013) (A damages model must "measure only those damages attributable to [the liability] theory. If the model does not even attempt to do that, it cannot" meet the requirements of Rule 23(b)(3). (citing Comcast, 133 S.Ct. at 1433)), cert. denied, 134 S. Ct. 1277 (2014); Leyva v. Medline Indus. Inc., 716 F.3d 510, 514 (9th Cir. 2013) ("[P]laintiffs must be able to show that their damages stemmed from the defendant's actions that created the legal liability." (citing Comcast, 133 S.Ct. at 1435)).

in terms of an "objective criterion"); Carrera v. Bayer Corp., 727 F.3d 300, 306 (3d Cir. 2013) (As an "essential prerequisite of a class action," plaintiffs "must show, by a preponderance of the evidence, that the class is currently and readily ascertainable based on objective criteria." (citing Marcus v. BMW of North America, LLC, 687 F.3d 583, 592–93 (3d Cir. 2012) (internal quotation marks omitted)). The class definition here satisfies these standards by being defined in terms of purchasers of Nexium during the class period (with some exceptions that also satisfy objective standards).

Third, where an individual claims process is conducted at the liability and damages stage of the litigation, the payout of the amount for which the defendants were held liable must be limited to injured parties.[16] At the class certification stage, the

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[16] We do not address here problems that arise where the distribution of the recovery is not based on an individual claims process: for example, where the amount of recovery for each individual class member is so small that it is not practical to engage in an individual claims process. In such circumstances some courts have resorted to awarding the recovery from the defendants to charities whose missions are consistent with the litigation, under the "cy pres" doctrine, or to a group of individuals that closely approximates the class, under the "fluid recovery" process. See, e.g., Comment: Manageability of Notice and Damage Calculation in Consumer Class Actions, 70 Mich. L. Rev. 338, 366 n.185 (1971) (describing the settlement of the case Daar v. Yellow Cab, 67 Cal. 2d 695 (1967), in which a taxi company reduced fares to offset gains it had made with higher rates). There is no suggestion here that an individual claims process is not feasible.

Nor do we deal here with the problem that arises where the amounts awarded to individual claimants are less than the aggregate award. See Newberg, supra, § 12:28 (outlining common ways of distributing "unclaimed" funds).

court must be satisfied that, prior to judgment, it will be possible to establish a mechanism for distinguishing the injured from the uninjured class members. The court may proceed with certification so long as this mechanism will be "administratively feasible," see Carrera, 727 F.3d at 307, and protective of defendants' Seventh Amendment and due process rights, see American Law Institute, Principles of the Law: Aggregate Litigation, §§ 2.02(a)(3), 2.07(d) cmt. j (2009) (indicating that the court should exercise discretion to authorize aggregate treatment only if it would "not compromise the fairness of procedures for resolving any remaining issues presented by such claims" and that "due process in aggregation . . . extend[s] to persons opposing the aggregate group litigating related claims on an aggregate basis").

The defendants here dispute the plaintiffs' compliance with the third set of requirements primarily because the class includes some number of brand-loyal consumers who would continue to purchase branded Nexium even when a generic becomes available. Defendants argue 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." Appellant's Br. 22. Defendants assert that the plaintiffs' expert admitted that her damages model did not limit recovery to injured parties.

While it is true that a proper mechanism for exclusion of brand-loyalist consumers has not yet been proposed, plaintiffs' expert made no concession that such a mechanism could not be developed, nor did defendants' expert say that it could not be developed.

In order to address whether an appropriate mechanism can be developed, it is useful to consider how injury would be established outside of the class action context – that is, in an individual consumer suit for antitrust damages. In that situation, as here, by definition there are no records concerning generic purchases during the class period since no generic was on the market. Under these circumstances there appear to be at least two ways that the consumer could establish injury. The first would be to argue for a presumption that consumers would purchase the generic if it were available, i.e., a presumption that economically rational consumers faced with two identical products would purchase the less expensive alternative. This presumption would be similar to the presumption of reliance in securities class actions and would be subject to rebuttal by the defendant. See Halliburton Co. v. Erica P. John Fund, Inc., 573 U.S. ___, 134 S.Ct. 2398, 2408, 2412 (2013) (presumption of reliance in Basic, Inc. v. Levinson, 485 U.S. 224 (1988), applies to class action, but is subject to rebuttal by defendants). We do not decide whether applying such a presumption would be appropriate.

But even if a presumption were determined not to be appropriate, another approach exists. This other approach would be to establish injury through testimony by the consumer that, given the choice, he or she would have purchased the generic. Such testimony, if unrebutted, would be sufficient to establish injury in an individual action. And if such consumer testimony would be sufficient to establish injury in an individual suit, it follows that similar testimony in the form of an affidavit or declaration would be sufficient in a class action. There cannot be a more stringent burden of proof in class actions than in individual actions. "Rigorous analysis," Falcon, 457 U.S. at 161, of Rule 23 requirements does not require raising the bar for plaintiffs higher than they would have to meet in individual suits.[17]

Thus, we have confidence 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. See Madison v. Chalmette Refining, LLC, 637 F.3d 551, 556 (5th Cir. 2011) (approving, in the context of class certification, consideration of possible "case management tools, including narrowing the claims and potential plaintiffs through summary

[17] The cases relied on by the dissent rejecting the use of affidavits involved affidavits concerning the past purchase of the product in question (necessary for class membership), not affidavits concerning likely future purchases of the consumers, as to which documents are not available. See Marcus, 687 F.3d at 593; Carrera, 727 F.3d at 304.

judgment [or] facilitating the disposition of the remaining plaintiffs' claims through issuance of a Lone Pine order [requiring affidavits from plaintiffs]").

Defendants have merely speculated that a mechanism for exclusion cannot be developed later. This is not enough to overcome plaintiffs' case for having met the requirements of Rule 23. See Smilow, 323 F.3d at 40 (decertification unnecessary where existence of individualized issues is "a matter of conjecture"); Gunnells v. Healthplan Servs., Inc., 348 F.3d 417, 430 (4th Cir. 2003) (defeating adequacy requirement of Rule 23 requires a conflict that is "more than merely speculative or hypothetical").

Defendants also assert that any mechanism of exclusion that requires determination of the individual circumstances of class members is improper. But the Supreme Court in Amgen and the circuits in other cases have made clear that the need for some individualized determinations at the liability and damages stage does not defeat class certification. 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." Amgen, 133 S. Ct. at 1196 (alterations and citations omitted). Rather, the question is whether there is "reason to think that [individualized] questions will overwhelm common ones and render class certification inappropriate . . . ." Halliburton, 134 S.Ct. at 2412 (2014) (emphasis added). For example, damages will not be

uniform across the class. But it is well-established that "[t]he individuation of damages in consumer class actions is rarely determinative under Rule 23(b)(3). Where . . . common questions predominate regarding liability, then courts generally find the predominance requirement to be satisfied even if individual damages issues remain." Smilow, 323 F.3d at 40; Newberg, supra, § 4:54 (It is a "black letter rule . . . that individual damage calculations generally do not defeat a finding that common issues predominate . . . .").

