

No. 26-606

In the
United States Court of Appeals
For the Tenth Circuit

**IN RE: GENENTECH, INC., HERCEPTIN (TRASTUZUMAB)
MARKETING AND SALES PRACTICES LITIGATION**

On Fed. R. Civ. P. 23(f) Petition for Permission to Appeal from the United
States District Court for the Northern District of Oklahoma, No. 16-md-
02700, Hon. Gregory K. Frizzell

**BRIEF OF AMICI CURIAE THE CHAMBER OF COMMERCE OF
THE UNITED STATES OF AMERICA AND
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF
AMERICA IN SUPPORT OF DEFENDANT-PETITIONER'S
RULE 23(f) PETITION**

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Amici are non-profit organizations. They have no parent corporations, and no publicly held company has 10% or greater ownership in amici.

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IDENTITY AND INTEREST OF AMICI CURIAE

The Chamber of Commerce of the United States of America is the world's largest business organization. As the nation's leading advocate for business, the Chamber represents 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.

Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary nonprofit association representing the country's leading innovative biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a healthier world. PhRMA advocates for public policies to ensure patients can access and afford medicines that prevent, treat, and cure disease. PhRMA member companies have invested over \$900 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States. *See* Jocelyn Ulrich, *ICYMI: Biopharmaceutical companies in America hit new investment milestone*, PhRMA (Aug. 14, 2026),

<https://tinyurl.com/5buy8t2p>.

Amici’s members and their subsidiaries are often targeted as defendants in class actions. Amici have a significant interest in this case because the proper application of Rule 23 raises issues of immense significance not only for their members, but also for the customers, employees, and other businesses that depend on them.¹

INTRODUCTION

“In an era of frequent litigation [and] 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) (emphasis added). This case concerns a dangerous misconstruction of Circuit law on predominance that paved the way for certification of a class inflated by uninjured class members who lack Article III standing.

The order below certified a Rule 23(b)(3) class of “[a]ll persons and entities . . . who purchased and administered Herceptin 440 mg multi-dose

¹ Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(E), amici state that no counsel for any party authored this brief in whole or in part and no entity or person, aside from amici curiae, their members, or their counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

vials” sold by Genentech in the United States over an approximately 20-year period. Order 45. The order certified the class on the theory “that Genentech materially misrepresented the Herceptin vial contents by labeling the vials as containing 440 mg of trastuzumab when they did not.” Order 36. Plaintiffs’ claimed injury is the receipt of “underfilled . . . vials,” or put differently, “payment for trastuzumab not actually received.” Order 33–34.

A critical problem is that “undisputed evidence” shows that vial samples were indeed filled with 440 mg or more of trastuzumab “throughout the proposed Class Period.” Order 33; *see* Doc. 762 at 36–37.² That is, many vials indisputably inflicted no injury on anyone, and many class members never received an underfilled vial nor a misrepresentation. Neither the district court nor Plaintiffs identified any workable method for identifying underfilled vials or which class members received them.³ Instead, the district court—relying principally on this Court’s decision in *Black v. Occidental Petroleum Corp.*, 69 F.4th 1161 (10th Cir. 2023)—cursorily

² All citations to the docket use the page numbers generated by CM/ECF.

³ The district court rejected Plaintiffs’ proposed models to show classwide injury, leaving Plaintiffs to prove injury by showing that class members individually purchased underfilled vials. *See* Order 33–35.

concluded that “the potential for uninjured plaintiffs” does not “destroy predominance.” Order 32.

This Court should grant Genentech’s petition to correct that manifest and consequential error before it goes to seed. The Court should clarify that the presence of uninjured class members can—and here, does—defeat predominance where there is no viable plan to winnow them out. *See Vallario v. Vandehey*, 554 F.3d 1259, 1263 (10th Cir. 2009) (explaining that Rule 23(f) review is appropriate where it is needed to “facilitat[e] the development of the law” and correct “manifestly erroneous” decisions).

