No. 23-55742

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

PAINTERS & ALLIED TRADES DISTRICT COUNCIL 82 HEALTH CARE FUND, third-party healthcare payor fund; ANNIE M. SNYDER, a California consumer; RICKEY D. ROSE, a Missouri consumer; JOHN CARDARELLI, a New Jersey consumer; MARLYON K. BUCKNER, a Florida consumer, on behalf of themselves and all others similarly situated; SYLVIE BIGORD, a Massachusetts consumer,

Plaintiffs-Appellees,

v.

TAKEDA PHARMACEUTICAL COMPANY LIMITED, a Japanese Corporation; TAKEDA PHARMACEUTICALS U S A INC, an Illinois corporation formerly known as Takeda Pharmaceuticals North America Inc; ELI LILLY AND COMPANY, an Indiana corporation,

Defendants-Appellants.

On appeal from the United States District Court for the Central District of California No. 2:17-cv-07223, Hon. John W. Holcomb

BRIEF FOR THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS-APPELLANTS

Jennifer B. Dickey
Jordan L. Von Bokern
U.S. CHAMBER
LITIGATION CENTER
1615 H Street NW
Washington, DC 20062

Ashley C. Parrish
KING & SPALDING LLP
1700 Pennsylvania Avenue NW
Washington, DC 20006
(202) 737-0500
aparrish@kslaw.com

Keri E. Borders
KING & SPALDING LLP
633 West Fifth Street, Suite 1600
Los Angeles, CA 90071

Counsel for Amicus Curiae
the Chamber of Commerce of the United States of America

January 26, 2024

CORPORATE DISCLOSURE STATEMENT

Amicus curiae the Chamber of Commerce of the United States of America ("Chamber") states that it is a non-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent corporation, and no publicly held company has 10% or greater ownership in the Chamber.

/s/ *Ashley C. Parrish*
Ashley C. Parrish

Counsel for amicus curiae
the Chamber of Commerce
of the United States of America

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

INTEREST OF AMICI CURIAE[1]

The Chamber of Commerce of the United States of America is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive branch, and the courts. To that end, the Chamber regularly files amicus curiae briefs in cases, like this one, that raise issues of concern to the nation's business community.

The Chamber's members and their subsidiaries include businesses that are often targeted in class actions. Because class certification creates immense pressure to settle even unmeritorious claims, the Chamber has a significant interest in ensuring that courts faithfully apply the requirements of Rule 23 before permitting a case to be certified as a class action.

---

[1] No counsel for any party authored this brief in whole or in part and no entity or person, aside from amicus curiae, its members, or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief. All parties consented to the filing of this brief. *See* Fed. R. App. P. 29(a)(2).

INTRODUCTION AND SUMMARY OF ARGUMENT

The class certification order in this case reflects a recurring problem: The district court failed to require that plaintiffs prove they are able to satisfy each element of Rule 23. In support of class certification, plaintiffs proffered a model that they asserted could establish causation, reliance, and injury on a class-wide basis. Instead of carefully evaluating the model, however, the district court took plaintiffs' model at "face value" and suggested that any inquiry into its flaws would be left for the jury at trial. Turning Rule 23 on its head, the district court faulted defendants for purportedly not proving that individual issues predominate over common ones, and improperly suggested that class certification was warranted on the view that plaintiffs offered a greater quantity of evidence than defendants (but without scrutinizing the quality and persuasiveness of that evidence).

The district court's class certification order impermissibly reverses the burden of proof and improperly fails to conduct the rigorous analysis that Rule 23 and controlling precedent require. This Court has held that plaintiffs have the burden to justify class certification, and defendants need only offer evidence sufficient to raise the possibility of

individualized class-member-by-class-member inquiries. *See Van v. LLR, Inc.*, 61 F.4th 1053, 1066 (9th Cir. 2023). Moreover, Rule 23 requires courts to evaluate not only the quantity but also the quality of evidence presented by both sides. *See Miles v. Kirkland's Stores Inc.*, 89 F.4th 1217, 1224 n.3 (9th Cir. 2024). And courts are not authorized to certify a class if it would prejudice defendants' ability to raised individualized defenses. *See Wal-Mart Stores, Inv. v. Dukes*, 564 U.S. 338, 348 (2011). Even when a class purportedly includes only a *de minimis* number of uninjured parties, plaintiffs must still demonstrate that they are able to identify and eliminate from the class any who have not suffered injury.

Because plaintiffs here did not meet their burden, the class should not have been certified. The district court's superficial analysis represents the type of lenient approach to class certification that is unfair to absent class members and improperly burdens American businesses and the economy as a whole. This Court should reverse.