Even in cases where "the issue of injury-in-fact [not just damages calculation] presents individual questions, . . . it does not necessarily follow that they predominate over common ones and that class action treatment is therefore unwarranted." Cordes & Co. Fin. Servs., Inc. v. A.G. Edwards & Sons, Inc., 502 F.3d 91, 108 (2d Cir. 2007) (emphasis added). We do not think the need for individual determinations or inquiry for a de minimis number of uninjured members at later stages of the litigation defeats class certification. As contemplated by Halliburton, the district court also explicitly recognized the need to "preserv[e] the Defendants' right to challenge individual damage claims at trial." Add. 24a.

B.

In light of these three requirements — ensuring the class is definite, limiting aggregate recovery to the amount of the injury, and ensuring recovery by only injured parties — it is

difficult to understand why the presence of uninjured class members at the preliminary stage should defeat class certification. Ultimately, the defendants will not pay, and the class members will not recover, amounts attributable to uninjured class members, and judgment will not be entered in favor of such members. Some number of uninjured members will receive a class notice, but the district court can easily assure that defendants will not pay for notice to uninjured members.[18] At worst the inclusion of some uninjured class members is inefficient, but this is counterbalanced by the overall efficiency of the class action mechanism. Moreover, excluding all uninjured class members at the certification stage is almost impossible in many cases, given the inappropriateness of certifying what is known as a "fail-safe class" – a class defined in terms of the legal injury.[19]

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[18] "District courts may order a class action defendant to pay the cost of class notification after they determine that the defendant is liable on the merits." Hunt v. Imperial Merch. Servs., Inc., 560 F.3d 1137, 1144 (9th Cir. 2009). However, fee shifting is discretionary, and the Supreme Court has cautioned that "courts must not stray too far from the principle" that plaintiff "should bear all costs relating to the sending of notice because it is he who seeks to maintain the suit as a class action." Oppenheimer Fund, Inc. v. Sanders, 437 U.S. 340, 350 (1978).

[19] As the district court noted, a fail-safe class is one in which "it is virtually impossible for the Defendants to ever 'win' the case, with the intended class preclusive effects." Add. 26a n.5; see Young v. Nationwide Mut. Ins. Co., 693 F.3d 532, 537 (6th Cir. 2012) (A fail-safe class "is prohibited because it would allow putative class members to seek a remedy but not be bound by an adverse judgment—either those class members win or, by virtue of losing, they are not in the class and are not bound." (citations, internal quotation marks omitted)).

In certifying a (b)(3) class there is an almost inevitable tension between excluding all non-injured parties from the defined class and including all injured parties in the defined class. Ideally, that tension should be resolved by adopting a class definition that includes no uninjured parties and excludes no injured parties. See Messner v. Northshore Univ. Healthsystem, 669 F.3d 802, 825 (7th Cir. 2012) ("Defining a class so as to avoid, on one hand, being over-inclusive and, on the other hand, the fail-safe problem is more of an art than a science."). We doubt that this will be feasible in many cases. Without the benefit of further proceedings, it is simply not possible to entirely separate the injured from the uninjured at the class certification stage. And as the Supreme Court noted in Amgen, "Rule 23 grants courts no license to engage in free-ranging merits inquiries at the certification stage." 133 S.Ct. at 1194–95.

Finally, Defendants' objections to certifying a class including uninjured members run counter to fundamental class action policies. As the Supreme Court has repeatedly recognized, while "[t]he class action device was designed as an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only," it is nonetheless "peculiarly appropriate when the issues involved are common to the class as a whole." Falcon, 457 U.S. at 155 (citing Califano, 442 U.S. at 701 (internal quotation marks omitted)). In particular, when amending

Rule 23 to include section (b)(3), "the Advisory Committee sought to cover cases in which a class action would achieve economies of time, effort, and expense, and promote . . . uniformity of decision as to persons similarly situated." Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 615 (1997) (citing Adv. Comm. Notes, 28 U.S.C. App., p. 697) (internal quotation marks omitted). In Amchem, the Supreme Court recognized what types of cases were best adjudicated under this amended section — "[w]hile 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 to court at all." Id. at 617 (internal quotation marks omitted).

The plaintiff class members in this case appear to be the very group that Rule 23(b)(3) was intended to protect. As we discuss later in this opinion, the actual overcharge to each class member was generally a small amount per prescription and too small to warrant individual litigation. See Carnegie v. Household Int'l, Inc., 376 F.3d 656, 661 (7th Cir. 2004) ("The realistic alternative to a class action is not 17 million individual suits, but zero individual suits, as only a lunatic or a fanatic sues for $30."). As this court noted in New Motor Vehicles, 522 F.3d at 8, "an erroneous failure to certify a class where individual claims are

small may deprive plaintiffs of the only realistic mechanism to vindicate meritorious claims."

C.

Despite the obvious utility of allowing the inclusion of some uninjured class members in the certified class and the lack of harm in doing so, the defendants rely on authority from the Supreme Court and from this court for the proposition that plaintiffs must nonetheless prove that every putative class member suffered injury to prevail on class certification. But the authority cited by the defendants do not impose any such requirement.

The defendants cite Wal-Mart, where the Supreme Court reversed the class certification because plaintiffs could not show Wal-Mart had a common policy of discriminating against women. 131 S.Ct. at 2553. As a result, plaintiffs did not meet the Rule 23(a) commonality requirement. Id. But the Wal-Mart Court nowhere stated that at the class certification stage, every member of the class must establish that he, she or it was in fact injured by the common policy of discrimination. Id. at 2550–55.

Defendants' reliance on Comcast is equally misdirected. As we explained above, Comcast did not require that plaintiffs show that all members of the putative class had suffered injury at the class certification stage – simply that at class certification, the damages calculation must reflect the liability theory. 133 S.Ct. at 1434.

