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UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

PAINTERS & ALLIED TRADES DISTRICT COUNCIL 82 HEALTH CARE FUND, third-party healthcare payor fund; et al., Plaintiffs-Appellees, v. TAKEDA PHARMACEUTICAL COMPANY LIMITED, a Japanese Corporation; et al., Defendants-Appellants.	No. 23-55742 D.C. No. 2:17-cv-07223-JWH-AS MEMORANDUM*

Appeal from the United States District Court
for the Central District of California
John W. Holcomb, District Judge, Presiding

Argued and Submitted November 14, 2024
Submission Deferred June 2, 2024
Re-submitted June 6, 2025
San Francisco, California

Before: S.R. THOMAS and MILLER, Circuit Judges, and ROSENTHAL,** District Judge.
Dissent by Judge MILLER.

* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

Takeda Pharmaceutical ("Takeda") and Eli Lilly ("Lilly"), the manufacturer and seller of anti-diabetes drug Actos, appeal the district court's order certifying a class of Third-Party Payors ("TPPs"), represented by Painters & Allied Trades ("Painters"). Painters alleges Takeda and Lilly violated the Racketeer Influenced and Corrupt Organizations ("RICO") Act by concealing Actos's alleged risk of bladder cancer, thus defrauding the TPPs. We have jurisdiction over class certification orders under 28 U.S.C. § 1292(e) and Fed. R. Civ. P. 23(f). Because the parties are familiar with the history of this case, we need not recount it in detail here. We affirm.

I

"We review the decision to certify a class and 'any particular underlying Rule 23 determination involving a discretionary determination' for an abuse of discretion." *Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC*, 31 F.4th 651, 663 (9th Cir. 2022) (en banc) (citation omitted). "We review the district court's determination of underlying legal questions de novo, and its determination of underlying factual questions for clear error." *Id.* (citations omitted).

"The Supreme Court has indicated that a court's determination regarding what a statistical regression model may prove or is capable of proving is not a question of fact, even though there may be disputed issues of fact raised by 'the

data contained within an econometric model.'" *Id.* (citation omitted). "Accordingly, we review the district court's determination that a statistical regression model, along with other expert evidence, is capable of showing class-wide impact, thus satisfying one of the prerequisites of Rule 23(b)(3) of the Federal Rules of Civil Procedure, for an abuse of discretion." *Id.*

Class certification requires "that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). At issue here is how these predominance and superiority requirements relate to civil RICO standing. "A civil RICO 'plaintiff only has standing if, and can only recover to the extent that, he has been injured in his business or property by the conduct constituting the violation.'" *Canyon Cnty. v. Syngenta Seeds, Inc.*, 519 F.3d 969, 975 (9th Cir. 2008) (quoting *Sedima, S.P.R.L. v. Imrex Co., Inc.*, 473 U.S. 479, 496 (1985)).

II

The District Court did not abuse its discretion by finding the predominance requirement satisfied. "[P]laintiffs must prove the facts necessary to carry the burden of establishing that the prerequisites of Rule 23 are satisfied by a preponderance of the evidence." *Olean*, 31 F.4th at 665. "[I]f 'each class member could have relied on [the plaintiffs' evidence] to establish liability if he or she had brought an individual action,' and the evidence 'could have sustained a reasonable jury finding' on the merits of a common question, then a district court may conclude that the plaintiffs have carried their burden of satisfying the Rule 23(b)(3) requirements as to that common question of law or fact." *Id.* at 667 (alteration in original) (quoting *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 455 (2016)).

Takeda and Lilly raise several challenges to the district court's predominance finding, generally focusing on Painters' econometrics expert report, the Comanor Report:[1] (A) that the district court did not conduct a "rigorous analysis" of the Comanor Report, (B) that Takeda and Lilly's individualized defenses defeat predominance, and (C) that the challenge of removing potential uninjured class members defeats predominance. None of these challenges prevail.

[1] To the extent that record information referenced in this opinion has been filed under seal, we hereby unseal it for the limited purpose of this disposition.

