No. 25-625

In the
Supreme Court of the United States

TAKEDA PHARMACEUTICAL COMPANY LIMITED, 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

REPLY BRIEF

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Respondents do not deny that the circuits are divided over whether class certification is available when a proposed class includes members who suffered no injury and class plaintiffs offer no viable method for removing those uninjured members. Nor do respondents deny the importance of the question, which this Court has twice granted certiorari to review without answering. Instead, respondents contend that this case does not implicate that circuit-splitting and consequential issue, because (they now claim) all class members actually *were* injured here. That is revisionist history in the extreme. Both courts below assessed certification on the express assumption that thousands of absent class members suffered no harm due to petitioners' alleged misrepresentations. They did so because respondents' own pleadings make plain that thousands of class members are indeed uninjured. That the decisions below nonetheless blessed class certification confirms that the "Article III and Rule 23 principles" that are "settled" in the Ninth Circuit, BIO.1, are fundamentally at odds with this Court's teachings and the caselaw of circuits that faithfully follow them. It also confirms the need for plenary review. In short, this case plainly implicates a question that has split the circuits and justified certiorari twice before. It is time for this Court to resolve it once and for all.

The decision below also creates a second split that cries out for this Court's intervention. Once again, the Ninth Circuit is a trailblazer in all the wrong ways, allowing class plaintiffs to paper over highly individualized reliance issues via formulae. While

respondents suggest that there is nothing to see here, they cannot deny that other courts applying this Court's precedent have refused to certify classes in comparable circumstances, or that the Second Circuit refused to certify a virtually identical TPPs class precisely because the individualized reliance issues underlying it are not amenable to classwide proof.

Respondents' attempts to conjure vehicle problems are unpersuasive. Respondents highlight the interlocutory posture, but the fact that this class-certification case arises from a Rule 23(f) appeal allows this Court to focus on the class-certification issues. It also avoids post-verdict developments that sometimes complicate review of purely legal class-certification issues. Respondents quibble with petitioners' characterization of the facts, but no amount of fly-specking can change the basic realities here: The Ninth Circuit has green-lighted a class that plainly includes uninjured class members and would not move forward in other circuits. This petition provides the Court a clean opportunity to provide much-needed guidance to lower courts and bring the Ninth Circuit's class-certification and standing law back in line with this Court's teachings. The Court should grant the petition on both questions presented and reverse.

I. The Decision Below Deepens An Existing Split And Creates A New One.

A. The Circuits Are Divided Over Whether and When Courts Can Certify a Damages Class With Uninjured Members—and This Case Deepens the Split.

The circuits are deeply divided over whether (and, if so, when) federal courts may certify classes containing both injured and uninjured members. Pet.17-19. Respondents do not argue otherwise. Nor could they, as this Court has twice granted certiorari to resolve that split (but so far to no avail). *See Lab'y Corp. of Am. Holdings v. Davis*, 145 S.Ct. 1133, *dismissed as improvidently granted*, 605 U.S. 327 (2025); *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 460 (2016). Respondents also do not deny that the Ninth Circuit's approach—allowing certification even of classes that include "more than a de minimis number of uninjured class members," *Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods, LLC*, 31 F.4th 651, 669 (9th Cir. 2022) (en banc), even without a "plan to screen out" those uninjured members, Pet.App.10—is at the far end of one extreme.

Unable to deny the split, respondents claim it is not implicated here. For the first time, they assert that the class "does not include any uninjured members." BIO.20. In addition to a waiver problem, that argument has a reality problem. Both courts below analyzed class certification on the premise that at least some class members were uninjured. Pet.App.9-10, 60. They did so because respondents' own models showed that up to "two percent of class members were uninjured." Pet.App.20 (Miller, J.,

dissenting). Indeed, respondents never argued below that every class member was injured; they argued only that the uninjured members "can be identified and excluded in a way" consistent with Rule 23—albeit without identifying what that "way" is. CA9.Painters.Br.60 (capitalization altered).[1]

At any rate, respondents' belated argument does not even work, as they are not really arguing that they have structured the class to avoid any uninjured members; they are just arguing that they think each class member has a high chance of being injured. *See* BIO.20. That does not begin to establish that every class member was in fact injured. To the contrary, even accepting respondents' (dubious) claim that each class member had a 98.5% probability of injury, applying that figure to the hundreds of thousands of class members—many of which were small plans that would have paid for only a small number of prescriptions—means that thousands of class members were uninjured. *See* CA9.ER.367 n.112.