The Supreme Court also addressed the treatment of potentially uninjured class members last term in Halliburton. In securities cases like Halliburton, investors can recover damages only if they can prove that they relied on the defendant's misrepresentation in deciding to buy or sell a company's stock. 134 S.Ct. at 2405. Under Basic, Inc. v. Levinson, 485 U.S. 224 (1988), a plaintiff securities class can satisfy the reliance requirement at class certification by invoking a presumption of reliance, rather than proving direct reliance on defendant's misrepresentation for each individual class member. Halliburton, 134 S.Ct. at 2408, 2412. Basic permits defendants to rebut this presumption using individualized evidence "showing that [the class member] did not rely on the integrity of the market price in trading stock." Id. at 2412. The Halliburton Court concluded that "[w]hile [the rebuttal] has the effect of leaving individualized questions of reliance in the case, there is no reason to think that these questions will overwhelm common ones and render class certification inappropriate under Rule 23(b)(3)." Id. (internal quotation marks omitted). Even if "the defendant might attempt to pick off the occasional class member here or there through individualized rebuttal . . . individual questions [did not] predominate" over common questions. Id. Thus, the Halliburton Court contemplated that a class with uninjured members could be

certified if the presence of a de minimis number of uninjured members did not overwhelm the common issues for the class.

The law in this circuit is not to the contrary. Defendants argue that this court in New Motor Vehicles held that to obtain class certification, plaintiffs must establish at class certification that "each class member was harmed by the defendants' practice." 522 F.3d at 28 (internal quotation marks and alterations omitted). To the extent that New Motor Vehicles is read to impose such a requirement, it has been overruled by the Supreme Court's Halliburton decision. But, in fact, New Motor Vehicles imposes no such requirement. In that case, plaintiffs alleged that defendant automobile manufacturers illegally colluded to restrict the flow of Canadian cars into the United States to maintain higher prices in the United States. Id. at 10. This court was concerned that even if plaintiffs showed that defendants' anti-competitive conduct increased the vehicle list price in the United States, plaintiffs did not have evidence showing that the list price was actually paid by the class members. Id. at 27–28. New Motor Vehicles recognized that plaintiffs' theory "must include some means of determining that each member of the class was in fact injured," and that at the liability stage, there must be a showing "that class members were injured at the consumer level." Id. at 28. There was no basis for concluding that the plaintiffs there

could separate the injured from the uninjured at the liability stage.

But New Motor Vehicles did not impose a requirement that the injury determination must be completed by the class-certification stage — only that "the district court [have] enough information to evaluate preliminarily whether the proposed model will be able to establish . . . which consumers were impacted by the alleged antitrust violation and which were not." Id. (emphasis added). Uninjured members of the putative class would be identified in the liability proceedings later in the case, as Halliburton contemplates.[20]

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[20] New Motor Vehicles does not suggest separation of the injured from the uninjured must be possible "without need for individual determination" — only that separating the injured from the uninjured must be possible using a common test rather than an individual ad hoc approach. 522 F.3d at 28. The other circuit cases defendants rely on do not suggest otherwise. For instance, in In re Hydrogen Peroxide Antitrust Litigation, the Third Circuit, which cited many of the cases the defendants cite, suggested that if "fact of [antitrust] 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 . . . predominance." 552 F.3d 305, 311 (3d Cir. 2008) (emphasis added) (citing Bell Atl. Corp. v. AT&T Corp., 339 F.3d 294, 302 (5th Cir. 2003)). However, the court explicitly noted that the "[p]laintiffs' burden at the class certification stage is not to prove the element of antitrust impact" even if "to prevail on the merits each class member must do so." Id. Rather, at class certification, plaintiffs must only show that "antitrust impact is capable of proof at trial through evidence that is common to the class rather than individual members." Id. (emphasis added). Similarly, the D.C. Circuit has stated that at the class certification stage, plaintiffs must "show that they can prove" — not that they have proved — "through common evidence, that all class members were in fact injured . . . ." In re Rail Freight Fuel Surcharge Antitrust Litig., 725 F.3d 244, 252 (D.C. Cir.

"Numerous courts have certified plaintiff classes even though the plaintiffs have not been able to use common evidence to show harm to all class members." Davis et al., The Puzzle of Class Actions with Uninjured Members, 82 G.W.L.Rev. 858, 859 (May 2014). In addition to Halliburton, cases from our sister circuits[21] and this circuit[22] hold that the presence of a de minimis number of

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2013). In a case where plaintiffs' methodology "detects injury where none *could* exist[,]" and there is "no reliable means of proving classwide injury[,]" class certification must be denied. Id. at 252–53 (emphasis added). But from this it does not follow that the existence of a de minimis number of uninjured class members bars certification if those members can be weeded out at a later stage.

[21] See, e.g., Messner, 669 F.3d at 819, 824–25 (vacating denial of class certification despite presence of potentially uninjured class members); Cordes & Co. Fin. Servs., 502 F.3d at 107–08 (same); In re Urethane, 768 F.3d at 1254 (affirming class certification despite the fact that "some [of the plaintiffs] avoid[ed] injury altogether"); Pella Corp. v. Saltzman, 606 F.3d 391, 394 (7th Cir. 2010) (affirming class certification despite possibility that class included uninjured members); Kohen v. Pac. Inv. Mgmt. Co., 571 F.3d 672, 677 (7th Cir. 2009) (same); DG ex rel. Stricklin v. Devaughn, 594 F.3d 1188, 1198, (10th Cir. 2010) ("[C]ertification requirements neither require all class members to suffer harm . . . nor Named Plaintiffs to prove class members have suffered such harm."); Mims v. Stewart Title Guar. Co., 590 F.3d 298, 308 (5th Cir. 2009) ("Class certification is not precluded simply because a class may include persons who have not been injured by defendant's conduct." (citation omitted)).

[22] See Gintis v. Bouchard Transp. Co., 596 F.3d 64, 67 (1st Cir. 2010) (Souter, J.) (vacating and remanding district court's denial of class certification and stating that "on remand, the focus will be on the plaintiffs' claim that common evidence will suffice to prove injury, causation and compensatory damages for at least a very substantial portion of the claims that can be brought by the putative class members" (emphasis added)); Tardiff, 365 F.3d at 6 ("[U]ndue complications as to liability [were] limited. . . . If there was in fact a rule, custom or policy of strip searching every arrestee or a substantially overlarge category, then it is a

uninjured class members is permissible at class certification. In fact, as one court has recognized at certification, "a class will often include persons who have not been injured by the defendant's conduct; indeed, this is 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, 571 F.3d at 677. "Such a possibility or indeed inevitability does not preclude class certification." Id. (citing 1 Alba Conte & Herbert Newberg, Newberg on Class Actions § 2:4, pp. 73—75 (4th ed. 2002)).

We think that a certified class may include a de minimis number of potentially uninjured parties. We need not decide whether it is ever permissible to define a proper class including more than a de minimis number of uninjured parties since we conclude that it has not been shown that the class here includes more than a de minimis number of uninjured parties.

IV.

