NO. 25-625

In the
Supreme Court of the United States

TAKEDA PHARMACEUTICAL COMPANY LIMITED, a Japanese Corporation, *et al.*,
Petitioners,

v.

PAINTERS & ALLIED TRADES DISTRICT COUNCIL 82 HEALTH CARE FUND, *et al.*,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF FOR THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

Jennifer B. Dickey
Audrey Dos Santos
U.S. CHAMBER LITIGATION CENTER
1615 H Street NW
Washington, DC 20062

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

Ashley C. Parrish
Counsel of Record
Christine M. Carletta
Megan Michur
KING & SPALDING LLP
1700 Pennsylvania Ave. NW
Washington, DC 20006
(202) 737-0500
aparrish@kslaw.com

Counsel for Amici Curiae

(Additional counsel listed on inside cover)

January 2, 2026

James C. Stansel
Melissa B. Kimmel
Julie Straus Harris
PhRMA
670 Maine Avenue SW
Suite 1000
Washington, DC 20024

Counsel for Amicus Curiae
Pharmaceutical Research
and Manufacturers of America

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STATEMENT OF INTEREST[1]

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than 3 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 Pharmaceutical Research and Manufacturers of America ("PhRMA") represents the country's leading innovative biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a healthier world. Together, PhRMA's members are fighting for solutions to ensure patients can access and afford medicines that prevent, treat, and cure disease. PhRMA member companies have invested more than $850 billion in the search for new treatments and

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[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for any party authored this brief in whole or in part and that no entity or person, aside from *amici curiae*, their members, or their counsel, made any monetary contribution toward the preparation or submission of this brief. Counsel of record for all parties received notice at least 10 days prior to the due date of the intention of *amici* to file this brief.

cures over the last decade, supporting nearly five million jobs in the United States.

Both the Chamber's and PhRMA'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, they have 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. Those interests are only heightened in cases where, as in this case, plaintiffs seek billions of dollars in damages pursuant to the Racketeer Influenced and Corrupt Organizations Act ("RICO").

INTRODUCTION AND SUMMARY OF ARGUMENT

This case raises an important, recurring question concerning courts' authority to deviate from Rule 23's requirements, here in a putative class action that seeks to recover billions in treble damages under RICO. Plaintiffs' novel claims are grounded on the theory that a pharmaceutical manufacturer's alleged non-disclosures caused insurance companies and other third-party payors to pay too much for, or to purchase too much of, one of its pharmaceutical products. The Court should grant certiorari because the Ninth Circuit's 2-1 decision departs from settled precedent, cannot be reconciled with this Court's instructions, and deepens a well-recognized split in circuit court authority concerning the effects uninjured class members have on class certification. The Court previously granted certiorari in *LabCorp v. Davis* to answer one of the questions presented, and

this case offers a new and opportune vehicle to resolve it.

The Court should grant review because, contrary to Rule 23's requirements, the Ninth Circuit improperly affirmed certification of the class, even though it contains potentially thousands of uninjured class members and, as a result, includes claims of absent class members who do not have standing. The Ninth Circuit acknowledged that neither plaintiffs nor the district court identified an appropriate mechanism for removing uninjured parties from the class. Its suggestion that there might nonetheless be an unidentified yet "obvious strategy" for ascertaining some uninjured parties, and its view that thousands of uninjured class members are insignificant because they make up only a small percentage of the class, conflicts with precedent.

The Court should also grant review because the decision below affirms a first-of-its-kind class action based on a disputed market-share extrapolation that relies on generalized assumptions about causation and injury. In taking that approach, the court of appeals permitted the trial court to accept plaintiffs' expert analysis "at face value" and faulted defendants for purportedly not proving that individualized issues predominate over common ones. But it is plaintiffs' burden to justify class certification. *See Halliburton Co. v. Erica P. John Fund, Inc.*, 573 U.S. 258, 276 (2014). Plaintiffs have not demonstrated that they can prove reliance, causation, and injury on a class-wide basis, and they should not be permitted to avoid those essential showings by dressing their individualized

claims in the guise of a novel fraud-on-the-market theory.

