No. 23-80051

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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

Plaintiffs-Respondents,

v.

TAKEDA PHARMACEUTICAL COMPANY LIMITED, *et al.*,

Defendants-Petitioners.

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

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* SUPPORTING PETITIONERS AND RULE 23(f) LEAVE TO APPEAL

Cory L. Andrews
John M. Masslon II
WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Ave., NW
Washington, DC 20036

Charles S. Dameron
Joseph E. Begun
LATHAM & WATKINS LLP
555 Eleventh Street, NW
Suite 1000
Washington, DC 20004
Telephone: (202) 637-2200
Facsimile: (202) 637-2201
charles.dameron@lw.com

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Counsel for Amicus Curiae *Washington Legal Foundation*

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INTEREST OF *AMICUS CURIAE*[*]

Washington Legal Foundation (WLF) is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. For decades, WLF has appeared as an *amicus curiae* in significant class-certification cases in order to combat attempts to abuse Rule 23. *See, e.g.*, *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190 (2021); *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338 (2011).

INTRODUCTION AND SUMMARY OF ARGUMENT

Some cases are well suited for class adjudication under Rule 23. This case is not one of them.

This case concerns allegations that two pharmaceutical manufacturers, Takeda and Eli Lilly, induced diabetes patients and third-party payors (TPPs) to pay for more prescriptions for a popular diabetes drug (Actos) than they would have if they had known of an allegedly elevated risk of bladder cancer in some patients. As the plaintiffs see it, if that alleged risk had been properly disclosed, doctors would have written fewer Actos prescriptions, and the patients and TPPs would have spent less money on Actos. But the parties agree that even *with* the disclosure, many patients' physicians would have continued to prescribe Actos. Thus, the plaintiffs'

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[*] No party's counsel authored any part of this brief. No one, apart from WLF and its counsel, contributed money intended to fund this brief's preparation or submission.

key evidentiary problem is how to distinguish those Actos prescriptions that *would have been* written despite such disclosure from those that *would not have been* written because of that disclosure. And, as the district court itself recognized, making that distinction entails an individualized inquiry into the medical factors relevant to each patient's prescription.

As the district court also recognized, the need for individualized "physician-patient" inquiries makes certifying a class of Actos *patients* impracticable. Pet. Ex. A at 35. Yet the court nevertheless certified a sweeping class comprising *every TPP in the country* that paid for five or more Actos prescriptions between 1999 and 2010. That decision rested on two manifest errors that contravene the basic premises of Rule 23 and warrant this Court's immediate review.

The first error is the district court's conclusion that the key question at issue here—which Actos prescriptions would not have been filled if the alleged risk of bladder cancer had been more fully disclosed?—may be answered mainly through common evidence, at least in resolving the TPP claims. But the TPP claims rise and fall with the individual patients' claims. As the district court correctly recognized, those individual patients' claims will be resolved largely through individualized evidence. So will the TPP claims.

The district court's second, independent error was its suggestion that whether individualized questions will predominate over common ones comes down to the

"tally" or "quantum" of individualized evidence in the record *at the class-certification stage*. Pet. Ex. A at 29, 36 n.146. That approach finds no footing in Rule 23. Indeed, the whole point of the class-certification inquiry in Rule 23(b)(3) cases is to scrutinize whether class adjudication will entail the costly preparation of individualized proof. Demanding a cumbersome presentation of that same proof before a class has even been certified is self-defeating.

The district court's clear misapplication of Rule 23 in this $7 billion case warrants this Court's review. The petition should be granted.

ARGUMENT

I. RESOLUTION OF THE PLAINTIFFS' CLAIMS WILL TURN ON INDIVIDUALIZED PROOF.

Class actions are an "exception to the usual rule" of individualized adjudication. *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 348 (2011) (quoting *Califano v. Yamasaki*, 442 U.S. 682, 700 (1979)). They are "peculiarly appropriate" when the "issues involved [in the case] are common to the class as a whole," and it is "unlikely that differences in the factual background of each claim will affect the outcome of the legal issue." *Califano*, 442 U.S. at 701. In those cases, "the class-action device saves the resources of both the courts and the parties by permitting an issue potentially affecting every [class member] to be litigated in an economical fashion." *Id.* Thus, Rule 23(b)(3) calls for class adjudication only where the "questions of law or fact common to class members predominate over any questions

affecting only individual members." Fed. R. Civ. P. 23(b)(3). For only in those cases will class adjudication of individual damages claims prove "convenient." *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 615 (1997) (quoting Fed. R. Civ. P. 23 advisory committee's notes to 1966 Amendment). As the Supreme Court has emphasized, class adjudication makes sense only in cases where a court will be able to resolve the issues "central to the validity of each one of the [individual] claims in one stroke." *Wal-Mart*, 564 U.S. at 350.