A

The district court properly conducted a "rigorous analysis," as required to certify a class. *See Olean*, 31 F.4th at 664. The required "rigorous analysis" will frequently "entail some overlap with the merits of the plaintiff's underlying claim," *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 351 (2011), but "[m]erits questions may be considered to the extent—but only to the extent—that they are relevant to determining whether the Rule 23 prerequisites for class certification are satisfied." *Amgen Inc. v. Connecticut Ret. Plans & Tr. Funds*, 568 U.S. 455, 466 (2013). In order to satisfy Rule 23, the plaintiffs must show that the elements of the cause of action "are capable of being established through a common body of evidence, applicable to the whole class." *Olean*, 31 F.4th at 666. "[A] district court cannot decline certification merely because it considers plaintiffs' evidence relating to the common question to be unpersuasive and unlikely to succeed in carrying the plaintiffs' burden of proof on that issue." *Id.* at 667.

In *Olean*, we held that the district court had conducted a rigorous analysis, because it had considered and rejected attacks on the class expert's report. *Id.* at 676. The district court had considered the class expert's testimony and report, the defendant expert's rebuttal testimony and report, and the class expert's reply. *Id.* at 675. It considered and rejected each of the defendant expert's attacks on the class

expert's report. *Id.* at 675–76. We held that was a sufficient "rigorous analysis." *Id.*

In contrast, in *Ellis*, we held that the district court had not conducted a rigorous analysis, because it "merely concluded that, because both Plaintiffs' and Costco's evidence was admissible, a finding of commonality was appropriate." *Ellis v. Costco Wholesale Corp.*, 657 F.3d 970, 984 (9th Cir. 2011).

Here, the district court conducted a sufficiently rigorous analysis. It considered and rejected each of Takeda's challenges to Painters' evidence, including the Comanor Report. The district court's review satisfied the standards set forth in *Olean*. Takeda and Lilly argue that various alleged defects in the Comanor Report mean it could not possibly pass a "rigorous analysis." These arguments fail.

First, the Comanor Report's "market-share extrapolation" analysis does not make the report insufficient to show classwide causation and injury. Unlike Takeda and Lilly's cited authorities, *UFCW Loc. 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 135 (2d Cir. 2010), and *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 91–92 (2d Cir. 2015), Comanor took additional steps to show that a market-share extrapolation was a reasonable approach.

Comanor used regression models[2] to show that the decline in prescriptions was caused by the failure to disclose: his models included many of the variables that Takeda and Lilly claim should have been included, particularly the release of generic pioglitazone. Even though he included these variables, Comanor still found a stark difference between pre-disclosure and post-disclosure prescriptions. Comanor also used regression models to show that 2013 was a suitable benchmark year, because the rate of Actos prescriptions was flatlining by then. Specifically, Comanor included a "trend squared" factor, which captures non-linearity in the post-damage period. The statistical significance of that factor supports the flatlining effect.

The district court considered those analytic steps, as well as additional supporting evidence, including Takeda's own "internal company emails, marketing studies, and other testimony." Thus, it was not an abuse of discretion to credit the Comanor Report, even with this market share extrapolation analytic step.

Second, the Comanor Report's assumptions about alternative diabetes treatments do not make the report insufficient to show classwide causation and

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[2] "Regression analyses are used to determine 'the relationship between an unknown [dependent] variable [such as price] and one or more independent variables [e.g., transaction characteristics, and supply and demand factors] that are thought to impact the dependent variable.'" *Olean*, 31 F.4th at 671 (alterations in original) (citation omitted).

injury.[3] Expert evidence may not be sufficient to satisfy Rule 23 requirements when it "contain[s] unsupported assumptions." *Olean*, 31 F.4th at 666 n.9. The district court properly considered and rejected Takeda and Lilly's critique of the alternative treatment assumptions. First, it reasoned that even Takeda and Lilly's expert pointed to only 30% of patients that switched from Actos to another regimen, and only 14.4% of *those* patients switched to a regimen that is equal or greater in cost than Actos; thus, only about 4% (i.e., 14.4% of 30%) of fraudulently-induced prescriptions resulted in no injury to TPPs. Next, the district court considered how that 4% might be distributed across TPPs: that distribution "must lie between one of two extremes: either those patients are maximally distributed across the TPP class, or they are maximally concentrated in one TPP (or perhaps some handful)." It concluded that no matter the distribution, only a de minimis number of TPPs would be uninjured. That consideration and rejection of Takeda and Lilly's attack on the Comanor Report satisfies the "rigorous analysis" standard. *See also id.* at 668 ("That the defendant might attempt to pick off the