The Ninth Circuit's permissive approach imposes sweeping, unwarranted burdens on American businesses and the broader economy. It threatens manufacturers with enormous class-action exposure whenever a plaintiff alleges that purported misstatements or omissions in marketing materials or drug labeling may have resulted in additional prescriptions or higher prices. It also exacerbates the problem of courts turning a blind eye to class-action abuse. Instead of treating class actions as a carefully circumscribed exception to the ordinary rule of individual litigation, the decision below circumvents Rule 23's requirements in a way that harms businesses and consumers alike.

ARGUMENT

Rule 23 provides crucial safeguards that must be satisfied *before* the named plaintiffs in a case are permitted to take advantage of class-action procedures. *See Taylor v. Sturgell*, 553 U.S. 880, 900–01 (2008). Enforcing these requirements is essential to protect against class-action abuse and ensure that claims are suitable for resolution on a class-wide basis. *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350–51 (2011). This Court's precedents have made clear that, because damages class actions are an "exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only," courts should not certify a class unless plaintiffs carry their burden to meet all of Rule 23's requirements. *Comcast Corp. v. Behrend*, 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. Unfortunately, class-action abuse continues apace, which benefits enterprising plaintiffs and their counsel but harms businesses, consumers, and everyone else. This case presents a good vehicle for the Court to provide important guidance to lower courts faced with potentially improper class actions.

I. The Court Should Grant Review to Resolve the Issue that this Court Previously Granted Certiorari to Address in *LabCorp v. Davis.*

This Court should grant review to address the Ninth Circuit's failure to comply with this Court's precedents and the conflicts between the decision below and decisions from other courts of appeals. Despite recognizing that at least several thousand class members are unlikely to have been injured, the Ninth Circuit concluded that plaintiffs' failure to identify and remove those uninjured parties from the class did not defeat predominance. *See* App.8–9. That approach cannot be reconciled with the requirement that plaintiffs bear the burden of satisfying all of Rule 23's requirements. *See Wal-Mart*, 564 U.S. at 350–51; *Halliburton*, 573 U.S. at 276; *Comcast*, 569 U.S. at 33.

A. To litigate a case as a class action, the named plaintiffs 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). As this Court has emphasized, when named plaintiffs seek to represent the interests of an absent putative class, they must "'affirmatively demonstrate'" their compliance with Rule 23 "through evidentiary proof."

Comcast, 569 U.S. at 33; *see also Wal-Mart*, 564 U.S. at 350, 353 (noting need for "significant proof" (quoting *Gen. Tel. Co. v. Falcon*, 457 U.S. 147, 159 n.15 (1982))).

That obligation has special force when some class members lack meritorious claims, including because they have not been injured and therefore cannot satisfy Article III's essential standing requirements. As this Court has held, class actions are "restricted to litigants who can show 'injury in fact' resulting from the action which they seek to have the court adjudicate." *Valley Forge Christian Coll. v. Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 473 (1982). "Article III does not give federal courts the power to order relief to any uninjured plaintiff, class action or not." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021) (quoting *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 466 (2016) (Roberts, C.J., concurring)). Accordingly, "a federal court may not certify a damages class that includes both injured and uninjured members" because "common questions do not predominate." *Lab'y Corp. of Am. Holdings v. Davis* (*LabCorp*), 605 U.S. 327, 328 (2025) (Kavanaugh, J., dissenting from dismissal); *see Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 612–13 (1997).