ARGUMENT

I. Because class actions are supposed to be an exception to the usual rule of individualized litigation, courts must rigorously enforce Rule 23's requirements.

The Supreme Court has long emphasized that class actions are "an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only." *Comcast Corp. v. Behrand*, 569 U.S. 27, 33 (2013) (quoting *Califano v. Yamasaki*, 442 U.S. 682, 700–01 (1979)); *see also Wal-Mart*, 564 U.S. at 348 (emphasizing the same point). Rule 23's requirements provide crucial safeguards, grounded in constitutional due-process principles, that must be satisfied *before* plaintiffs are permitted to take advantage of class-action procedures. *See Taylor v. Sturgell*, 553 U.S. 880, 901 (2008). Rigorously enforcing Rule 23 helps to ensure that courts do not stray beyond their proper judicial role. The class-action mechanism should not be used to resolve difficult regulatory questions at the request of plaintiffs and unnamed class members who have not suffered concrete, particularized injuries.

Unfortunately, district courts far too often bend the rules to authorize class-action litigation, undermining controlling precedent and turning upside down the presumption in favor of individual litigation.

This Court should take this opportunity to re-emphasize the basic requirements that govern requests for class certification.

First, the burden of satisfying Rule 23's requirements falls squarely on the named plaintiffs. *See Wal-Mart*, 564 U.S. at 350. In meeting that burden, "actual, not presumed, conformance" with the rule is "indispensable." *Gen. Tel. Co. v. Falcon*, 457 U.S. 147, 160 (1982). Accordingly, plaintiffs "seeking class certification must *affirmatively demonstrate* [their] compliance with [Rule 23]—that is, [they] must be prepared *to prove* that there are *in fact* sufficiently numerous parties, common questions of law or fact, etc." *Wal-Mart*, 564 U.S. at 350 (emphasis altered); *see also Comcast*, 569 U.S. at 33 (named plaintiff must "'affirmatively demonstrate'" compliance with Rule 23 "through evidentiary proof" (quoting *id.*)). If plaintiffs cannot meet that burden by a "preponderance of the evidence," the class should not be certified. *Van*, 61 F.4th at 1066–67; *see* Fed. R. Civ. P. 23(c)(1) advisory committee's note to 2003 amendment (noting that a court should refuse certification unless it is "satisfied that the requirements of Rule 23 have been met").

Second, a court must "conduct a 'rigorous analysis' to determine whether" plaintiffs have met their burden. *Comcast*, 569 U.S. at 35

(citing *Wal-Mart*, 564 U.S. at 351); *see also Olean Wholesale Grocery Coop. v. Bumble Bee Foods LLC*, 31 F.4th 651, 664 (9th Cir. 2022). Making that determination often "entail[s] some overlap with the merits of the plaintiff[s'] underlying claim." *Wal-Mart*, 569 U.S. at 351. The court must decide whether the case can be effectively tried as a class action without prejudicing defendants' ability to litigate their individualized defenses. *See id.* at 361–62; *see also Unger v. Amedisys Inc.*, 401 F.3d 316, 321 (5th Cir. 2005) (explaining that Rule 23's plain text requires a court to "find," not merely assume, the facts sufficient to permit class certification).

It is therefore often necessary for a court to "look beyond the pleadings to understand the claims, defenses, relevant facts, and applicable substantive law in order to make a meaningful determination of the certification issues." *Yates v. Collier*, 868 F.3d 354, 362 (5th Cir. 2017) (quotation marks omitted); *see also Ellis v. Costco Wholesale Corp.*, 657 F.3d 970, 981–83 (9th Cir. 2011) ("a district court *must* consider the merits if they overlap with the Rule 23(a) requirements"). Where appropriate, the required analysis includes "[w]eighing conflicting expert testimony," "[r]esolving expert disputes," and "judging the

persuasiveness of the evidence presented." *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 323–24 (3d Cir.), *as amended* (Jan. 16, 2009).

Third, "given the transformative nature of the class-certification decision," a "particularly rigorous" analysis is required to ensure that all putative class members have suffered a common injury-in-fact. *Flecha v. Medicredit, Inc.*, 946 F.3d 762, 770 (5th Cir. 2020) (Oldham, J., concurring). Rule 23's "demanding" predominance requirement ensures that "proposed classes are sufficiently cohesive to warrant adjudication by representation." *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 623, 624 (1997). That cohesion exists only when all class members "possess the same interest and suffer *the same injury*." *E. Tex. Motor Freight Sys., Inc. v. Rodriguez*, 431 U.S. 395, 403 (1977) (emphasis added) (quoting *Schlesinger v. Reservists Comm. to Stop War*, 418 U.S. 208, 216 (1974)).