Defendants' alternative argument is that more than a de minimis number of class members were uninjured here, barring class

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fair guess that most arrestees so classed were strip searched on this basis. (emphasis added)); Mowbray, 208 F.3d at 296 (noting that "most class members' claims were unaffected" by "idiosyncratic" statute of limitations issues, affirming certification because "the mere fact that such concerns may arise and may affect different class members differently does not compel a finding that individual issues predominate over common ones" (emphasis added)).

certification. In addressing this argument, we conduct a detailed inquiry into the parties' and experts' economic analyses, keeping in mind that this is an indirect purchaser action. The Supreme Court in Illinois Brick, in holding that indirect purchasers may not bring suit for damages under the Clayton Act, noted the "uncertainties and difficulties in analyzing price and output decisions 'in the real economic world rather than an economist's hypothetical model'" and reasoned that actions by indirect purchasers would often result in "long and complicated" proceedings when such purchasers attempted to prove that a price increase was passed on to them. 431 U.S. at 732.

Twenty-four states eventually disagreed, creating private causes of action for indirect purchasers under state antitrust laws. That such actions are thus allowed under those laws does not eliminate the real economic and litigation complexities identified by the Supreme Court. It should therefore not be surprising that determining whether and when certification of indirect purchaser class actions may bear the added complexity entails considerable thought and effort.

Here, a class member suffered antitrust injury if that individual or entity was overcharged for Nexium during the class period. There is no serious dispute that the majority of class members were injured. It is undisputed that the price that would have been paid by class members for generic Nexium but-for

defendants' conduct ("but-for price") is lower than the actual price paid by class members during the class period for branded Nexium ("class period price"). For those class members who were reimbursed for their purchases by an insurance plan and paid only a copayment, it is similarly undisputed that the generic copayment is almost always lower than the brand-name copayment. The dispute here focuses on various purchasers who were atypical and allegedly uninjured.

In proving injury, plaintiffs relied on the expert testimony of Professor Meredith Rosenthal, Professor of Health Economics and Policy at the Harvard School of Public Health and an Academic Affiliate of Greylock McKinnon Associates, a consulting and litigation support firm. Rosenthal assumed that plaintiffs had proven defendants' anti-competitive conduct and offered an opinion on the antitrust impact of the alleged generic foreclosure. To calculate the class period price — the actual prices paid by class members for branded Nexium during the class period, Rosenthal used data from the IMS National Prescription Audit. However, because no generic forms of Nexium were on the market, there was no data to show firsthand the prices of branded and generic Nexium after generic entry. To calculate the but-for prices, Rosenthal relied on the "yardstick" approach which approximates the but-for market by using data from similar markets.

Because Nexium is a proton-pump inhibitor, Rosenthal examined other drugs in that therapeutic class for their suitability as a yardstick. She selected Prevacid (lansoprazole) because it was launched closest in time to Nexium (November 2009), and had a similar profile of generic entrants as Nexium in terms of number and size. Rosenthal corroborated her calculations of the but-for prices using defendants' documents, which contained estimates of Nexium prices after generic entry. Rosenthal's calculations showed that nearly all class members suffered an antitrust injury as a result of defendants' conduct.

Defendants argued that even though injured class members comprise a majority of the putative class, more than a de minimis number of class members were not injured, identifying five groups of class members that likely suffered no injury. Defendants' arguments were based on the expert testimony of Professor James W. Hughes, Thomas Sowell Professor of Economics at Bates College.

Plaintiffs bear the burden of an initial showing that a proposed class satisfies the Rule 23 requirements. Smilow, 323 F.3d at 38; accord Messner, 669 F.3d at 811; In re Hydrogen Peroxide, 552 F.3d at 311–12. But "[plaintiffs] need not make that showing to a degree of absolute certainty. It is sufficient if each disputed requirement has been proven by a preponderance of evidence." Messner, 669 F.3d at 811 (citing Teamsters Local 445 Freight Div. Pension Fund v. Bombardier Inc., 546 F.3d 196, 202 (2d

Cir. 2008)); accord Alaska Elec. Pension Fund v. Flowserve Corp., 572 F.3d 221, 228 (5th Cir. 2009). Once plaintiffs have made their initial showing, defendants have the burden of producing sufficient evidence to rebut the plaintiff's showing.

Here, it is difficult to determine exactly what findings the district court made with respect to each of the five allegedly uninjured groups presented by the defendants. However, the district court generally credited Rosenthal's calculations. It pointed out that Rosenthal's figures showed "approximately 5.8 percent of all class prescriptions were attributable to brand . . . transactions with no overcharge." Add. 24a (emphasis added) (internal quotation marks omitted). Neither the parties nor the district court presented a precise estimate of the number or percentage of uninjured class members, but on balance, the district court found defendants' challenges did not suffice to overcome predominance.

We consider here defendants' contentions with respect to the five allegedly uninjured groups and the record materials. We conclude that defendants' argument that no class can be certified stems in large part from four errors in their analysis of the "uninjured" groups.

First, defendants incorrectly assume that class members are shielded from injury by plan arrangements that the district court found did not exist.

Second, defendants incorrectly assume that a class member who is injured for only a part of the class period did not suffer injury, even though they have now conceded that an injury for part of the class period is sufficient to establish injury. "Paying an overcharge caused by the alleged anticompetitive conduct on a single purchase suffices to show — as a legal and factual matter — impact or fact of damage." Davis & Cramer, Antitrust, Class Certification, and the Politics of Procedure, 17 Geo. Mason L. Rev. 969, 984–85 (2010) (internal quotation marks omitted) (citing Paper Sys., Inc. v. Nippon Paper Indus. Co., 281 F.3d 629, 633 (7th Cir. 2002)).

Third, defendants incorrectly assume that if a class member offsets an overcharge through later savings attributable to the same or related transaction, there is no injury. But antitrust injury occurs the moment the purchaser incurs an overcharge, whether or not that injury is later offset. See Adams v. Mills, 286 U.S. 397, 407 (1932) (“In contemplation of law the claim for damages arose at the time the extra charge was paid. Neither the fact of subsequent reimbursement by the plaintiffs from funds of the shippers nor the disposition which may hereafter be made of the damages recovered is of any concern to the wrongdoers.” (citations omitted)); see also Hawaii v. Standard Oil Co. of Cal., 405 U.S. 251, 262 n.14 (1972) ("[C]ourts will not go beyond the fact of this injury to determine whether the victim of the overcharge has

partially recouped . . . ."). Here, if a class member is overcharged, there is an injury, even if that class member suffers no damages.

Fourth, defendants incorrectly treat individual prescriptions of Nexium as a proxy for individual consumers. For example, defendants mistakenly cite the district court's findings that "only approximately 5.8 percent of all class prescriptions . . . [had] no overcharge" and that "Nexium co-pay coupons were only used in 2-4 percent of prescriptions," Add. 24a (emphases added), to support the conclusion that "at least 7.8 to 9.8% of the consumers — more than 100,000 consumers in all — suffered no injury." Appellant's Br. 20 (emphasis added). However, there is no necessary relationship between the percentage of prescriptions and the percentage of consumers since a class member may fill one prescription with an overcharge and another with no overcharge.