Consistent with these principles, if the named plaintiffs cannot prove that putative absent class members have an injury sufficient to establish Article III standing, the case cannot proceed as a class action under Rule 23(b)(3). *See TransUnion*, 594 U.S. at 431 ("[e]very class member must have Article III standing in order to recover individual damages"). Contrary to

the Ninth Circuit's conclusions, a trial court cannot ignore these issues by noting that uninjured class members make up only a small percentage of the class or by speculating that there might be an "obvious strategy" for identifying some of the uninjured class members. *See* App.10. Before a class can be certified, courts must require (at a minimum) that the named plaintiffs identify a reasonable "winnowing mechanism" to cull meritless claims, and the process must be "robust enough to preserve the defendants' Seventh Amendment and due process rights to contest every element of liability and to present every colorable defense." *In re Rail Freight Fuel Surcharge Antitrust Litig. – MDL No. 1869*, 934 F.3d 619, 625 (D.C. Cir. 2019); *see also* App.20 (Miller, J. dissenting) ("[T]he 'absence of any winnowing mechanism' means that 'the need for individualized proof of injury and causation destroy[s] predominance.'" (quoting *Rail Freight*, 934 F.3d at 624–25)); *In re Asacol Antitrust Litig.*, 907 F.3d 42, 58 (1st Cir. 2018).

B. The Ninth Circuit's permissive approach to class certification violates basic requirements of 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). Moreover, as the petition explains, the lower court's decision deepens an existing split in authority. Other courts have correctly recognized, in conflict with the decision below, that a putative class may not be certified when it includes uninjured members and the named plaintiffs have offered no means to identify and remove them from the class. *See Johannessohn v. Polaris Indus. Inc.*, 9 F.4th 981, 987–88 (8th Cir. 2021); *Asacol*, 907 F.3d at 53–54;

Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC, 31 F.4th 651, 669 (9th Cir. 2022) (en banc).

This Court has recognized the importance of this question by granting certiorari to address it in *LabCorp v. Davis*. It dismissed that case without resolving the merits, presumably because of a mootness issue that complicated the litigation. *See* 605 U.S. at 328 (Kavanaugh, J., dissenting from dismissal). This case presents no mootness issue, and it would be a good vehicle to finally resolve this important question.

II. The Court Should Grant Review to Reenforce Limits on the Use of Representative Evidence to Secure Class Certification.

This case also offers an opportunity for this Court to provide needed guidance to the lower courts on the limits of using statistical sampling techniques to support formation of a class. Time and again, the Ninth Circuit has split with other circuits by permitting classes that suffer from individualized reliance issues to proceed based on impermissible "representative" evidence. As the petition explains, by allowing a class to be formed in such circumstances, the decision below violates *Wal-Mart, Amchem*, and *Comcast*, and it deepens a divide in lower-court authority over the meaning of those decisions.

A. This Court has made clear that a common question exists only when "the same evidence will suffice for each member to make a prima facie showing," and that no common question exists where the answer requires "evidence that varies from

member to member." *Tyson Foods*, 577 U.S. at 453 (quoting 2 William B. Rubenstein, Newberg and Rubenstein on Class Actions § 4:50 (6th ed.)). Representative or averaging evidence is permissible only if that proof "could have sustained a reasonable jury finding" as to every class member in an individual action. *Id.* at 455–56. These same principles confirm that reliance-based claims cannot be certified when the law that the defendant allegedly violated demands proof that a plaintiff received, credited, and acted upon a particular representation. Such reliance requirements pose "an insuperable barrier to class certification" because they compel an inquiry into each consumer's individualized interactions and motivations. *Wal-Mart*, 564 U.S. at 351 n.6; *Amchem*, 521 U.S. at 624.

Many of the lower courts have properly held that claims for fraud and violations of consumer-protection statutes that require a showing of reliance or causation cannot be adjudicated on a class-wide basis when different consumers are exposed to different information, at different times, and for different reasons. *McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215, 223–24 (2d Cir. 2008); *In re Ford Motor Co. E–350 Van Prods. Liab. Litig. (No. II)*, 2012 WL 379944, at *28–29 (D.N.J. Feb. 6, 2012). Courts have also rejected attempts to use generalized or aggregated proof where material variations determine liability. *See Wal-Mart*, 564 U.S. at 352–55; *Rail Freight*, 934 F.3d at 623–24.