The need to prove a common, class-wide injury is essential to ensuring "sufficient unity so that absent members can fairly be bound by decisions of class representatives." *Amchem*, 521 U.S. at 620–21. Indeed, in "an era of frequent litigation—and especially "class actions"—"courts must be more careful to insist on the formal rules of standing, not less

so." *Ariz. Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125, 146 (2011). When Rule 23's predominance requirement is not satisfied, including because a class includes uninjured class members, there is nothing to be gained by class certification, "except the blackmail value of a class certification that can aid the plaintiffs in coercing the defendant into a settlement." *Rutstein v. Avis Rent-A-Car Sys., Inc.*, 211 F.3d 1228, 1240 n.21 (11th Cir. 2000).

II. The district court erred in certifying a class without applying a rigorous analysis to individualized issues of causation and injury.

The district court failed to engage in the rigorous analysis that the law requires. As a result, the court failed to address the fatal problems that infect plaintiffs' proposed class. Those problems include that plaintiffs cannot prove causation and reliance on a class-wide basis, and that plaintiffs have proposed no feasible method for eliminating uninjured class members before trial.

Plaintiffs allege that manufacturers conspired to fraudulently market a drug (Actos) by allegedly failing to provide warnings concerning the risk of bladder cancer. Significantly, no class member seeks recovery for any alleged physical injury. This is not a products-liability case. *See*

In re Johnson & Johnson Talcum Powder Prods. Mktg, Sales Pracs. & Liab. Litig., 903 F.3d 278, 280 (3d Cir. 2018) (discussing problems when a plaintiff has "entirely consumed a product that has functioned for her as expected" but nonetheless claims that with more information she would not have purchased the product). Nor do plaintiffs dispute that many doctors would have prescribed the drug in question even if defendants had provided different warnings. As the district court acknowledged, defendants could come forward with individualized evidence showing that the alleged misrepresentations were not relevant to individual prescription decisions and, as a result, with respect to those prescriptions, no injury resulted from the alleged conduct that forms the basis for plaintiffs' claims. *See Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co.*, 2023 WL 4191651, at *6 (C.D. Cal. May 24, 2023).

Claims that rely on class-wide allegations of fraud are rarely suitable for class action treatment because of the need to address individualized issues of causation, reliance, and injury. *See In re St. Jude Med., Inc.*, 522 F.3d 836, 838 (8th Cir. 2008) ("Because proof often varies among individuals concerning what representations were received, and

the degree to which individual persons relied on the representations, fraud cases often are unsuitable for class treatment."). That is especially true in the prescription-drug context, where class-wide proof is often impossible given "the individualized nature of physicians' prescribing decisions." *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 89–90 (2d Cir. 2015). Individualized preferences and circumstances shape real-life prescriber behavior and, as a result, class-wide presumptions about that behavior are almost always inappropriate. *See Poulous v. Caesars World, Inc.*, 379 F.3d 654, 665–66 (9th Cir. 2004) (concluding that because "[g]amblers do not share a common universe of knowledge and expectations—one motivation does not 'fit all'" and, as a result, an individualized "showing of reliance is required" to prove causation to support RICO claim); *see also In re Am. Med. Sys., Inc.*, 75 F.3d 1069, 1085 (6th Cir. 1996) (warning against class certification of drug or medical device product liability actions where, among other things, each plaintiff "receives different information and assurances from his treating physician").

Those general principles apply with full force in this case. Because many doctors would have prescribed the drug (Actos) even if defendants

had provided different warnings, plaintiffs cannot show on a class-wide basis that the alleged misrepresentations were even a but-for cause of class members' alleged injuries. Moreover, although plaintiffs asked the district court to assume that there are only a *de minimis* number of uninjured class members, they offered no "suitable and realistic plan" that would allow them to identify the uninjured class members and without eliminating defendants' ability to litigate their individual defenses. *Zinser v. Accufix Rsch. Inst., Inc.*, 253 F.3d 1180, 1189 (9th Cir. 2001) (quoting *Chin v. Chrysler Corp.*, 182 F.R.D. 448, 454 (D.N.J. 1998)).