Consider a securities case premised on a "fraud-on-the-market" theory of liability. *See, e.g.*, *Erica P. John Fund, Inc. v. Halliburton Co.*, 563 U.S. 804 (2011). Such a theory rests on the legal presumption that a public, material misrepresentation about a security will be reflected in the security's price, and that *any* investor who trades in the market will rely on the security's price as an unbiased assessment of that security's value. *Id.* at 811. But for that presumption, class litigation of such securities fraud would be impossible, "since individual issues" of reliance would "overwhelm[ ] the common" issues in the case. *Id.* at 810 (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 242 (1988)). The presumption allows the issue of reliance to be litigated on a class-wide basis, making it possible to resolve class members' claims in a single stroke. *Id.*

That is not true here. As the district court recognized, the claims at issue in this case turn on a question about what physicians who prescribed Actos (and the

diabetes patients who took it) *would have done* if Actos's label had warned of alleged bladder-cancer risks. Pet. Ex. A at 35. The district court held that there can be no presumption that physicians would have stopped prescribing Actos in the face of such a warning; indeed, the plaintiffs' own expert concluded that over 40% of Actos purchases would have been made even if Actos had carried that warning. *Id.* at 36-37. Further, the district court recognized that the inquiry into *which* patients would have dropped Actos is "highly individualized" because some alternative "medicines and treatment regimens would be ineffective" and "some patients would have no . . . option other than Actos, notwithstanding the bladder cancer risks." *Id.* at 35. That inquiry "necessarily reside[s] with the [individual] patients and their physicians." *Id.* Thus, the district court correctly concluded that a class of Actos patients was impossible because "individualized questions of fact [would] predominate" in any litigation. *Id.* at 37.

Yet the district court still certified a nationwide class of TPPs that reimbursed those individual patients' prescriptions. In support of that result, the district court determined that expert regression analysis—combined with "direct evidence of internal company emails, marketing studies, and other testimony," *id.* at 24—might establish that some patients would have switched away from Actos (and thus that some TPPs paid for surplus Actos prescriptions) thus establishing through common evidence "but-for causation . . . for a single TPP or even for a class of them." *Id.* at

26. At the same time, however, the district court recognized that it is "an open question whether a class of TPPs may successfully leverage common evidence of the kind offered here . . . without running into the need for individualized analysis—or, at least, without running into so much individualized analysis that individual questions of fact begin to overwhelm the common ones." *Id.* And it further recognized that "Takeda or Lilly could . . . depose individual prescribing physicians to contest Plaintiffs' theory of but-for causation," and that "such evidence would constitute individualized evidence" leading to "individualized factual determinations [that] would swamp common ones." *Id.* at 27.

The district court's reasoning is at war with itself. The district court, having recognized that individual patients' claims would require individualized "physician-patient" inquiries, *id.* at 35, and having recognized that the same inquiries were likely to loom large in any claims brought by the TPPs, *id.* at 27, should have logically concluded that such claims cannot be adjudicated on a class-wide basis. The purpose of the class-action device is to enable the "convenient" adjudication of multiple claims simultaneously, *Amchem Prods.*, 521 U.S. at 615 (citation omitted), and there is nothing convenient about deposing innumerable physicians to test the individual claims of thousands (or even hundreds of thousands) of TPPs en masse. Once the district court recognized the "real and significant risk" of such individualized

adjudication, the decision to deny the class-certification motion should have been straightforward. Pet. Ex. A at 27.

As the petitioners argue, the Second Circuit reached just that result on similar facts in *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010). There, the Second Circuit correctly held that TPP class plaintiffs could not rest their overpayment claims on generalized proof "when individual physicians prescribing Zyprexa may have relied on Lilly's alleged misrepresentations to different degrees, or not at all . . . [and] when different TPPs may have paid for different 'excess' quantities of prescriptions." *Id.* at 136. Because—as the district court itself acknowledged—individualized evidence about the decisions of prescribing physicians could dominate the adjudication of the claims here, they should be adjudicated on an individualized basis. The district court's contrary decision was "manifestly erroneous," and warrants immediate review. *Chamberlan v. Ford Motor Co.*, 402 F.3d 952, 959 (9th Cir. 2005).

II. THE DISTRICT COURT'S CLASS-CERTIFICATION ANALYSIS WAS CLEARLY WRONG.

The district court not only reached the wrong conclusion; it did so through a class-certification analysis that is indefensible, and that—if uncorrected—could generate recurring problems for the class-certification process in other cases.

At class certification, the district court's basic responsibility is to "com[e] to rest on the certification question" following "a rigorous analysis" as to whether the

requirements of Rule 23 are satisfied. *Wal-Mart*, 564 U.S. at 350-51 (quoting *Gen. Tel. Co. of the Sw. v. Falcon*, 457 U.S. 147, 160-61 (1982)). And, in coming to rest in *favor* of class certification, a district court must find that the "party seeking class certification" has "affirmatively demonstrate[d] his compliance with the Rule." *Id.* at 350. Thus, where a party opposing class certification has credibly "summon[ed] the spectre of class-member-by-class-member adjudication," the district court "must determine" whether the party seeking certification has proven that "class-member-by-class-member assessment of the individualized issue will be unnecessary or workable." *Van v. LLR, Inc.*, 61 F.4th 1053, 1069 (9th Cir. 2023).