[3] We assume, without deciding, that to be injured, a TPP must have paid more for a fraudulently-induced Actos prescription than it would have paid for an alternative prescription; if the alternative prescription were more expensive, then the TPP did not suffer any "concrete financial loss" because of the alleged fraud. *See Chaset v. Fleer/Skybox Int'l, LP*, 300 F.3d 1083, 1086–87 (9th Cir. 2002).

occasional class member here or there through individualized rebuttal does not cause individual questions to predominate." (citation omitted)).

Third, the Comanor Report's assumption that prescriptions are statistically independent does not make the report insufficient to show classwide injury and causation. The same reasoning about the distribution of more expensive treatments applies here: if the fraudulently-induced prescriptions estimate is not randomly distributed, then the fraudulently-induced prescriptions must be distributed in some other way, between those two extremes. Neither situation would mean it was an abuse of discretion to find the predominance requirement satisfied.

B

Takeda and Lilly's individualized defenses do not defeat predominance. "[A] plaintiff need not rebut every individualized issue that could possibly be raised." *Van v. LLR, Inc.*, 61 F.4th 1053, 1066 (9th Cir. 2023). "If the plaintiff demonstrates that class issues exist, the defendant must invoke individualized issues and provide sufficient evidence that the individualized issues bar recovery on at least some claims, thus raising the spectre of class-member-by-class-member adjudication of the issue." *Id.* at 1067. Defenses that the defendant "might advance or for which it has presented no evidence" are insufficient to summon that

spectre. *True Health Chiropractic, Inc. v. McKesson Corp.*, 896 F.3d 923, 932 (9th Cir. 2018).

Here, Painters met its initial burden to show that class issues exist: it showed that the elements of its civil RICO claim are common issues, and produced an expert report to show common issues also predominate in civil RICO standing. This shifted the burden to Takeda and Lilly.

Takeda and Lilly did not satisfy their burden, because neither of the two physician depositions they offered at class certification showed that any TPP lacked civil RICO standing.[4] To the contrary, both physicians testified to decreasing their Actos prescriptions because of the bladder cancer disclosure. That shows causation and injury, not a lack of causation and injury. Takeda and Lilly thus failed to "provide sufficient evidence that the individualized issues bar recovery on at least some claims," and offered no more than speculation about individualized defenses at trial. *See Van*, 61 F.4th at 1067–68.

[4] Takeda and Lilly argue that the district court erred by considering the quantity of their evidence at class certification, rather than anticipated evidence at trial. Any such error was harmless, because Takeda and Lilly did not meet their evidentiary burden.

C

Any challenge of removing uninjured class members also does not defeat predominance. "That the defendant might attempt to pick off the occasional class member here or there through individualized rebuttal does not cause individual questions to predominate." *Olean*, 31 F.4th at 668 (citation omitted). We have affirmed class certification orders where the plaintiff's statistical expert admits a nonzero percentage of the class may be uninjured. *See id.* at 672 (class expert concluded that only 94.5% of class members were injured).

Here, the Comanor Report concluded each class member has at most a 1.5% chance of being uninjured, or at least a 98.5% chance of being injured. Precisely, TPPs with exactly five Actos prescriptions have a 98.5% chance of injury, but those TPPs with more than five prescriptions have even greater chances of injury: their chance of having at least one fraudulent prescription increases with each additional prescription. But even if all class members had only a 98.5% chance of injury, that is still greater than the 94.5% that was sufficient in *Olean*. *Olean* made no mention of needing a trial plan to screen out the remaining 5.5%; here there is no need for a trial plan to screen out the (at most) 1.5%. Moreover, there is an obvious strategy for separating the injured from the uninjured: focus on the TPPs

with small numbers of Actos prescriptions. TPPs with large numbers of Actos prescriptions have infinitesimal chances of being uninjured.