ARGUMENT

I. The petition presents an ideal opportunity to clarify when a winnowing mechanism is necessary to establish predominance.

Class certification is such a momentous event that courts must apply a “rigorous analysis” to the requirements of Rule 23. *Comcast Corp. v. Behrend*, 569 U.S. 27, 35 (2013). That analysis includes a “‘close look’ at whether common questions predominate over individual ones” under Rule 23(b)(3). *Id.* at 34. Here, many class members were not injured. Whatever other problems the presence of uninjured class members creates, *see Lab’y Corp. of Am. Holdings v. Davis*, 605 U.S. 327, 332–34 (2025) (Kavanaugh, J., dissenting

from dismissal as improvidently granted), establishing predominance requires at least a workable plan to winnow out the uninjured. This Court should grant Genentech’s petition to make that requirement clear.

A. Rule 23 demands rigorous analysis of its prerequisites.

The Supreme Court admonishes district courts to “conduct a ‘rigorous analysis’ to determine whether” a proposed class satisfies Rule 23. *Comcast*, 569 U.S. at 35 (citing *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 351 (2011)). Chief among Rule 23’s requirements is that damages class representatives “affirmatively demonstrate” that common questions predominate over individual ones. *Id.* at 33 (quoting *Wal-Mart*, 564 U.S. at 350). This “demanding” predominance requirement ensures that “proposed classes are sufficiently cohesive to warrant adjudication by representation.” *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 623–24 (1997).

To satisfy predominance, plaintiffs must offer “a theory of liability that is . . . capable of classwide proof.” *Comcast*, 569 U.S. at 37. Otherwise, a liability finding about a named plaintiff cannot determine “in one stroke” whether defendants are liable to the entire class, and liability cannot be a “common” issue. *Wal-Mart*, 564 U.S. at 350. Plaintiffs must *prove* — not just

allege—that their claims “in fact” can be litigated on a classwide basis without individualized mini-trials. *Comcast*, 569 U.S. at 33–34.

B. Establishing predominance requires proof of a workable mechanism to winnow out uninjured putative class members.

The need for rigorous analysis is acute where a defendant “provide[s] evidence that at least some class members lack meritorious claims . . . thus summoning the spectre of class-member-by-class-member adjudication.” *Van v. LLR, Inc.*, 61 F.4th 1053, 1069 (9th Cir. 2023).⁴ In that scenario, “the district court must determine . . . whether a class-member-by-class-member assessment of the individualized issue will be unnecessary or workable.” *Id.* That determination requires a “winnowing mechanism” to cull those meritless claims. *Rail Freight*, 934 F.3d at 625. The “winnowing mechanism must be truncated enough to ensure that the common issues predominate, yet robust enough to preserve the defendants’ Seventh Amendment and due

⁴ See also *In re Rail Freight Fuel Surcharge Antitrust Litig.*, 934 F.3d 619, 624 (D.C. Cir. 2019) (for class members who “cannot prevail on the merits,” their “claims must be winnowed away as part of the liability determination”); cf. *Wallace B. Roderick Revocable Living Tr. v. XTO Energy, Inc.*, 725 F.3d 1213, 1220 (10th Cir. 2013) (“[I]f fewer than all of the class members enjoyed the legal right that the defendant allegedly infringed . . . , any common questions may well be submerged by individual ones.” (quoting *Sacred Heart Health Sys., Inc. v. Humana Mil. Healthcare Servs., Inc.*, 601 F.3d 1159, 1170 (11th Cir. 2010))).

process rights to contest every element of liability and to present every colorable defense” for each putative class member’s claims. *Id.*

The district court must have that viable winnowing plan at the outset, before certifying the class. *In re Asacol Antitrust Litig.*, 907 F.3d 42, 58 (1st Cir. 2018). Without that plan in place, plaintiffs cannot “‘affirmatively demonstrate’ that the commonality and predominance requirements are satisfied.” *Rail Freight*, 934 F.3d at 622 (quoting *Wal-Mart*, 564 U.S. at 350); accord *Asacol*, 907 F.3d at 61 (Barron, J., concurring).