B. In this case, plaintiffs allege that manufacturers conspired to fraudulently market a drug (Actos) by allegedly failing to provide warnings

concerning the risk of bladder cancer. But that claim, like most that rely on allegations of fraud, hinges on inherently individualized inquiries into physician prescribing decisions, which raise individualized issues of reliance, causation, 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."). As other circuits have held, the "individualized nature of physicians' prescribing decisions" defeats class certification. *See Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 92 (2d Cir. 2015); *UFCW Loc. 1776 v. Eli Lilly & Co.* (*Zyprexa*), 620 F.3d 121, 136 (2d Cir. 2010).

In cases involving physicians' ultimate prescribing decisions, class-wide proof is often impossible because those decisions are, by their very nature, "multifaceted" and "individualized." *Sergeants*, 806 F.3d at 89–90, 92. Physicians undergo years of training and study, including ongoing medical education; they consult with other doctors; they attend conferences and seminars; they consult scientific literature; and they obtain the patient's relevant clinical experience, both with the particular drug and overall medical history. Physicians thus learn about "a drug through multiple sources, only one of which might be the drug manufacturer's promotions and literature." *Ironworkers Loc. Union 68 v. AstraZeneca Pharms., LP*, 634 F.3d 1352, 1362 (11th Cir. 2011); *see Sidney Hillman Health Ctr. v. Abbott Labs.*, 873 F.3d 574, 577 (7th Cir. 2017) (explaining that physicians

change their prescribing practices based on a host of information, some of which "may have dominated over anything [the manufacturer] did"); *Zyprexa*, 620 F.3d at 135 (noting that physicians take into account numerous individualized considerations when prescribing medication). Moreover, physicians are not the only decision-makers in the causal chain, which includes (among others) pharmacy benefit managers and third-party payors, both of whose decisions affect whether a particular drug is eligible for reimbursement and therefore selected for use.

C. The complex and individualized nature of decisions to prescribe and reimburse the cost of prescription medications should have precluded class certification in this case. The certified class contains numerous third-party payors that have different formularies and reimburse prescriptions from a medley of prescribers, with each exercising diverse medical judgments with respect to unique patients who have varied diagnoses and assorted medical histories. Many doctors would have prescribed Actos to individual patients even if defendants had provided different warnings. Plaintiffs did not show on a class-wide basis that the alleged misrepresentations caused class members' alleged injuries.

Instead of recognizing that these individualized issues preclude class certification, the Ninth Circuit affirmed the district court's reliance on plaintiffs' flawed statistical model, which predicted that almost all members of the third-party-payor class would have suffered some injury. *See* App.9–10. But the district court did not weigh the conflicting evidence between plaintiffs' and defendants' respective experts, nor did

it resolve the disputes between them. App.16 (Miller, J. dissenting). In fact, 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," without ruling on defendants' contrary evidence and arguments demonstrating that plaintiffs' analysis was flawed. App.16 (Miller, J. dissenting) (quotation marks omitted).

By affirming the district court's erroneous analysis, the Ninth Circuit violated the bedrock requirement that the requisite analysis must be 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 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" (quoting Benjamin Kaplan, *Continuing Work Continuing Work of the Civil Committee: 1966 Amendments of the Federal Rules of Civil Procedure (I)*, 81 Harv. L. Rev. 356, 390 (1967))). Contrary to the panel's mistaken suggestions, *see* App.8, *defendants* are not required to prove anything with respect to predominance. It is plaintiffs' burden to prove that discovery and trial can occur without individualized issues predominating over common issues.

III. The Court Should Grant Review Because Lower Courts' Erosion of Class-Certification Standards Inflicts Broad Harm on Businesses and Consumers.

The questions presented are important, recurring, and of great constitutional and practical significance. Nationwide class actions, like this one, often seek damages in the billions of dollars, even though many class members have never suffered actual, concrete harm. The lower court's permissive approach and refusal to apply this Court's precedents calls out for this Court's intervention.