III

The district court also did not abuse its discretion by finding the Rule 23(b)(3) superiority requirement was satisfied. The party seeking class certification "bears the burden of demonstrating 'a suitable and realistic plan for trial of the class claims.'" *Zinser v. Accufix Rsch. Inst., Inc.*, 253 F.3d 1180, 1189 (9th Cir.), *opinion amended on denial of reh'g,* 273 F.3d 1266 (9th Cir. 2001) (citation omitted). Class superiority analysis "requires the court to focus on the efficiency and economy elements of the class action so that cases allowed under subdivision (b)(3) are those that can be adjudicated most profitably on a representative basis." *Id.* at 1190 (citation omitted).

Here, the district court properly considered judicial efficiency and economy. Given the finding of predominance, a class action is likely more manageable than individual actions. *See Newberg and Rubenstein on Class Actions* § 4:74 (6th ed.) ("[A] finding of predominance is typically, though not invariably, coupled with a finding that a class is manageable.").

IV

Finally, the district court did not abuse its discretion by certifying the class against Lilly. Lilly argues that, because it stopped promoting Actos in 2006 and stopped receiving royalties for it in 2009, it cannot have caused any injury after those dates.

But the TPP class need not establish injury and causation as to each defendant. Injury and causation are elements of RICO standing, not the RICO claim. *See Canyon Cnty.*, 519 F.3d at 975. These elements show that the plaintiff qualifies to invoke the statute, not that an individual defendant is liable. Thus, Painters had no need to show RICO standing separately for Lilly. The district court did not abuse its discretion by certifying the class as to Lilly.

V

For these reasons, we affirm the district court's class certification order.

AFFIRMED.

Painters & Allied Trades Dist. Council 82 Health Care Fund, et al. v. Takeda Pharm. Co. Ltd., et al., No. 23-55742

MILLER, Circuit Judge, dissenting:

In this putative class action, plaintiffs allege that Takeda Pharmaceutical Company Limited and Eli Lilly and Company fraudulently concealed the risks of a drug that they distributed. An essential element of any fraud claim is reliance on the defendant's allegedly fraudulent statements. Because reliance must ordinarily be established with evidence particular to each plaintiff, fraud claims are not normally suitable for class actions—at least outside of the securities context, in which the fraud-on-the-market theory allows courts to presume reliance on the part of all purchasers of publicly traded securities. *See Basic, Inc. v. Levinson*, 485 U.S. 224, 241–45 (1988).

If plaintiffs were patients who used the defendants' drug, or physicians who prescribed it, they would not be able to bring fraud claims in a class action. But the lawyers who brought this case have tried to circumvent that limitation: Rather than suing on behalf of those directly injured by the alleged fraud, they have instead sued on behalf of third-party payors who reimbursed the cost of drugs that were prescribed and used by others. In an effort to bring what is effectively a fraud-on-the-market class action, plaintiffs rely on supposed statistical proof to establish that the prescriptions they reimbursed were issued in reliance on the defendants' alleged fraud.

The district court did not conduct the requisite rigorous analysis of plaintiffs' statistical theory. Had it done so, it would have determined that the theory fails to establish reliance on a class-wide basis. Because individual questions predominate and class adjudication of this case is unlikely to be workable, I would reverse the grant of class certification.

I

Takeda developed and manufactured Actos, an oral anti-diabetic drug known generically as pioglitazone. In 1999, Actos received FDA approval to enter the U.S. market, and Takeda and Lilly then worked together to market the drug. In September 2010, the FDA announced that it was conducting a safety review of Actos based on its apparent association with an increased risk of bladder cancer. In June 2011, the FDA released the results of its review, informing the public that "use of the diabetes medication Actos (pioglitazone) for more than one year may be associated with an increased risk of bladder cancer." Two months later, the FDA added a bladder cancer warning to Actos's label.

Painters & Allied Trades District Council 82 Health Care Fund (Painters)—a third-party payor that reimburses its members for drug prescriptions as part of its health and welfare coverage—and five individual patients who used Actos brought a class action against Takeda and Lilly. As relevant here, they asserted several claims under the Racketeer Influenced and Corrupt Organizations Act (RICO), 18

U.S.C. § 1964(c), and state consumer protection laws. They alleged that Takeda and Lilly knew about Actos's heightened risk of bladder cancer as early as 1999 but fraudulently concealed that risk until 2010, when the FDA first announced the potential relationship between Actos and bladder cancer.