Instead of recognizing that individualized issues preclude class certification, the district court allowed plaintiffs to rely on a flawed statistical model predicting that 56.77% of the drug prescriptions during the class period were fraudulently induced and asserting that, as a result, almost all members of the class would have suffered some injury. *See* 2023 WL 4191651, at *12. But the district court made no findings that the model was accurate or that plaintiffs would be able to use the model to identify *which* members suffered injury and *which* did not. Instead, the district court accepted plaintiffs' model and estimates "at face value," *id.*, without ruling on defendants' contrary evidence and arguments

demonstrating that plaintiffs' analysis was flawed. According to the court, it would be wrong to "prejudge" plaintiffs' evidence before trial, *id.* at*12 n.88, and defendants should have put forward their own model for identifying which class members suffered no injury, *id.* at *17. The court suggested that because the evidence presented by defendants—a representative example of prescribers—did not outweigh what it characterized as a "mountain" of common evidence provided by plaintiffs, the "tally" of evidence weighed in favor of certification. *See id.*

The district court's approach improperly shifts the burden of proof and confuses the class-certification inquiry. The law is clear: A court must conduct a rigorous analysis sufficient to determine whether plaintiffs have demonstrated that their claims can be tried on a class-wide basis and without eliminating defendants' rights to raise individualized defenses, even when that inquiry requires examining the merits. *See, e.g., Wal-Mart*, 564 U.S. at 351–52; *Comcast*, 569 U.S. at 33–34; *see also Amchem*, 521 U.S. at 615 (Rule 23's requirements demand a "close look"). *Defendants* are not required to prove anything with respect to predominance; instead, if plaintiffs have come forward with evidence of predominance, defendants are merely required to come forward with

representative evidence sufficient to "summon[] the spectre of class-member-by-class-member adjudication." *Van*, 61 F.4th at 1069. Moreover, evaluating competing evidence is "not a mere bean-counting exercise." *Miles*, 89 F.4th at 1224 n.3. Instead, "[b]oth the quantity and quality" of the evidence matters. *Id.* It is plaintiffs' burden to prove that discovery and trial can occur without individualized issues predominating over common issues. *Van*, 61 F.4th at 1067 n.11; *see also Ellis*, 657 F.3d at 984.

More fundamentally, the district court failed to recognize that "cases are not tried on the evidence of one party." *Johannessohn v. Polaris Indus. Inc.*, 9 F.4th 981, 986 (8th Cir. 2021). Before certifying a class, a district court must "account for issues implicated by the asserted claims *and defenses*." *Prantil v. Arkema Inc.*, 986 F.3d 570, 578 (5th Cir. 2021) (emphasis added). Ignoring a defendant's individualized evidence of no injury is fatal to a class-certification decision. *See id.* at 579 (vacating class certification because district court failed to consider how individualized issues in both claims and defenses would actually be tried); *see also Ellis*, 657 F.3d at 987 (reversing district court because it failed to consider whether relief could be granted absent "individualized

determinations"); *Johannessohn*, 9 F.4th at 986 (affirming denial of certification because defendant "would be entitled to present contrary evidence" that plaintiff's purported proof of injury does not apply to certain class members). Indeed, certifying a class without accounting for the defendant's right to litigate individual defenses violates due process and the Rules Enabling Act, which mandates that courts interpret Rule 23 in a manner that does not "abridge, enlarge or modify any substantive right." 28 U.S.C. § 2072(b). When analyzing predominance, a district court must account for individualized defenses on injury—an element of liability, not merely damages. A court cannot make these individualized issues disappear by considering only plaintiffs' evidence. *See In re Hydrogen Peroxide*, 552 F.3d at 307 (emphasizing that a district court "must consider all relevant evidence and arguments" and "must resolve all factual or legal disputes relevant to class certification").

In short, it was plaintiffs' burden to prove that individualized questions did not predominate, and it was the district court's obligation to rigorously analyze plaintiff's purported proof. Simply accepting at face value the assertions made by plaintiffs' expert is not sufficient. *See id.* at 323 (emphasizing that plaintiffs' expert testimony "should not be

uncritically accepted" at class certification). The presence of uninjured class members precludes class certification because the individualized efforts needed to separate them from any actually affected class members would destroy predominance. *See Lara v. First Nat'l Ins. Co.*, 25 F.4th 1134, 1139 (9th Cir. 2022).

III. Relaxing the requirements for class certification harms our businesses and the economy as a whole.

There are strong policy reasons for rigorously enforcing Rule 23's requirements. Especially in cases, like this one, where plaintiffs are raising a novel theory of recovery—an unprecedented "quantity effect" theory—courts should reject any invitation to relax the requirements for class certification. These novel claims should be litigated on an individual basis, not as a sprawling class action.