There are "serious real-world consequences" when the lower courts take a relaxed approach to enforcing Rule 23's essential requirements. *LabCorp*, 605 U.S. at 333 (Kavanaugh, J., dissenting from dismissal). Class-action litigation in the United States imposes staggering costs on U.S. businesses and consumers. Those costs are "one of the fastest-growing areas of legal spending," with U.S. companies spending $4.21 billion — 12.5 percent of corporate litigation budgets — defending class actions in 2024 alone. *See* 2025 Carlton Fields Class Action Survey 3–6 (2025), *available at* https://tinyurl.com/474nkhvt; *see id.* at 7 (noting that claims are expected to grow another 7.6 percent in 2025). The costs are widespread — roughly 72 percent of major companies face class actions — and surging, due, in part, to an increasingly "aggressive litigation environment" with baseless class-action suits that "courts remain reluctant to dismiss." *See id.* at 8, 16 (discussing growth in "baseless claims"). And class action 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 1, 5 (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" (emphasis omitted)).

The uncertainties and costs imposed by class actions create immense pressure for businesses to agree to "settlements that they sometimes must reluctantly swallow rather than betting the company on the uncertainties of trial." *LabCorp*, 605 U.S. at 333 (Kavanaugh, J., dissenting from dismissal). That coercive pressure to settle applies even in cases, like this one, where the defendants are likely to succeed on the merits. *See Epic Sys. Corp. v. Lewis*, 584 U.S. 497, 524 (2018) (arguing that class actions can "unfairly place pressure on the defendant to settle even unmeritorious claims" (cleaned up)); *Coopers & Lybrand v. Livesay*, 437 U.S. 463, 476 (1978); *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 740 (1975); *see also* Joanna C. Schwartz, *The Cost of Suing Business*, 65 DePaul L. Rev. 655, 660 (2016) (noting that "the threat of discovery expense will push cost-conscious defendants to settle even anemic cases" (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007))). In fact, that pressure is particularly marked here because plaintiffs have advanced RICO or other similar claims that pose the threat of treble damages. *AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 350 (2011) (noting that "[f]aced with even a small chance of a devastating loss, defendants will be pressured into settling questionable claims").

This case thus exemplifies the problems that arise when lower courts improperly certify sweeping class actions as vehicles for litigating claims that are individualized and lacking in merit. The irony here is unmistakable: The district court correctly concluded that a consumer class action could not be certified because of the inherently individualized nature of the treatment and prescribing decisions made by individual patients and their physicians, yet it nonetheless permitted the claims of third-party payors to be litigated on a class-wide basis, even though their claims necessarily turn on the same individualized issues.

The costs that class-action abuse imposes on U.S. businesses are passed on to consumers in the form of higher prices; to retirement account holders in the form of lower returns; and to workers in the form of lower salaries and lesser benefits. Joseph A. Grundfest, *Why Disimply?*, 108 Harv. L. Rev. 727, 732 (1995). The Ninth Circuit's affirmation here of an "[o]verbroad and incorrectly certified class[]" harms everyone: businesses, consumers, retirees, and workers alike. *LabCorp*, 605 U.S. at 333 (Kavanaugh, J., dissenting from dismissal).

CONCLUSION

The Court should grant the petition for certiorari.

Respectfully submitted,

Jennifer B. Dickey
Audrey Dos Santos
U.S. CHAMBER LITIGATION CENTER
1615 H Street NW
Washington, DC 20062

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

Ashley C. Parrish
Counsel of Record
Christine M. Carletta
Megan Michur
KING & SPALDING LLP
1700 Pennsylvania Ave. NW
Washington, DC 20006
(202) 737-0500
aparrish@kslaw.com

Counsel for Amici Curiae

James C. Stansel
Melissa B. Kimmel
Julie Straus Harris
PhRMA
670 Maine Avenue SW
Suite 1000
Washington, DC 20024

Counsel for Amicus Curiae Pharmaceutical Research and Manufacturers of America

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