In light of the correct standards, we discuss each of the five allegedly uninjured groups in turn — Groups 1 to 5. The question in each instance is whether the but-for price absent generic foreclosure would have been lower than the actual class period price of Nexium.

Group 1. This group consists of TPPs that would have allegedly paid a higher but-for price for generic Nexium than they actually paid for branded Nexium during the class period.

Defendants contend that they were not injured because they benefitted from rebates that reduced the actual class period price for branded Nexium.[23] Defendants argue that Group 1 members were not injured because with the rebates, the actual class period Nexium price was lower than the but-for generic price. However, defendants have not shown that this is the case. Using Hughes' calculations, after accounting for the rebates, the average actual class period branded Nexium price was $121, while the but-for generic price would have been $113.[24] Therefore, Group 1 TPPs who

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[23] These rebates were negotiated between PBMs and AstraZeneca. Both Rosenthal and Hughes agree that AstraZeneca paid approximately $12.9 billion in rebates to PBMs from 2008 to 2012. Because PBMs are not part of the class, the rebates only affect the class to the extent that they are "passed-through" from PBMs to TPPs. There is some disagreement as to whether the rebates are passed-through as a discounted price when the PBMs bill the TPPs or whether TPPs are charged the list price and then refunded a portion based on the rebate amount. If the latter, then all Group 1 TPPs were injured because the rebates are only a damages setoff and do not affect the fact of injury.

Rosenthal calculated that approximately $10.3 billion in rebates was passed through to TPPs (an average discount of 39%), although Hughes alleges that the entire $12.9 billion was passed through (an average discount of 49%). For the purposes of these calculations, we assume that Hughes is correct – that all of the rebates were passed through.

[24] Defendants also argue that Rosenthal improperly relied on averages to determine the fact of injury, with the result that some class members at the extreme would not suffer injury even though the average consumer did. We think that the defendants cannot simply speculate that a more than de minimis number of class members departed from the average. They have failed to submit evidence that this is the case. Nor is it the case that plaintiffs' average but-for price is so close to the average class period price that any deviation with either figure would eliminate the overcharge.

would have purchased generic Nexium during the class period were injured.

Group 2. TPPs usually pay for the prescription drug directly and then charge plan members a copayment (a flat payment) or a coinsurance (a percentage of the drug price). Sometimes TPPs incentivize generic drug purchases by plan members by charging a lower copayment for a generic drug than for its brand-name counterpart. Defendants allege that under such plan arrangements, "the decrease in the co-payment is more than the total net price drop," Add. 21a (citing Def.' Mem. Opp. Class Certification) — i.e., the difference between the actual branded Nexium price paid for by the TPP during the class period (absent generic entry) and the but-for generic price is less than the difference between the branded Nexium copayment (absent generic entry) and the but-for generic copayment. As a result, defendants argue that Group 2 members — TPPs that offered such plan arrangements — suffered no injury because the decreased revenue from copayments offset the increased savings from the lower generic price. But as discussed above, that erroneous inference assumes that the decrease in copayment revenue should offset the increased actual savings in determining injury when it should not.

In any event, defendants have presented no evidence to support this prediction. Rosenthal's projections show that the price difference between the branded Nexium price absent generic

entry and the but-for generic price would have been $47 at the beginning of the class period and $196 at the end. Plaintiffs' deposition testimony and other evidence established that a typical plan offered by TPPs has only a $10 or $20 spread between the generic and brand-name copayments. The defendants provided no evidence of any plans with a greater spread. The record shows that there are likely no Group 2 members who were uninjured by defendants' conduct.

Group 3. Some TPPs, according to Hughes, had fixed price agreements to pay PBMs the same amount for every drug in a given therapeutic class, regardless of the actual drug price.[25] As a result, defendants claim that Group 3 TPPs suffered no injury because they would have paid the same for generic Nexium in the but-for world as they actually paid for branded Nexium during the class period. But the defendants did not provide any evidence that such agreements existed. Rosenthal stated that she has never encountered such an agreement in her research. The district court found that "[Hughes] does not establish the actual existence of [such] uninjured TPP groups." Add. 23a. The district court did not err in finding insufficient evidence that Group 3 actually exists.

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[25] These hypothetical agreements are presumably with PBMs whereby the TPPs reimburse pharmacies the same amount for every drug in a particular therapeutic class.

Group 4. This group comprises consumers who used coupons that reduced the copayment that they paid for branded Nexium during the class period. The assumption is that the coupons would not have been available in the but-for world and that the consumers would have switched to generic Nexium. These coupons were offered by AstraZeneca starting in August 2011. Eligible patients could use a "Nexium Savings Card" to pay only an $18 copayment for their prescription (with a maximum discount of $50). Defendants assert that Group 4 members were not injured because with coupons, the actual branded Nexium copayment during the class period was lower than the but-for generic copayment would have been. But the average branded Nexium copayment with the coupon was $18 (before generic entry), while the average but-for generic copayment would have been only $10-11. Thus these consumers were likely injured as well.

Group 5. This group comprises consumers who would continue to purchase only brand-name Nexium even after generic entry, known as brand-loyalists. There are Group 5 members who paid the actual cost of the drug (i.e., uninsured consumers) or a percentage thereof (i.e., consumers with a coinsurance plan). Defendants argue that these class members would have suffered no injury because, after generic entry, the price of branded Nexium would have increased over the class period. Defendants also contend that some plans charged a higher copayment for branded

drugs than for their generic substitutes with the result that brand-loyalist members of such plans would suffer no injury from the foreclosure of generic entry.[26] In other plans, the copayment for the branded drug increased with generic entry. As a result, defendants contend that Group 5 consumers are not injured because they would pay more with generic entry.

We agree that some Group 5 consumers were likely not injured by defendants' conduct. The question is whether that is more than a de minimis number. The district court found, based on Rosenthal's projections, that 5.8% of all prescriptions during the entire six-year class period would have been for branded Nexium. Defendants argue that this shows that 5.8% "of the consumers" were uninjured. Appellant's Br. 20. This does not follow for at least the following reasons:

First, the number of prescriptions is not a necessary surrogate for the number of consumers.

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[26] Consumers who are members of plans with flat copayment structures (i.e., that charge the same copayment for both brand-name drugs and generic substitutes) were also uninjured whether they would have switched to the generic or were brand-loyalists. But these consumers are already excluded by the class definition — "'flat co-pay' 'Cadillac Plan' consumers who made purchases only via fixed dollar co-payments that do not vary between Nexium and its AB-rated generic equivalent." Add. 41a(f).

One minor change to the class definition is required to exclude members of plans where the generic copayment after generic entry would be the same as the branded copayment before generic entry.