Class action litigation costs in the United States take an enormous toll on U.S. businesses. In 2022, those costs expanded to $3.64 billion, further accelerating a trend of rising costs that started in 2015. *See* 2023 Carlton Fields Class Action Survey, at 4–6, *available at* https://classactionsurvey.com (noting that claims are expected to grow another 6.8% in 2023, an increase for the eighth straight year). The costs are widespread, as almost 60% of major companies are engaged in defending

against class actions, with an increasing sense that "courts are becoming more lenient in allowing class actions to move forward," creating "a significant cost that is disproportionate to the merits" of the claims that are litigated. *See id.* at 6, 11, 12 (discussing growth in "baseless claims"). Defending even *a single* class action can cost a business nine figures. *See* Adeola Adele, *Dukes v. Wal-Mart*: Implications for Employment Practices Liability Insurance 1 (July 2011). And those cases can persist for years with no resolution of even the threshold class certification issues, leaving businesses in a state of uncertainty. *See* U.S. Chamber Inst. for Legal Reform, Do Class Actions Benefit Class Members? An Empirical Analysis of Class Actions, at 1, 5 (Dec. 2013), *available at* http://bit.ly/3rrHd29 (noting that "[a]pproximately 14 percent of all class action cases remained pending four years after they were filed").

The massive exposure created by class certification—especially when the certified class includes large numbers of uninjured members—creates immense pressure for defendants to settle. *See* Henry J. Friendly, Federal Jurisdiction: A General View 120 (1973) (recognizing the risk of "blackmail settlements"); *see also Shady Grove Orthopedic Assocs. P.A., v. Allstate Ins. Co.*, 559 U.S. 393, 445 n.3 (2010) (Ginsburg, J., dissenting)

(noting that when "a class action poses the risk of massive liability unmoored to actual injury," the "pressure to settle may be heightened"). "With vanishingly rare exception[s], class certification sets the litigation on a path toward resolution by way of settlement, not full-fledged testing of the plaintiffs' case by trial." Richard A. Nagareda, *Class Certification in the Age of Aggregate Proof*, 84 N.Y.U. L. Rev. 97, 99 (2009). Class certification inflicts "hydraulic pressure" on defendants to settle because it threatens them with the possibility of losing many cases all at once. *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 165, 167 & n.8 (3d Cir.), *as amended* (Oct. 16, 2001). And those pressures increase when plaintiffs obtain certification of a class inflated by uninjured class members.

As the Supreme Court has recognized, class actions can "unfairly place pressure on the defendant to settle *even unmeritorious* claims." *Epic Sys. Corp. v. Lewis*, 584 U.S. 497, 524 (2018) (emphasis added) (cleaned up); Fed. R. Civ. P. 23 advisory committee's note to 1998 amendment (defendants may "settle rather than incur the costs of defending a class action and run the risk of potentially ruinous liability"); *see also AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 350 (2011)

(noting "the risk of 'in terrorem' settlements that class actions entail"). Indeed, the pressure exists even when the outcome is likely to be favorable for defendants. *See Coopers & Lybrand v. Livesay*, 437 U.S. 463, 476 (1978); *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 740 (1975). That is particularly true in cases where the need for class-action litigation is most attenuated because they advance RICO or other similar claims that pose the threat of treble damages. *Concepcion*, 563 U.S. at 350 (noting that "[f]aced with even a small chance of a devastating loss, defendants will be pressured into settling questionable claims").

The district court's lenient approach ignores these pressures, which may force defendants to settle with a sprawling class that includes individuals and entities who suffered no injury and thus have no claim. The resulting economic distortions would harm not just defendants, but also the consumers who end up bearing the costs of litigation (and litigation avoidance) in the form of higher prices. *See* Joseph A. Grundfest, *Why Disimply?*, 108 Harv. L. Rev. 727, 732 (1995). There is no reason this Court should permit this case to proceed as a class action.

CONCLUSION

This Court should reverse the class certification order.

Respectfully submitted,

/s/ *Ashley C. Parrish*

Jennifer B. Dickey
Jordan L. Von Bokern
U.S. CHAMBER
LITIGATION CENTER
1615 H Street NW
Washington, DC 20062

Ashley C. Parrish
KING & SPALDING LLP
1700 Pennsylvania Avenue NW
Washington, DC 20006
(202) 737-0500
aparrish@kslaw.com

Keri E. Borders
King & Spalding LLP
633 West Fifth Street
Suite 1600
Los Angeles, CA 90071

Counsel for Amicus Curiae
the Chamber of Commerce of the United States of America

Date: January 26, 2024

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) because it contains 3,569 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

The brief's type size and typeface comply with Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point size.

Date: January 26, 2024

/s/ *Ashley C. Parrish*
Ashley C. Parrish

Counsel for amicus curiae
the Chamber of Commerce
of the United States of America