Perhaps sensing the flaws in their late-breaking argument, respondents try to shift the blame. According to respondents, petitioners should have deposed all those hundreds of thousands of TPPs to determine which ones were injured before challenging class certification or the court's jurisdiction. BIO.22-23. That is backwards. *Plaintiffs* bear the burden to establish standing, *TransUnion LLC v. Ramirez*, 594

[1] Of course, the Ninth Circuit relieved respondents of any burden to do so before certifying a class, holding that "there is no need for a trial plan to screen out the (at most) 1.5%." Pet.App.10. That makes the need for this Court's intervention all the more pressing. *See* Pet.27.

U.S. 413, 430-31 (2021), and to "affirmatively demonstrate" that the class they seek to certify complies with Rule 23, *Comcast Corp. v. Behrend*, 569 U.S. 27, 33-34 (2013). It was therefore on respondents to prove that every class member seeking to recover damages has standing—or, failing that, to provide a winnowing mechanism that will permit the district court to remove uninjured members while avoiding individualized issues. Respondents have not done the former, and while they claim they *could* do the latter, the Ninth Circuit squarely held that they need not come up with any "plan" to do so in advance. Pet.App.10; *see* Pet.24-27. This case thus not only implicates the split, but starkly illustrates why this Court must resolve it.

B. The Decision Below Creates Another Circuit Split on Whether a Class Can Show Individualized Reliance Via General Proof.

Faced with a class pressing nearly indistinguishable fraud-on-the-market claims, the Second Circuit held that the claims were not susceptible to classwide proof because they depend on "the independent actions of prescribing physicians," who consider various factors such as a patient's medical history and the physician's "own experience with prescribing" the medicine. *UFCW Loc. 1776 v. Eli Lilly & Co. (Zyprexa)*, 620 F.3d 121, 135 (2d Cir. 2010); Pet.20-22. Other circuits have likewise refused to certify classes raising claims that similarly require member-by-member proof of reliance. Pet.22-23. The Ninth Circuit, by contrast, papered over those issues and allowed the TPPs class to proceed. Pet.23-24.

Respondents contend that different facts, not different approaches to Rule 23, explain those divergent outcomes. BIO.26-32. But respondents did not present novel or more persuasive common evidence than the plaintiffs in *Zyprexa* and *Sergeants Benevolent Association Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71 (2d Cir. 2015). And this is not a case in which physician-prescribing decisions were based only on marketing campaigns. On the contrary, as Judge Miller explained in his dissent (and as the majority did not dispute), "the record shows that individualized prescribing decisions" were *not* uniformly influenced by alleged fraud. Pet.App.25. The Ninth Circuit—which did not disturb the district court's refusal to certify a patients class founded on the exact same fraud allegations—blessed this class simply because it is composed of TPPs rather than patients. Pet.24.

Contra BIO.28, the Second and Ninth Circuits do not agree that "a TPP can establish but-for causation in a quantity effect pharmaceutical RICO case using a combination of regression and persuasive common evidence." To be sure, the Second Circuit has suggested that there may be outlier cases in which physicians "faced 'the same more-or-less one-dimensional decisionmaking process,' such that the alleged misrepresentation would have been 'essentially determinative' for each plaintiff." *Sergeants*, 806 F.3d at 88. But it has never suggested that most (or even some) RICO fraud-on-the-market cases like this one fit that description. On the contrary, when faced with RICO claims requiring proof of individual reliance, the Second Circuit has

refused to certify. *Zyprexa*, 620 F.3d at 135-36; *Sergeants*, 806 F.3d at 90-91.