The district court never made that determination. As noted above, the district court expressly recognized the "real and significant risk [ ] that individualized factual determinations would swamp common ones" in this case. Pet. Ex. A at 27. But it held that it was "premature" to investigate that risk because the extent of individualized evidence was "not clear" from the class-certification record. *Id.* at 28. Instead, it simply waved away the "spectre of class-member-by-class-member adjudication," *Van*, 61 F.4th at 1069, by classifying as "conjecture" and "speculat[ion]" the possibility that Takeda and Lilly would call individual physicians to make their case at trial, Pet. Ex. A at 29. In the district court's view, that risk could safely be ignored because Takeda and Lilly had presented excerpts from only two individual prescribing physicians' depositions at the class-certification stage.

Id. at 29. Thus, the district court assumed that "if the trial was held today," *only* those two physicians would be presented as witnesses, and "individualized issues would not predominate." *Id.*

That assumption was error. Indeed, as the petitioners have argued, it is the same error that caused this Court to grant Rule 23(f) review and reverse in *Van*. There, as here, the district court assumed that because the defendant had presented individualized evidence at the class-certification stage as to only a "de minim[i]s" number of class members, class certification was appropriate. *Van*, 61 F.4th at 1068. But as this Court recognized, that analysis rested on a basic "misunderstanding of the Rule 23 inquiry," since the defendant's invocation of even "a small number" of individualized proofs sufficed to show "that an inquiry into the [individualized] circumstances" of each class member "might be necessary." *Id.* at 1068-69. The same is true here: Takeda and Lilly had only to introduce a few prescribing physicians' depositions at the class-certification stage to show that the collection and presentation of such individualized evidence could overwhelm the proceedings after class certification.

Indeed, if the district court's analysis were to prevail, it would defeat the whole point of the predominance inquiry at the class-certification stage, which is meant to weed out putative class actions that cannot be "efficiently" adjudicated on a class basis because "questions of law or fact common to class members" do not

"predominate over any questions affecting only individual members." Fed. R. Civ. P. 23(b)(3). It cannot be that the only way of establishing that class adjudication would be inefficient is by inefficiently submitting countless pieces of individualized evidence. Such an approach would only increase the delays and costs attendant to a form of proceeding that is supposed to facilitate the "convenient" litigation of multiple claims. *Amchem Prods.*, 521 U.S. at 615 (citation omitted). This Court should grant the petition and reverse to reaffirm the common-sense proposition that a sampling of individualized evidence may suffice to show that individualized issues will predominate over common issues.

* * *

Class actions are the exception rather than the rule because "[h]owever convenient class suits may be," they entail a substantial departure from the ordinary principles of litigation. Zechariah Chafee, Jr., *Some Problems of Equity* 203 (1950); *see also, e.g.*, *Taylor v. Sturgell*, 553 U.S. 880, 884 (2008). Where a case requiring a high degree of individualized adjudication is certified as a class action, it is not merely inconvenient. It also threatens the rights of the parties and the absent class members, whose chance to fully and fairly litigate the individual claims is severely diminished. That is especially so where, as here, the sheer size of a potential damages verdict (here, up to $7 billion) would force most defendants "to settle without relation to the merits of the class's claims." *Chamberlan*, 402 F.3d at 960

(quoting *In re Lorazepam & Clorazepate Antitrust Litig.*, 289 F.3d 98, 108 (D.C. Cir. 2002)). Rule 23(f) provides the only effective mechanism for protecting the parties' procedural rights in such an instance.

Rule 23(f) was built precisely for cases like this one. *See id.* This Court's review is warranted.

CONCLUSION

The petition for permission to appeal should be granted.

June 14, 2023

Respectfully submitted,

s/ Charles S. Dameron

Cory L. Andrews
John M. Masslon II
WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Ave., NW
Washington, DC 20036

Charles S. Dameron
Joseph E. Begun
LATHAM & WATKINS LLP
555 Eleventh Street, NW
Suite 1000
Washington, DC 20004
Telephone: (202) 637-2200
Facsimile: (202) 637-2201
charles.dameron@lw.com

Counsel for Amicus Curiae *Washington Legal Foundation*

CERTIFICATE OF COMPLIANCE

I certify that the foregoing Brief of the Washington Legal Foundation As *Amicus Curiae* Supporting Petitioners And Rule 23(f) Leave To Appeal complies with type-volume limits because, excluding the parts of the document exempted by Fed. R. App. R. 32(f), the brief contains 2,439 words, and is proportionately spaced using a roman style typeface of 14-point.

s/ Charles S. Dameron
Charles S. Dameron

Counsel for Amicus Curiae *Washington Legal Foundation*