The district court dismissed the RICO claim for failure to adequately plead proximate causation. On appeal, we held that "Plaintiffs have satisfactorily alleged that Defendants proximately caused their claimed damages at the pleadings stage," and we reversed the district court's dismissal. *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co.*, 943 F.3d 1243, 1260 (9th Cir. 2019). On remand, the district court denied Takeda and Lilly's motions to dismiss, and plaintiffs proceeded to seek certification of a national third-party-payor class represented by Painters as well as a California consumer class represented by the individual patients. The district court declined to certify the California consumer class, a ruling that is not challenged on appeal, so the only plaintiffs before us are the third-party payors.

II

To certify a class under Federal Rule of Civil Procedure 23(b)(3), the district court "must be 'satisfied, after a rigorous analysis, that the prerequisites'" of the rule are met. *Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC*, 31 F.4th 651, 664 (9th Cir. 2022) (en banc) (quoting *General Tel. Co. of Sw. v. Falcon*,

457 U.S. 147, 161 (1982)). Among other things, the court must determine that "the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). "The predominance inquiry 'asks whether the common, aggregation-enabling, issues in the case are more prevalent or important than the non-common, aggregation-defeating, individual issues.'" *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 453 (2016) (quoting 2 Newberg and Rubenstein on Class Actions § 4:49 (5th ed. 2012)).

Assessing the predominance of common questions begins "with the elements of the underlying cause of action." *Erica P. John Fund, Inc. v. Halliburton Co.*, 563 U.S. 804, 809 (2011). As noted, plaintiffs asserted civil RICO claims premised on mail and wire fraud. Those claims require them to demonstrate that they suffered injury to their business or property "'by reason of' the RICO violation." *Canyon Cnty. v. Syngenta Seeds, Inc.*, 519 F.3d 969, 972 (9th Cir. 2008); 18 U.S.C. § 1964(c). To do so, they must show that "*someone* relied on the defendant's misrepresentations." *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 658 (2008). And to make class certification appropriate, they must do so with common proof. *See Olean*, 31 F.4th at 666.

Plaintiffs rely on the expert reports of Dr. William S. Comanor, while Takeda and Lilly submit the opposing views of their own expert, Dr. James W. Hughes. When there is a "battle of the experts," the district court's rigorous analysis cannot stop with finding plaintiffs' expert evidence to be admissible. *Ellis v. Costco Wholesale Corp.*, 657 F.3d 970, 982 (9th Cir. 2011). Rather, to determine "whether expert evidence is capable of resolving a class-wide question in one stroke," the court must take the additional steps of "[w]eighing conflicting expert testimony" and "[r]esolving expert disputes." *Olean*, 31 F.4th at 666 (alteration in original) (quoting *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 323–24 (3d Cir. 2008)). If the district court were to "duck hard questions by observing that each side has some support, or that considerations relevant to class certification also may affect the decision on the merits," it would be "a delegation of judicial power to the plaintiffs, who [could] obtain class certification just by hiring a competent expert." *West v. Prudential Sec., Inc.*, 282 F.3d 935, 938 (7th Cir. 2002).

The district court abused its discretion in certifying the class of third-party payors because it did not weigh Comanor's and Hughes's conflicting evidence and resolve the disputes between them. To the contrary, the court expressly stated that it accepted "Comanor's report at face value and [did] not prejudge its accuracy," adding that it was leaving it "to the finder of fact to weigh Comanor's testimony in view of any cross-examination or contradicting evidence or testimony from

Takeda's experts." The district court thus failed to "face and squarely decide[]" questions raised by the defendants and conclude that Comanor's analysis was capable of establishing the elements of plaintiffs' claims on a class-wide basis. *West*, 282 F.3d at 938.

The district court's error is reflected not just in the language of its certification order but also in the substance of its analysis. The court did not grapple with three critical objections raised by Takeda and Lilly, each of which casts doubt on whether plaintiffs can establish the effects of the alleged fraud by common proof.