Second, consumers who purchased Nexium using cash or a coinsurance at the beginning of the class period were injured (even if they made later purchases that did not reflect injury) because in the early period the but-for branded Nexium price would have been lower than the actual branded Nexium price in the early period.

Third, a consumer was injured if he or she would have purchased generic Nexium even once during the class period. Because Nexium is a maintenance drug, there is a high likelihood that a generic purchase would occur. Indeed, only 2% of prescriptions three years after generic entry would have been for branded Nexium. Significantly, state laws allow pharmacists to substitute generic products (some mandate substitution unless a physician prevents substitution).

As Rosenthal explained, defendants are relying on the mere hope that there is a "likelihood of there being a substantial number of consumers whose only purchases during the entire Class Period were brand purchases . . . ." J.A. 203. While on this record it is impossible to precisely quantify the uninjured members in Group 5, we conclude that plaintiffs have provided more than enough evidence to meet their Rule 23 burden.

What counts as a "de minimis" deviation "from a prescribed standard must, of course, be determined with reference to the purpose of the standard." Wisconsin Dept. of Revenue v.

William Wrigley, Jr., Co., 505 U.S. 214, 232 (1992). We thus define "de minimis" in functional terms. Here, if common issues "truly predominate over individualized issues in a lawsuit, then the addition or subtraction of any of the plaintiffs to or from the class [should not] have a substantial effect on the substance or quantity of evidence offered." Vega v. T-Mobile USA, Inc., 564 F.3d 1256, 1270 (11th Cir. 2009) (alteration in original, citation omitted). Upon examination of the record, we see no basis for overturning the district court's ultimate conclusion that the number of uninjured members here is not so large as to render the class impractical or improper, or to cause non-common issues to predominate. Nor do we see a basis for concluding the number of uninjured class members here is so large as to violate defendants' 7th Amendment or due process rights, in light of the fact that uninjured members can be excluded and the district court expressly "preserve[d] the Defendants' rights to challenge individual damage claims at trial." Add. 24a.

Plaintiffs' evidence has shown that the vast majority of class members were probably injured. "Rigorous analysis" of the evidence does not show that the number of uninjured class members is more than de minimis. The district court was well within its discretion to have found that the plaintiffs' "rebuttal to [defendants'] challenges [was] persuasive" and sufficient for a "showing of common antitrust impact to the putative class." Add.

24a. The defendants' speculation cannot defeat the plaintiffs' showing. See In re Urethane, 768 F.3d at 1254 (no abuse of discretion in not decertifying where plaintiffs had evidence of artificially inflated baseline for price negotiations, and defendants alleged plaintiffs "could have avoided the announced price increases, such as [by] negotiating for a lower price or switching to a substitute" (emphasis added)); Messner, 669 F.3d at 825 (once plaintiffs had shown broad antitrust impact, certification could not be denied just because defendants pointed to a class of uninjured members but "[gave] no indication how many such individuals actually exist"); Kohen, 571 F.3d at 676–79 (where evidence did not show "great many" uninjured persons, defendants' pointing to "possibility" that unidentified number of class members were uninjured is insufficient to defeat certification, especially since defendants could depose a "random sample of class members to determine how many were [uninjured] and . . . could urge the district court to revisit its decision to certify"); see also In re Whirlpool Corp. Front-Loading Washer Products Liability Litig., 722 F.3d 838, 854–55 (6th Cir. 2013) (commonality not defeated simply because, though plaintiffs' evidence showed washer models were nearly identical, defendants merely contended the class included owners who are "pleased with the performance of their" machines and are thus dissimilar to consumers who complained of a mold problem), cert. denied Whirlpool Corp. v. Glazer, 134 S.Ct. 1277 (2014).

In the context of the plaintiffs' having shown that the class does not "consist[] largely . . . of members who are ultimately shown to have suffered no harm," Messner, 669 F.3d at 824, the number of uninjured members here seems comparable to the "2.4 percent decrease in the size of the class [due to removal of uninjured members]" that the Seventh Circuit concluded was "certainly not significant enough to justify denial of certification." Id. at 826 (emphasis added).

V.

Defendants also raise the separate but related argument that because each putative class member has not suffered injury, the class does not have standing.

Article III standing is an "indispensable part" of any case that must be present at every stage of the case. See Lujan v. Defenders of Wildlife, 504 U.S. 555, 561 (1992) (noting that standing must be "supported . . . at the successive stages of litigation"). Injury is a prerequisite to standing, and named plaintiffs need to satisfy this standing requirement throughout the stages of the litigation. See Stearns v. Ticketmaster Corp., 655 F.3d 1013, 1021 (9th Cir. 2011) ("At least one *named* plaintiff must satisfy the actual injury component of standing in order to seek relief on behalf of himself or the class."), cert. denied, 132 S.Ct. 1970 (2012); Kohen, 571 F.3d at 676 ("[A]s long as one member of a certified class has a plausible claim to have suffered

damages, the requirement of standing is satisfied."); see also DG ex rel. Stricklin, 594 F.3d at 1197–98; In re Prudential Ins. Co. Am. Sales Practices Litig. Agent Actions, 148 F.3d 283, 306–7 (3d Cir. 1998). It is undisputed that the named plaintiffs have shown that they were overcharged for at least one Nexium transaction during the class period, establishing standing. See Baker v. Carr, 369 U.S. 186, 204–06 (1962). The named plaintiffs thus have standing to sue for their injuries and to request, under Rule 23(b)(3), that the court allow them to represent and secure a judgment on behalf of a class.

To the extent that it is necessary that each and every member of the class who secures a recovery also has standing,[27] the requirement will be satisfied – only injured class members will recover.[28]

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[27] Some circuits have suggested that this is a requirement. See Denney v. Deutsche Bank AG, 443 F.3d 253, 263–64 (2d Cir. 2006) ("[While] [w]e do not require that each member of a class submit evidence of personal standing [at the class certification stage,] . . . [t]he class must . . . be defined in such a way that anyone within it would have standing."); Halvorson v. Auto-Owners Ins. Co., 718 F.3d 773, 778 (8th Cir. 2013).

[28] Defendants' Rules Enabling Act argument is similarly inapposite. While the Act would preclude recovery for uninjured class members, it imposes no requirement at the class certification stage beyond ensuring that a methodology can be developed that is capable of excluding uninjured members.

VI.

In summary, we conclude that plaintiffs have met their burden in showing that the 23(b)(3) requirements are met with respect to the TPPs in the certified class because all TPPs would have suffered injury. We also conclude that defendants have not established that more than a de minimis number of uninjured consumers are included in the certified class.

