No. 25-625

IN THE

Supreme Court of the United States

TAKEDA PHARMACEUTICAL COMPANY LIMITED, A JAPANESE CORPORATION, *et al.*,

Petitioners,

v.

PAINTERS AND 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

RESPONDENTS' BRIEF IN OPPOSITION

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COUNTERSTATEMENT TO QUESTIONS PRESENTED

1. When the probability of each class member being injured is greater than or equal to 98.5%, does class certification under Rule 23(b)(3) comport with the standing requirements of Article III?

2. Whether, in assessing causation in a quantity-effect pharmaceutical fraud case brought pursuant to 18 U.S.C. § 1964(c) and (d), a district court abuses its discretion in finding that the element of but-for causation can be established using common evidence consisting of internal studies, peer-reviewed literature, econometric regression models, and other admissible evidence.

CORPORATE DISCLOSURE STATEMENT

Respondent Painters and Allied Trades District Council 82 Health Care Fund ("Painters") does not have any parent corporation nor does any publicly held corporation own more than 10% of any stock.

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INTRODUCTION

Petitioners ask this Court to intervene in a fact-bound interlocutory dispute that provides no basis for certiorari. The decisions below apply settled Article III and Rule 23 principles to an unusual but straightforward record: overwhelming common proof demonstrates that Petitioners' decade-long fraudulent concealment of Actos's bladder-cancer risk caused third party payers ("TPPs") to purchase greater quantities of Actos prescriptions. The district court carefully evaluated that evidence, and the Ninth Circuit—after rigorous review—correctly held that common issues predominated, notwithstanding Petitioners' speculation that some theoretical fraction of class members—none of whom have been identified—might not have paid for a fraudulently-induced Actos prescription.

Nothing in this Court's precedents requires denial of class certification merely because defendants can hypothesize about the existence of uninjured members, particularly where, as here, the probability that any given class member was injured exceeds 98 percent and the injury-producing conduct and its economic effects are provable through common, admissible evidence. This case does not present an appropriate vehicle for this Court to address whether a class can be certified with uninjured class members because the record demonstrates that every class member is, more likely than not, injured.

Nor does the petition present a certiorari-worthy question concerning whether but-for causation under the Racketeer Influenced and Corrupt Organizations Act ("RICO") may be established using representative

common evidence. That issue is not the subject of any circuit split. To the contrary, courts of appeal uniformly recognize—consistent with this Court's ruling in *Tyson Foods, Inc. v. Bouaphakeo*—that causation can be established on a classwide basis where the common evidence could be used to establish the element in an individual action. That settled principle was faithfully applied by the district court and the Ninth Circuit, leaving nothing for this Court to resolve.

The petition should be denied.

STATEMENT OF THE CASE

I. The Fraud: For Over a Decade, Petitioner Drug Companies Concealed Actos's Bladder Cancer Risk to Sell Greater Quantities of the Drug

A. Enterprise Origins: How Takeda came to Partner with Lilly

Actos, chemically known as pioglitazone, is a medication for type II diabetics. 2-ER-77.[1] Actos works at the cellular level by activating the peroxisome proliferator-activated receptors ("PPAR") gamma receptor that controls gene expression, rendering cells more sensitive to insulin and, in turn, able to better process blood sugar. 2-ER-78. Unfortunately, Actos also activates the PPAR alpha receptor, which causes (among other things) cells

1. All record citations are to the Ninth Circuit record. "2" refers to volume 2 of the Ninth Circuit excerpts of record ("ER"). There are a total of four ER volumes, as well as five supplemental excerpts of record volumes ("SER"). For example, page 23 of volume 3 of the SER would be cited as 3-SER-23.

in the bladder to mutate and develop into cancer. 2-ER-88–92. The Petitioner drug companies, Takeda and Lilly, both knew Actos could cause bladder cancer, but they deliberately concealed and misrepresented that risk to increase sales for over a decade.

The story starts in the 1980s, when Takeda—a Japanese chemical company—wanted to break into the lucrative U.S. pharmaceutical marketplace. Takeda entered a joint venture with the Upjohn Company—an established U.S. pharmaceutical manufacturer—to develop Actos. 2-ER-78. However, pre-clinical animal trials raised concerns about the drug's "margin of safety," which led Upjohn to withdraw from the partnership in 1994. 2-ER-79. Takeda continued Actos development but asked Upjohn to frame its decision to withdraw as a business decision, not safety concerns. 5-SER-907. This prompted Upjohn employees to express concern "about the lack of frankness (and honesty?) of" Takeda. 5-SER-905.