First, Comanor's statistical analysis does not show but-for causation. A review of Comanor's methodology reveals its flaws: Comanor first ran a time-series regression on sales data from October 2010 to December 2013—that is, after the class period—to examine the quantity of Actos prescriptions and its correlation with several independent variables, including the bladder cancer warning; he then selected December 2013 as the presumptive steady state and predicted Actos's share of the total anti-diabetic market in that month, which he described as the percentage of "fully informed" Actos prescriptions given the known risk of bladder cancer; finally, he applied that percentage to the entire 134-month class period from 1999 to 2010 to estimate the quantity of "fully informed" Actos prescriptions

that would have been written each month if the bladder cancer risk had been known from the beginning.

Hughes, the defendants' expert witness, explained why that approach is inadequate to show but-for causation: Comanor's data consists of a single time series of observations between October 2010 and December 2013, but one cannot use such data to identify causal effects because there is no way to separate the effect of the 2011 FDA announcement from the effect of other events, such as the introduction of new treatment options, the launch of generic drugs, and changes in drug prices. Even if Comanor had included all possible confounding factors as independent variables in his analysis, which he did not, his single time-series regression cannot conclusively show and isolate the causal effect of the bladder cancer risk. Furthermore, a regression performed on a single 39-month time series *after* the relevant class period does not give rise to an inference of causation *during* the 134-month class period. Comanor's use of a "trend squared" factor to predict the "fully informed" quantity of Actos prescriptions in December 2013 adds nothing to the analysis: Actos's actual market share data in that month is readily available, and the defendants do not dispute that Actos prescriptions were in a steady state by then.

Had the district court weighed Comanor's models against Hughes's competing analysis, considered Hughes's criticisms, and concluded that Comanor's

models can demonstrate but-for causation, we would have had to review its conclusions deferentially. *See Olean*, 31 F.4th at 676. But it did not. Instead of conducting the requisite rigorous analysis, the district court reviewed out-of-circuit cases that discussed statistical regression models, which it said gave it "confidence" that Comanor's economic analysis constituted common evidence that "can be used to establish but-for causation under a quantity-effect theory." *See, e.g.*, *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21, 45–47 (1st Cir. 2013); *In re Celexa and Lexapro Mktg. & Sales Pracs. Litig.*, 915 F.3d 1, 14 (1st Cir. 2019); *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 97 (2d Cir. 2015). I do not question the conclusion of those cases that "an aggregate regression analysis . . . *might* be sufficient to prove causation on a class-wide basis." *Sergeants*, 806 F.3d at 97 (emphasis added). But it does not follow that *this* regression analysis is sufficient to prove causation. That is something that must be shown based on the evidence, and it was not shown here.

That failure is fatal to class certification, as the only common proof that plaintiffs offered to prove injury and causation was Comanor's expert evidence. (Plaintiffs also provided evidence of "internal company emails, marketing studies, and other testimony," but that evidence is insufficient to show common causation and injury because it does not demonstrate the but-for difference in Actos

prescriptions due to the bladder cancer risk or provide a way to quantify the financial loss suffered by the third-party payors.)

Second, even accepting Comanor's regression analysis, plaintiffs lack a feasible method of identifying those class members who suffered no injury. The parties agree that not all plaintiffs relied on the alleged concealment of the bladder cancer risk because some of them still would have paid for Actos prescriptions even had the risk been disclosed. In other words, at least some plaintiffs were uninjured.

Although we have allowed for the possibility of certifying "a class that potentially includes more than a de minimis number of uninjured class members," *Olean*, 31 F.4th at 669, we have also explained that the "predominance requirement is not satisfied when the need to identify uninjured class members 'will predominate and render an adjudication unmanageable,'" *id.* at 669 n.13 (quoting *In re Asacol Antitrust Litig.*, 907 F.3d 42, 53–54 (1st Cir. 2018)). In *Olean*, an antitrust class action involving price fixing among suppliers of packaged tuna, we affirmed the district court's class certification order based on expert evidence that showed that "94.5 percent of [tuna] purchasers had at least one purchase above the predicted but-for price." *Id.* at 672. That is, we concluded that certification was permissible even if 5.5 percent of class members were uninjured. Other circuits have rejected class certification when the percentage of uninjured class members is