Uninjured class members, in particular, pose a predominance problem. See Petition 9–10. “When individualized questions relate to the injury status of class members, Rule 23(b)(3) requires that the court determine whether individualized inquiries about such matters would predominate over common questions.” *Olean Wholesale Grocery Coop. v. Bumble Bee Foods LLC*, 31 F.4th 651, 668 (9th Cir. 2022) (en banc). “Because the Supreme Court has clarified that ‘[e]very class member must have Article III standing in order to recover individual damages,’ Rule 23 also requires a district court to determine whether individualized inquiries into this standing issue would predominate over common questions.” *Id.* at 668 n.12 (quoting *TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021)); see also *Cordoba*

v. DIRECTV, LLC, 942 F.3d 1259, 1273 (11th Cir. 2019) (standing for uninjured class members presents a “powerful problem under Rule 23(b)(3)’s predominance factor”); *Asacol*, 907 F.3d at 53–54 (if a substantial number of class members “in fact suffered no injury,” the “need to identify those individuals will predominate”).

In cases with uninjured class members, common questions may predominate if the evidence resolves *each* class member’s standing simultaneously—with no need for winnowing. *See, e.g., Black*, 69 F.4th at 1184 (finding predominance satisfied where the rejection of plaintiffs’ evidence of antitrust impact “would not result in individualized questions” but rather “would end the litigation for all”). But that rationale does not apply to cases like this one that require individualized post-certification screening. *See Roderick*, 725 F.3d at 1217–20 (explaining that individualized issues regarding lease language and marketability may destroy predominance and that “predominance [was] not established simply by virtue of a uniform payment methodology”). Such member-by-member adjudication destroys predominance.

C. The district court abused its discretion in certifying a class with many uninjured class members and no workable mechanism to weed them out.

This case requires—but lacks—“a reasonable and workable plan” to winnow out uninjured class members. *Asacol*, 907 F.3d at 58.

The district court identified Plaintiffs’ claimed harm as the receipt of “underfilled . . . vials,” or “payment for trastuzumab not actually received.” Order 33–34. Thus, to be injured under Plaintiffs’ theory, class members must have received underfilled vials. Order 33. Many vials sold during the class period, however, were *not* underfilled, so class members who received only those vials are uninjured. *See* Order 33 (refusing “to presume that ‘every Class Member suffered injury on every vial purchased’ . . . given the undisputed evidence of vial samples above 440 mg”); Doc. 762 at 36–37. The district court further recognized that Plaintiffs had no method of proving injury on a classwide basis. *See* Order 33–35 (rejecting both of Plaintiffs’ proposed damages models). Instead, Plaintiffs will have to establish one-by-one that each class member purchased an underfilled vial. *See* Order 34–35. Without any workable plan to winnow out uninjured class members’ claims, trial will be swamped by individualized injury questions.

The district court short-circuited that problem by categorically assuming that the presence of uninjured class members is irrelevant to predominance. *See* Order 32.⁵ That dangerous error warrants this Court’s review. This Court has not explicitly required a workable plan to winnow out uninjured class members from damages classes. But the Court should join the other circuits that expressly recognize it as key to the rigorous analysis of predominance. *See supra* Part I.B.

The district court’s order cries out for clarity only this Court can provide. The district court relied on *Black* for the categorical proposition that “the potential for uninjured [class members] [does not] destroy predominance.” Order 32. *Black* held no such thing. The *Black* plaintiffs proposed a method for proving injury on a classwide basis. *See, e.g.*, 69 F.4th at 1184 (observing that “a failure of proof on the element of antitrust impact” “would not result in individualized questions” but would “end the litigation for all”); *see also id.* at 1179. Thus, there was no need to cull uninjured class

⁵ The district court likewise shrugged off its own “conclu[sion] [that] individualized issues *predominate* as to damages” by asserting that this related problem categorically “does not defeat predominance.” Order 35 & n.24 (emphasis added). In any event, as Genentech explains, this question goes to the liability issue of breach, not just injury and damages. Petition 16.

members' claims. Here, however, the district court itself held that Plaintiffs have no way of showing classwide injury. Order 33–35. *Black* thus does not support short-circuiting predominance.