In 1996, a rodent study showed bladder tumor formation and an increase in transitional cell cancer. 5-SER-892. To address this, Takeda enlisted the help of Dr. Sam Cohen, a pathologist at the University of Nebraska. 4-SER-733. Dr. Cohen developed the "Cohen Hypothesis," positing that when male rats are exposed to Actos, it alters the pH level of urine leading to the formation of crystals—something that would not occur in humans. 5-SER-879. The theory, however, is a sham; the Cohen Hypothesis could only explain the formation of cancer caused by irritation from crystals formed in the bladder, not transitional cell cancers observed in the rodent bladders. 2-ER-81. Moreover, bladder cancer was also observed in female rats, which do not have the pH problem. 2-ER-81.

In December 1998, before Actos was approved, Takeda and Lilly negotiated a partnership. 4-SER-738. Lilly was informed about why Upjohn withdrew from Actos development. 5-SER-902–903. However, Takeda asked Lilly "to keep saying that Upjohn's decision is based on the results of their internal business evaluation" and not "safety issues." 5-SER-902–903. Lilly agreed to keep the secret and Takeda agreed to indemnify Lilly for any litigation damages caused by Actos, including claims related, specifically, to bladder cancer. 3-SER-344 (1999 PowerPoint noting "Pioglitazone's Product Liability Risk" and identifying "bladder cancer" as one of the "Most Significant Adverse Events Risks for Pioglitazone[.]"); 4-SER-802 (indemnity agreement). Thus, despite specifically identifying and planning for product liability associated with bladder cancer, Petitioners chose not to warn about bladder cancer on the labeling.[2]

B. Takeda and Lilly Promoted Actos as a PPAR Alpha Agonist Until the FDA Indicated that PPAR Alpha Agonists Cause Bladder Cancer

FDA approved Actos in July 1999 and, immediately, the Petitioners started promoting Actos. 2-ER-107. They promoted Actos by claiming that, in addition to activating the PPAR gamma receptor, which increased insulin sensitivity, it also activated the PPAR alpha receptor that was believed, at that time, to reduce bad cholesterol. 2-ER-87. However, in 2002, Takeda received a call from the FDA alerting it to a bladder cancer problem with

2. The label mentioned bladder tumors in a rat study but disavowed any link to humans. 3-SER-334. In 2011, a bladder cancer warning was added, 2-SER-131, and the current label contains a clear warning on the first page. 3-SER-416.

antidiabetic drugs that were dual PPAR gamma/alpha agonists. 2-ER-88. The FDA immediately terminated a dual PPAR agonist drug that was in development and explained that when Actos was used as a comparator in a different company's study, it promoted bladder cancer. 2-ER-88–89. The FDA specifically noted that it "is becoming concerned" about whether "the general population is being adequately informed about the possible risk" related to bladder cancer. 2-ER-89.

Petitioner drug companies did not change the label. Instead, they convened a high-level "Actos FDA Response Meeting" where they outlined a strategy. 2-ER-90. That strategy included sticking to "Sam Cohen's hypothesis despite many challenges[,]" arguing "against clinical testing[,]" making sure to "not 'turn over any stones[,]'" and paying "experts at every opportunity." *Id*. Ultimately, the ploy worked. The Petitioner drug companies convinced the FDA that Actos did not activate the alpha receptor and, therefore, did not increase the risk of bladder cancer. 2-ER-91.

The Petitioner drug companies, however, had a problem: they had marketed Actos as a PPAR alpha agonist for years. 2-ER-92–93. One consultant explained: "the FDA is thumping you with the thought that mixed agonists cause bladder cancer and we just spent the last 4 months fighting this ... given the FDA[']s insistence that 'mixed agonists' are the bad guys, the first is to get away from them." 2-ER-92–93. He cautioned, "[I] don't think that marketing the mixed agonist stuff will in any way make up for the loss in revenue ... from the 'cancer' stigmata[.]" 2-ER-93. So, the Petitioner drug companies instructed their salesforce and marketing personnel to

destroy all materials linking Actos to PPAR alpha activity. 4-SER-735–36 .

At the end of 2003, Takeda and Lilly quietly studied how a bladder cancer warning would impact utilization. The first study was "Barriers to TZD Prescribing Qual Report[.]"[3] 2-SER-214. Researchers conducted "in-depth telephone interviews" with primary care physicians ("PCPs") and endocrinologists. 2-SER-218, 281.[4] Physicians were presented with a hypothetical "new" product profile and "asked for their impressions and likelihood of use[.]" 2-SER-282. The profile presented included "[p]eriodic urinary monitoring ... to detect hematuria (blood in urine)." 2-SER-282. Of the twelve physicians presented with the profile, four were "concerned about the underlying problem causing hematuria." 2-SER-283. After they were told the monitoring was due to potential bladder tumors, of "the 8 physicians who expressed initial interest" it "declined greatly among 6" and "slightly for 2 physicians[.]" 2-SER-283–284. For the "4 physicians initially concerned with hematuria, the risk of bladder tumors was serious enough that *all* felt they *would not use the product*[.]" 2-SER-283–284 (emphasis added).