higher. *See, e.g.*, *In re Rail Freight Fuel Surcharge Antitrust Litig.*, 934 F.3d 619, 623–24 (D.C. Cir. 2019) (12.7 percent); *Asacol*, 907 F.3d at 45 (10 percent). The precise threshold at which uninjured class members no longer constitute a de minimis number remains an open question. For purposes of the predominance inquiry, however, the dispositive question is not the numerical threshold but whether plaintiffs can present a "mechanism that can manageably remove uninjured persons from the class." *Asacol*, 907 F.3d at 54. Such a "winnowing mechanism must be truncated enough to ensure that the common issues predominate," and the "absence of any winnowing mechanism" means that "the need for individualized proof of injury and causation destroy[s] predominance." *Rail Freight*, 934 F.3d at 624–25.

Here again, plaintiffs rely on Comanor's analysis. Using his estimate that 56 percent of Actos prescriptions were fraudulently induced—and, thus, that 44 percent were not—he calculated that "the probability of a [third-party payor] paying for one or more fraudulently induced prescriptions in a randomly selected sample of five" is 98 percent (that is, 100 percent minus 44 percent to the fifth power). Having defined the class as those third-party payors who "purchased at least five independent prescriptions of Actos," plaintiffs infer that no more than two percent of class members were uninjured.

Comanor's calculation is correct as far as it goes, but it depends entirely on the assumption that each prescription is statistically independent of the others—in other words, that the fact that one of a third-party payor's prescriptions was fraudulently induced does not increase the likelihood that its other prescriptions were also fraudulently induced. Only on that assumption can one validly multiply the probability of fraudulent inducement of individual prescriptions to arrive at an overall probability that a third-party payor was injured. And only then can plaintiffs rely on the strategy of separating the uninjured from the injured by focusing on third-party payors with at least five Actos prescriptions. But as Hughes explained, a physician who has experience using Actos with one patient may be more likely to prescribe it to a second. In addition, different third-party payors serve different patient populations; some might have been highly sensitive to the risk of bladder cancer, while others might have been less so. The prescriptions reimbursed by a given third-party payor are therefore not independent of each other.

The district court addressed whether different prescriptions were independent of each other in the sense of not being "refill" prescriptions, but it did not grapple at all with the question of statistical independence. It does not help to say that fraudulently induced prescriptions must have been distributed somewhere between the two extremes of maximally distributed and maximally concentrated,

because whatever the distribution is, it defeats the assumption of independence based on randomness. And without the assumption of independence, Comanor's multiplication of individual probabilities is not valid, so there is no basis for saying that the number of uninjured class members is merely de minimis. If there is some method of winnowing out uninjured class members without resorting to individualized inquiries, the district court did not say what it is.

Third, even if Comanor's statistical methodology could show causation and demonstrate that all but a de minimis number of class members were injured, Takeda and Lilly would still be entitled to present and litigate defenses to the claims of individual class members. *See Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 367 (2011). Even after plaintiffs establish that a class-wide issue exists, the district court must determine "whether individualized questions . . . will overwhelm common ones and render class certification inappropriate under Rule 23(b)(3)." *Van v. LLR, Inc.*, 61 F.4th 1053, 1067 (9th Cir. 2023) (quoting *Olean*, 31 F.4th at 669). Critically, the defendants need not submit "proof of who will win or lose at trial." *Id.* at 1068–69. As long as they "invoke[] an individualized issue" and "provide[] evidence that at least some class members lack meritorious claims because of this issue," they will have "summon[ed] the spectre of class-member-by-class-member adjudication." *Id.* at 1069.

Takeda and Lilly advance individualized affirmative defenses based on physicians' prescribing decisions, which vary from plaintiff to plaintiff. In a similar class action alleging pharmaceutical fraud, the Second Circuit held that generalized proof of injury cannot support a quantity-effect theory "when individual physicians prescribing [the drug] may have relied on [the pharmaceutical company's] alleged misrepresentations to different degrees, or not at all." *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 136 (2d Cir. 2010). While we have rejected the Second Circuit's determination that individual physicians' prescribing decisions could "constitute intervening causes that sever the chain of *proximate* cause" (that is, because the alleged fraud caused injury only indirectly), we have not ruled out the possibility that their decisions could serve as defenses to *but-for* causation (that is, because the alleged fraud did not cause injury at all). *Painters*, 943 F.3d at 1257 (emphasis added). And plaintiffs offer no theory of why such a defense would not be legally available.