No other decision of this Court renders uninjured class members irrelevant either. To the contrary, *Dunn v. Santa Fe Natural Tobacco Co.* recognized that sorting out the uninjured *can* “overwhelm common questions.” 185 F.4th 999, 1022 (10th Cir. 2024).

Cline v. Sunoco, Inc. (R&M), 159 F.4th 1171 (10th Cir. 2025), and *Naylor Farms, Inc. v. Chaparral Energy, LLC*, 923 F.3d 779 (10th Cir. 2019), did not present this winnowing issue because the plaintiffs in those cases “provided evidence that their expert could determine damages” – and thus injury – “on a class-wide basis through use of a model.” *Cline*, 159 F.4th at 1191 (quotation and brackets omitted) (discussing *Naylor Farms*). That evidence is precisely what the district court recognized was missing here.

And in *Cline* and *Rider ex rel. Cherry Rider Family Trust v. OXY USA, Inc.*, 175 F.4th 1214, 1227–28 (10th Cir. 2026), there were at least some records in defendants' possession that were offered to winnow out uninjured class members. There is no such plan here, despite the district court's express acknowledgment that many class members are uninjured. That makes this

an ideal vehicle to join other circuits in clarifying that district courts must identify a workable plan to winnow out uninjured class members in their rigorous analysis of predominance.

II. Lax analysis of uninjured class members hurts businesses and the economy.

The enormous costs of improper class certification underscore the need for this Court's review. Class-action litigation costs in the United States are eye-popping. In 2025, those costs exceeded \$4.5 billion. *See* Carlton Fields, 2026 *Carlton Fields Class Action Survey* 6 (2026), <https://ClassActionSurvey.com>. Defending *even one* class action can cost a business over \$100 million. *See, e.g.,* Adeola Adele, *Dukes v. Wal-Mart: Implications for Employment Practices Liability Insurance* 1 (July 2011). Nearly 75% of companies reported actively managing class actions against them in 2025. 2026 *Carlton Fields Class Action Survey* 8.

Certifying a class creates immense pressure on defendants to settle even meritless cases. Judge Friendly aptly termed these “blackmail settlements.” Henry J. Friendly, *Federal Jurisdiction: A General View* 120 (1973). As the Supreme Court explained, “[c]ertification of a large class may so increase the defendant’s potential damages liability and litigation costs

that he may find it economically prudent to settle and to abandon a meritorious defense.” *Coopers & Lybrand v. Livesay*, 437 U.S. 463, 476 (1978). And these settlements hurt not only businesses themselves, but also the broader economy. *See Lab’y Corp.*, 605 U.S. at 333 (Kavanaugh, J., dissenting from dismissal as improvidently granted) (businesses “pass on th[e] costs” of coerced settlements to consumers).

Judicial recommitment to rigorous enforcement of both Article III and Rule 23 at the class-certification stage would help curb these staggering costs. These requirements, if properly enforced, ensure that parties do not waste time and money—and defendants do not face undue settlement pressure—litigating a certified class action through trial only for a court to conclude at final judgment that uninjured class members have overwhelmed the litigation.

CONCLUSION

For these reasons and those in Genentech’s petition, the Court should grant Genentech permission to appeal.

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) because it contains 2,590 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

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/s/ Brian D. Schmalzbach
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CERTIFICATE OF SERVICE

I hereby certify that on October 21, 2026, the foregoing was electronically filed with the Clerk of the Court for the United States Court of Appeals for the Tenth Circuit using the appellate CM/ECF system. All participants in the case are registered CM/ECF users and will be served by the system.

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