Respondents briefly suggest that the First Circuit has endorsed the Ninth Circuit's approach, BIO.28, but none of the cases they cite ruled on the Rule 23(b) questions at issue. In contrast, *In re Asacol Antitrust Litigation*, 907 F.3d 42 (1st Cir. 2018), explicitly did—and, as explained in the petition, *Asacol* is irreconcilable with the decision below. The First Circuit there reversed certification of a class where "any class member" may fall into the uninjured bucket, because it is impossible to distinguish the injured from the uninjured absent full-blown trials and "there are apparently thousands who in fact suffered no injury." 907 F.3d at 53-54; *see* Pet.18. That fact pattern is indistinguishable from this one. Yet, unlike the First Circuit, the Ninth Circuit upheld class certification.

Shifting the level of generality, respondents try distinguish RICO and non-RICO cases. BIO.29-31. But RICO cases do not have talismanic qualities that make them unique for purposes of Rule 23. Like a plaintiff bringing a common-law fraud claim, *e.g.*, *Vogt v. Progressive Cas. Ins. Co.*, 129 F.4th 1071, 1073 (8th Cir. 2025); *see* Pet.22, RICO plaintiffs must prove that the alleged fraud was both the but-for and the proximate cause of their injuries. And while RICO does not require *first*-party reliance, plaintiffs "will not be able to establish even but-for causation if no one relied on the" purported fraud. *Bridge v. Phx. Bond & Indem. Co.*, 553 U.S. 639, 658 (2008). So, just like a plaintiff seeking certification of a consumer-fraud class, as in *Speerly v. General Motors, LLC*, 143 F.4th

306 (6th Cir. 2025) (en banc); *see* Pet.22-23, respondents needed to show individual reliance—i.e., that each physician who filled an Actos prescription relied on the alleged fraud, not something else like the availability of alternatives. Because litigants cannot do so without hundreds of thousands of mini- (or full-blown) trials, courts routinely refuse to certify such classes. Pet.20-23. Only the Ninth Circuit gives them a rubber stamp. That conflict cries out for this Court's resolution.

II. The Decision Below Contravenes Article III, Rule 23, And This Court's Precedents.

A. A Damages Class Cannot Be Certified When There Is No Common Way to Tell Whether Every Member Was Injured.

The decision below cannot be squared with basic principles of Article III or Rule 23. Article III requires each plaintiff to establish standing to pursue each claim pressed and each form of relief sought. *See TransUnion*, 594 U.S. at 431; *Town of Chester v. Laroe Ests., Inc.*, 581 U.S. 433, 440 (2017). Rule 23(a)'s commonality requirement requires putative class plaintiffs to show that all members of the class "have suffered the same injury." *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 349-50 (2011). And if putative class plaintiffs cannot make that showing, then it will be all but impossible to satisfy Rule 23(b)'s "far more demanding" predominance standard. *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 624 (1997).

This class falls short on all fronts. Pet.24-27. As explained, this class contains potentially thousands of uninjured members who lack standing to recover. Given that a class containing both injured and

uninjured members "does not meet [Rule 23's predominance] requirement," the fact that the percentage may be small is of no event. *Lab'y Corp.*, 605 U.S. at 332 (Kavanaugh, J., dissenting).

What is more, respondents have not put forward a feasible mechanism for determining which class members were actually injured, and the Ninth Circuit expressly held that they were not required to do so. Pet.App.10. There is thus no way to know whether a court will *ever* be able to determine which members' claims actually belong in federal court. Quite the opposite: There is every indication that the only way to identify and exclude the uninjured would be to conduct thousands and thousands of mini (or full-blown) trials in which "members of a proposed class will need to present evidence that varies from member to member." *Tyson Foods*, 577 U.S. at 453.

Respondents assert that their evidence shows that "each class member, more likely than not, has Article III standing." BIO.32. That submission underscores the problem. Merely showing that it is "more likely than not" that someone in the class was injured, or even that there is a high chance that most class members were injured, is not enough. To recover damages, a plaintiff must prove that he *himself* was "actual[ly]" injured, *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992), as damages are meant to compensate for harms that are actually realized. *Cf. TransUnion*, 594 U.S. at 435-36. Here, however, while respondents arguably have shown that it is "more likely than not" that most class members suffered some injury, they provided no way of determining which class members fit into the injured vs. uninjured bucket. The Ninth

Circuit thought that sufficed, but by that logic, courts may award a recovery to 100% of a class based only on a showing that on average each class member has a 51% probability of injury. Article III and Rule 23 demand far more. *See Asacol*, 907 F.3d at 55-56; WLF.Amicus.Br.7-12.