Takeda and Lilly point to the depositions of two medical professionals who treated the individual plaintiffs in the failed consumer class, noting that both continued to prescribe Actos even after the cancer risks were fully disclosed. They argue that they are "entitled to depose and call as witnesses the thousands of doctors who still would have written Actos prescriptions—or who would have written even more expensive prescriptions—in Plaintiff's but-for world."

The district court acknowledged that it had to consider Takeda and Lilly's affirmative defenses, explaining that "Takeda or Lilly could still depose individual prescribing physicians to contest Plaintiffs' theory of but-for causation . . . [and] testify that they would have continued to prescribe Actos, notwithstanding the bladder cancer risk." But it reasoned that Takeda and Lilly's depositions paled in comparison to plaintiffs' "mountain of evidence regarding but-for causation that is common to the class" and that "[a]s the tally stands, individualized issues would not predominate over but-for causation if the trial was held today."

The district court erred in requiring at the certification stage the kind of proof from Takeda and Lilly that might be introduced at trial to support their individualized, physician-based defenses. In *Van*, the defendant invoked an individualized issue—that it did not cause injury to some class members because it offered them a discount to offset an improperly assessed sales tax—and submitted evidence that 18 of 13,680 discounts provided to class members were made for that purpose. *Id.* We held that even though the defendant's evidence "consisted of only a small number of invoices," it was nevertheless "sufficient to prove that an inquiry into the circumstances and motivations behind each of the 13,680 discounts might be necessary." *Id.* Here, Takeda and Lilly provided evidence that individual physician decisions could bar recovery on some claims: At least two medical professionals testified that they continued to prescribe Actos after the bladder

cancer warning. That testimony is enough to "summon[] the spectre" of the need for individualized inquiries into the decisions of prescribing physicians. *Van*, 61 F.4th at 1069; *see id.* at 1068 n.13 (noting that the defendant had "substantiated the individual issue" whether it "provided two or eighteen examples"). To prevail at trial, Takeda and Lilly might need to produce more evidence of individual prescribing decisions, but the district court abused its discretion in requiring them to produce that evidence at the certification stage.

Because Takeda and Lilly presented sufficient evidence to support their affirmative defenses and raise the prospect of individualized adjudication, the district court further erred in failing to determine whether "a class member-by-class-member assessment of the individualized issue will be unnecessary or workable." *Van*, 61 F.4th at 1069. If the individualized inquiries become "prohibitively cumbersome," then the common questions no longer predominate and plaintiffs cannot meet the requirements of Rule 23(b)(3). *Bowerman v. Field Asset Servs., Inc.*, 60 F.4th 459, 469 (9th Cir. 2023). In addition, because each plaintiff "has to litigate numerous and substantial separate issues to establish [its] . . . right to recover individually," a class action becomes unmanageable and no longer superior. *Zinser v. Accufix Rsch. Inst., Inc.*, 253 F.3d 1180, 1192 (9th Cir. 2001); *see* Fed. R. Civ. P. 23(b)(3)(D) (providing that the assessment of superiority depends in part on "the likely difficulties in managing a class action").

Here, the record shows that individualized prescribing decisions would defeat plaintiffs' reliance on the fraud and overwhelm the common issues of injury and but-for causation. In evaluating the California consumer class, which brought claims under state law, the district court acknowledged that "some patients would have no . . . option other than Actos, notwithstanding the bladder cancer risks," and that the prescription "determinations necessarily reside with the patients and their physicians." When the district court ultimately denied class certification to the California consumers, it did so because the need for individualized inquiries defeated predominance. The national third-party-payor class is no different.

* * *

The district court certified a sprawling class action based on millions of prescribing decisions by thousands of individual physicians. Some of those decisions may have been influenced by the defendants' alleged fraud. Many others surely were not. Because the court did not conduct the required rigorous analysis—and because such an analysis would have shown that individual issues predominate—the court abused its discretion in certifying a class.