In large part, the remaining difference between plaintiffs and defendants is that the defendants would require a determination at the class certification stage as to which parties were injured and which not, whereas the plaintiffs would leave to later stages of litigation such sorting of injured and uninjured parties. We conclude that so long as it is established that such a mechanism can be identified, the presence of a de minimis number of uninjured members at the class certification stage does not defeat a class action. We conclude that such a mechanism can be identified here. The district court did not abuse its discretion in certifying the class.

Costs to appellees.

AFFIRMED

-Dissenting Opinion Follows-

KAYATTA, Circuit Judge, dissenting.

The chief difficulty we confront in this case arises from the fact that some of the members of the class have not suffered the antitrust injury upon which this entire case is predicated. This percentage, while small, could constitute as many as 24,000 consumers[29] who would have no valid claim against the defendants under the state antitrust laws even if the named plaintiffs win on the merits.

The majority correctly recognizes that certification of a class that includes uninjured consumers hinges on there being a method of identifying and removing those consumers prior to entry of judgment, and that any such method must be both administratively feasible and protective of the defendants' Seventh Amendment and due process rights. Slip Op. at 17-18. The majority also correctly recognizes that the district court has not identified--much less rigorously analyzed--any method for identifying and excluding these thousands of consumers prior to entry of judgment. Slip Op. at 18-19. Rather, the district court certified the class

[29] Neither side has precisely defined the size of the class, but the defendants, without challenge, suggest that it includes over a million consumers. Appellants' Br. at 20 (noting that 7.8% to 9.8% of the consumers in the class would constitute a group of over 100,000, meaning that the class would number more than a million). The majority's careful analysis suggests, in turn, that the percentage of uninjured consumers may be comparable to the 2.4% in Messner v. Northshore University Healthsystem, 669 F.3d 802, 826 (7th Cir. 2012). In a putative class including over a million consumers, that's at least 24,000 people.

because it considered the Rule 23 predominance inquiry satisfied by the fact that the vast majority of consumers in the class had been injured. As for the uninjured, the court simply kicked the can down the road by noting that the court "preserve[d] the Defendants' right to challenge individual damage claims at trial." In re Nexium (Esomeprazole) Antitrust Litig., 297 F.R.D. 168, 179 (2013).

The path thus marked for our court is clear. We should vacate the order certifying a class that includes uninjured consumers, and remand to the district court to proceed in accordance with the principles set forth in the majority's opinion. To the extent that certification remains relevant, given the posture of the case, the possibility would remain that the plaintiffs might yet propose and the district court approve some method of culling uninjured consumers from the class in an administratively feasible manner that protects defendants' rights. Instead, the majority dons the hats of both plaintiffs' counsel and the district court by first proposing, sua sponte, a culling method that no party has proposed--limiting recovery to consumers who file affidavits--and then announcing itself quite satisfied with that method. Slip Op. at 20. I therefore respectfully dissent. By upholding the district court on the basis of a culling method that it itself has fashioned, the majority errs both on the merits and as a matter of appellate procedure.

First, on the merits of the majority's proposed culling method, at least one sister circuit has twice noted the limitations of using affidavits in the manner proposed by the majority. See Carrera v. Bayer Corp., 727 F.3d 300, 304, 307 (3d Cir. 2013) (remanding an order certifying a class of all purchasers of a weight-loss supplement in Florida where documentary proof of purchase was "unlikely" and noting that the method of ascertaining whether someone is in the class must be "administratively feasible" and that affidavits of purchase are not sufficient); Marcus v. BMW of N. Am., LLC, 687 F.3d 583, 594 (3d Cir. 2012) (remanding a class certification order on the grounds that a class of original purchasers of BMWs with run-flat tires during the class period was not readily ascertainable via a "reliable, administratively feasible" method, and cautioning against including class members based on mere affidavits that their tires had gone flat).

The majority's response to the persuasive force of this precedent is fashioned out of a vacuum. The majority cites Madison v. Chalmette Refining, LLC, 637 F.3d 551, 556 (5th Cir. 2011), a case that both makes no mention of affidavits and actually reverses a class certification order because the district court failed to analyze in detail how individual issues would be resolved at trial, and instead took a "figure-it-out-as-we-go-along approach."[30] 637

[30] The majority gleans a potential blessing of affidavits from Chalmette by noting that among the criticisms of the district court by the Fifth Circuit was the failure to consider use of a so-called

F.3d at 557 (quoting Robinson v. Texas Auto. Dealers Ass'n, 387 F.3d 416, 426 (5th Cir. 2004)).

But regardless of whether or not affidavits may have a role to play in this or any class action, the larger issue is that a court of appeals should not assume that Rule 23 has been satisfied on the basis of a culling method that it itself has proposed. Many circuit court judges have little to no substantial experience with the nuts and bolts of class litigation, so fashioning litigation management devices is not in our institutional wheelhouse. Many of the facts relevant to assessing whether a certain management procedure will achieve a certain objective will not be discernible by a court until one party proposes it, and the other has a chance to critique it. At that

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"Lone Pine" order, a device used in mass accident litigation to streamline a case. Lore v. Lone Pine Corp., No. L-33606-85, 1986 WL 637507 (N.J. Super. Ct. Law Div. Nov. 18, 1986). A Lone Pine order, in turn, can include a requirement that those willing to sue first produce "some evidence to support a credible claim," which may include affidavits from a physician or real estate appraiser as evidence of injury. See Steering Comm. v. Exxon Mobil Corp., 461 F.3d 598, 604 n.2 (5th Cir. 2006). Lone Pine orders are for mass accident cases, which the drafters of Rule 23(b)(3) recognized are generally not certifiable. Fed. R. Civ. P. 23 advisory committee's note to subdiv. (b)(3) (1966) ("A 'mass accident' resulting in injuries to numerous persons is ordinarily not appropriate for a class action because of the likelihood that significant questions, not only of damages but of liability and defenses to liability, would be present, affecting the individuals in different ways."). So while a court might consider how a trial might be held in a mass accident case with use of a Lone Pine order, and by potentially requiring affidavits, nothing in Chalmette remotely suggests that affidavits would suffice as an administratively feasible tool for establishing injury in a manner protective of defendant's jury trial rights.

point, the district court would usually weigh the pros and cons of the procedure and make a decision, employing the fair amount of discretion assigned to it. We, in turn, come along at or near the end of the process. And we are pretty good at explaining the principles that cabin the district court's exercise of discretion, and at analyzing what by that point have usually become stationary targets presented in competing briefs.