Respondents alternatively contend that they *have* proposed a mechanism for removing uninjured class members, namely, the five-independent-prescriptions proviso. BIO.32. But the Ninth Circuit did not accept that argument, and for good reason: Respondents have no common proof of which prescriptions were truly "independent" of each other. And even setting aside the flaws with that "mechanism," it does nothing to solve the basic problem: While that proviso may make it more likely that *many* class members were injured, it does not show which ones were and were not. Respondents cannot make that showing without putting on evidence from the hundreds of thousands of physicians who prescribed Actos, thereby swamping any common issues present in the case.

B. A Class Cannot Convert Reliance Into a Common Issue by Supplying Generic Evidence of Its Statistical Likelihood.

Like the Ninth Circuit, respondents insist that this case can be resolved based on common evidence. BIO.33-35. That is wrong. As the district court acknowledged, the consumers class could not be certified because "a muddled mix of common and individualized evidence would be needed to resolve the elements of causation and reliance." Pet.App.85. Contrary to what the district court and the Ninth Circuit seemed to think, those problems do not vanish

simply because this class is composed of TPPs instead of consumers. If anything, going up the drug-prescription ladder to the TPPs *increases* the number of variables that make proof of reliance on a classwide basis all but impossible. *See* Chamber.Amicus.Br.11.

Respondents' own expert report—the supposedly "robust eviden[ce]" supporting certification, BIO.33—underscores the problem. The report indicated that over 40% of Actos prescriptions filled during the proposed class period would have been written irrespective of the alleged misrepresentations. *See* Pet.App.59. Yet nothing in that report or elsewhere identifies a common method for determining which prescriptions *were* the product of reliance, let alone which TPPs paid for them. To do so, the court would have to probe the hundreds of thousands of prescribing decisions underlying the TPPs' reimbursements.

In essence, respondents are trying to paper over inherently individual reliance issues by positing that there is a high likelihood that *someone* was injured by the alleged misrepresentations. But the question is not whether *someone*—or even most class members—was injured; it is whether there is a viable way to determine which class members were *not*. Because respondents have failed to show that there is, this class cannot meet Rule 23's requirements for the same reasons the class in *Walmart* could not. Pet.29-30. No amount of creative pleading can make it otherwise.

III. This Case Is An Excellent Vehicle To Resolve These Exceptionally Important Issues.

Respondents do not deny the importance of the questions presented. And their efforts to conjure

vehicle problems backfire. There is no serious prospect that the Ninth Circuit will suddenly abandon its nearly decade-old approach to class certification. *Contra* BIO.25. And while respondents emphasize that this case arises in an "interlocutory posture" under Rule 23(f), BIO.24, that is feature, not a bug: It means that this case cleanly presents the class-certification issues and is unburdened by post-verdict issues. Certainly no vehicle problems prevented Judge Miller from pointing out the legal errors in the majority's approach.

In a footnote, respondents mention a motion for summary judgment that the district court stayed at respondents' request pending the Ninth Circuit's disposition of a different appeal. BIO.25 n.11. None of that comes anywhere close to creating a vehicle problem—especially when respondents have not identified any "unresolved factual questions" that would make a difference here, *Kennedy v. Bremerton Sch. Dist.*, 139 S.Ct. 634, 635 (2019) (Alito, J., respecting the denial of certiorari). To be sure, delay may be useful for a plaintiff seeking to sneak uninjured members into a class to extract settlements or drive up verdicts that are difficult to "reverse engineer" on appeal. *Tyson Foods*, 577 U.S. at 464 (Roberts, C.J., concurring). But the whole point of Rule 23(f) was to avoid such pressures and give appellate courts a chance to provide clarity on the legal issues surrounding class certification. The Ninth Circuit is in desperate need of clarity and correction.

CONCLUSION

The Court should grant the petition.

Respectfully submitted,

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