The majority's opinion, in contrast, skips all that. It simply assumes that the question of how uninjured consumers can be identified and excluded can be answered with affidavits.[31] Untested by the adversary system, unexamined by any trial judge, and fashioned without awareness of its fit to the parties' needs and goals, the majority's method raises more questions than it answers. Will it require two forms of notice to class members--one to TPPs and one to consumers? What happens to those consumers who do not return an affidavit (of whom there may be many, given the low dollar amount of any potential recovery)? Will they be deemed to have opted out of the class? Or will they be deemed to have

[31] The majority also toys with the idea that courts could create a presumption that a consumer would buy a generic if it was available. Even assuming we could do so in a federal question case, but see 28 U.S.C. § 2072(b) (prohibiting the use of any procedural device to "abridge, enlarge, or modify any substantive right"), given that indirect purchasers cannot sustain an antitrust claim under federal law, see Illinois Brick Co. v. Illinois, 431 U.S. 720, 746-48 (1977), the only time such a presumption could be employed is in a state-law diversity suit where a federal court is without authority to create such a presumption. See Erie R. Co. v. Tompkins, 304 U.S. 64, 78 (1938).

remained in, but lost their claims due to lack of injury? Even more daunting, what happens if tens or hundreds of thousands of Nexium purchasers file affidavits? How exactly will defendants exercise their acknowledged right to "challenge individual damage claims at trial"? Will the defendants seek to depose everyone who has returned an affidavit, effectively challenging plaintiffs' counsel to a discovery game of chicken? The majority simply hedges on these questions by assuming--without any basis at all, and likely unreasonably--that the affidavits will be "unrefuted."

Throwing up an idea to see if it might stick is just not what courts of appeals do best. Rather, it is only after the adversaries have gone to the mat and the dust has settled that we can fairly review a district court's assessment of whether a proposed method would be feasible. For this reason, if the district court does not identify a culling method to ensure that the class, by judgment, includes only members who were actually injured, this court has no business simply hoping that one will work. See Gen. Tel. Co. of the Sw. v. Falcon, 457 U.S. 147, 160 (1982) (noting that "actual, not presumed, conformance" with the rule is "indispensable"); In re New Motor Vehicles Can. Exp. Antitrust Litig., 522 F.3d 6, 28 (1st Cir. 2008) (requiring the district court to evaluate a proposed model for proving fact of injury prior to certification). In this important respect, any attempt to reconcile the majority's holding with the approach taken

by our circuit in New Motor Vehicles will result in hopeless confusion unless one concludes that the dissent in New Motor Vehicles has become the law without en banc review.

On a related note, I must also part company with the majority's dalliance with a percentage-based rule inspired by the Seventh Circuit's decision in Messner v. Northshore University Healthsystem, 669 F.3d 802, 826 (7th Cir. 2012). The majority quite rightly says that the test for determining whether the inclusion of uninjured class members should defeat class certification is "functional." Slip Op. at 44. But then it backslides: it notes that a 2.4% decrease in the size of the class due to the removal of uninjured members was not so large as to defeat certification in Messner, 669 F.3d at 824, and concludes that the number of uninjured members here "seems comparable" to the number in Messner. Slip Op. at 46.

If 2.4% is okay, why not 5.7%? Or any number under 50%? The percentage tells one almost nothing about the functional sufficiency of the method. The relevant inquiry for a court considering certifying a class that includes uninjured members is whether the court will be able to feasibly cull out those members before entry of judgment. It may be relatively easy to cull 5% out of a class of 30. Culling out 5% of 1 million is almost certainly not. Here, "just 2.4%" is likely to be at least 24,000 people. Moreover, nobody knows who the 24,000 are. So the culling process

may need to review individually all the affidavits of class members who return them. How this is feasible, the majority does not explain.[32]

I also take issue with the majority's suggestion that when a proposed class includes some uninjured members who will have to be removed post-certification, it is the defendants who bear the burden of demonstrating that it cannot be done. The Supreme Court has been clear that the party seeking certification bears the burden of demonstrating that the requirements of Rule 23 are satisfied. Wal-Mart Stores, Inc. v. Dukes, 131 S. Ct. 2541, 2551 (2011). So, too, has this circuit. Smilow v. Sw. Bell Mobile Systems, Inc., 323 F.3d 32, 38 (1st Cir. 2003).

The majority acknowledges this, Slip Op. at 14, 34, and yet goes on to suggest the opposite: "Defendants have merely speculated that a mechanism for exclusion cannot be developed later. This is not enough to overcome plaintiffs' case for having met the requirements of Rule 23." Slip Op. at 21. But plaintiffs have *not* met their burden because, as the majority acknowledges, the proposed class includes some number of uninjured members, Slip Op. at 42, and the plaintiffs have not explained how they will be

[32] Oddly, the majority avoids any discussion of how affidavits will, as a practical matter, affect trial, even while citing Vega v. T-Mobile USA, Inc., 564 F.3d 1256, 1270 (11th Cir. 2009) for the proposition that there is no predominance when the addition or subtraction of class members has a substantial effect on the quantity of the evidence offered. See Slip Op. at 44.

removed before judgment, Slip Op. at 18-19. (It is also notable that the majority felt compelled to propose a culling method sua sponte--if the plaintiffs had indeed met their burden, this step would not be necessary.) When the plaintiffs have only shown that the number of uninjured members is relatively small, the class still cannot satisfy Rule 23 unless there exists a method for excluding those uninjured members prior to judgment. In such a context, it is no more the defendants' burden to prove that this cannot be done than it is this court's job to come up with a way that it can. Cf. Wallace B. Roderick Revocable Living Trust v. XTO Energy, Inc., 725 F.3d 1213, 1218 (10th Cir. 2013) (vacating a certification order in part because the district court appeared to shift the burden to the defendant to prove lack of commonality).

Finally, it bears noting that in the time that this interlocutory appeal was pending, the district court tried most of the liability issues in this case, leaving the end payors' fact-of-injury for a future proceeding. That trial concluded with a defense verdict just as these opinions were about to issue. The district court solicited no affidavits from consumers, nor does it appear that there was a plan to do so. So even if the majority's proposed culling method were tenable, we know that the district court did not employ it. In short, the majority affirms a certification order based entirely on a fiction that we know to be false. And unless one-way intervention is allowed, but see Am.

Pipe & Constr. Co. v. Utah, 414 U.S. 538, 546-49 (1974) (discussing the history and application of the one-way intervention rule), it is likely too late to let class members self-identify after taking a peek at the verdict.

These changing facts on the ground warrant caution before affirming a class certification order based on a possibility that the district court might do something that it did not do, and which it is likely that it could not do. Will there be an appeal from the verdict that will succeed? Is there any plan to send notice?[33] Is the basis for interlocutory review now eliminated? Although I agree entirely with the key principle that serves as the predicate for the majority's opinion--that certification of a class that includes uninjured members is possible if the district court identifies a feasible method for culling those members prior to entry of judgment in a way that protects defendants' rights--I do not believe that the majority has properly applied that principle in this case. I respectfully dissent.

[33] This is a Rule 23(b)(3) action in which notice to class members is mandatory. Fed. R. Civ. P. 23(c)(2)(B).