The second study, in February 2004, involved a larger sample, and was called "Future of Diabetes[.]" 2-SER-140. The researchers conducted 50 focus groups with

3. "TZD" stands for thiazolidinedione, the class of drugs that contains Actos.

4. According to Takeda, "results of physician surveys undertaken for purposes of marketing are reliable as directional estimate of overall market, market share, and future trends[.]" 4-SER-708, 715.

462 physicians. 2-SER-142. Participants were presented with a product profile for a diabetes drug called "X" which included hematuria monitoring. 2-SER-172. The researchers noted that "[p]hysicians were divided in their levels of concern over a new product ... that has periodic urinary monitoring required to detect hematuria (blood in the urine)." 2-SER-172. However, "[o]nce told that the reason for the monitoring is due to bladder cancer risk, physicians considered it a very significant deterrent to usage[.]" 2-SER-172 (emphasis added). The data showed that 72% of PCPs and 83% of endocrinologists were significantly less likely to prescribe a diabetes drug with a bladder cancer risk. 2-SER-205.

In 2005, a clinical trial ("PROactive") completed. During the trial, nineteen people developed bladder cancer, fourteen in the Actos group and five in the control group—a statistically-significant increase in bladder cancer. 3-SER-486. However, when the study was published, the paper reported fourteen cases of bladder cancer in the Actos group and six in the placebo group. 3-SER-497. By adding an additional tumor to the placebo group, the elevated rate was no longer statistically significant. *Id*. The additional tumor was benign and, per the study's protocol, should not have been counted—indeed, that tumor was not cancerous. 3-SER-486. It was deliberately added to hide the bladder cancer finding. Despite this clear epidemiological link to bladder cancer, Petitioners did not warn about bladder cancer.

Around this same time, Takeda performed a statistical analysis of the FDA's Adverse Event Reporting System database, which showed a signal for bladder cancer when comparing Actos to other drugs. *See In re Actos®*

(Pioglitazone) Prod. Liab. Litig., No. 6:11-MD 2299, 2014 WL 12776173, at *7 (W.D. La. Sept. 5, 2014). However, Takeda edited the table to omit this statistical analysis from the reports provided to the FDA. *Id.*

Also, around this time, Takeda finished its first preliminary analysis of data collected from the Kaiser Permanente Northern California ("KPNC") database, monitoring the incidence of bladder cancer in Actos users. *Id.* The analysis revealed a statistically significant increased bladder cancer risk for people taking Actos. *Id.*

In reporting the PROactive and KPNC results to FDA, Takeda executives commented that "reports on malignancy to the authorities are of critical importance for Actos" and directed regulatory personnel to "ensure that the interpretation is right to avoid unnecessary arguments against the safety of Actos ... by all means." 5-SER-818. Anticipating FDA action, Takeda predicted the best-case scenario would require a label change with "relatively benign wording around bladder cancer findings[.]" 5-SER-817. The most likely "'worst case scenario' could be for the Agency to ask for an immediate label change incorporating bladder cancer findings[.]" 5-SER-817.

In 2006, another FDA medical reviewer, Dr. Robert Misbin, attempted to expose the bladder cancer issue. 3-SER-455, 469–472. He noted that Takeda and Lilly resisted requests by the FDA to add bladder cancer language to the Actos label. 3-SER-470. Regarding the PROactive data, Dr. Misbin noted that there were only five bladder cancers in the placebo group, not six, and when properly calculated, there was a statistically significant

tripling of the risk.[5] 3-SER-471. Takeda and Lilly largely ignored Dr. Misbin. No bladder cancer warning was added to the label.

In 2009, interim results of the KPNC data showed that Actos increased the risk of bladder cancer by nearly 500%. 2-ER-103. The Petitioner drug companies could not explain it away—at least not to the FDA. On September 17, 2010, the FDA announced an official investigation into the bladder cancer risk. *Id*. Then, in June 2011, the European Medicines Agency suspended the use of pioglitazone products in France and Germany because of bladder cancer risk. 2-ER-104. A week later, the FDA determined that Actos increased the risk of bladder cancer and directed Takeda to add a warning to the Actos label. *Id*.

As Takeda's marketing department and executives predicted, once the bladder cancer warning was made, Actos sales collapsed. 2-ER-105. Between the initial FDA alert in September 2010 and the final warning in June 2011, Actos sales plummeted by 80%, just as the Petitioner drug companies predicted in 2003. 2-ER-106. In August 2012, Actos went generic, and Takeda lost market exclusivity over Actos. *Id*. However, by concealing and misrepresenting the bladder cancer risk for over decade, from 1999 to 2010, the Petitioner drug companies were able to make billions of dollars selling Actos.

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5. Dr. Misbin was recently deposed, revealing even more evidence of the Petitioners' duplicity. However, while discovery continues to proceed before the trial court, such evidence is not in the record before this Court. Such is a consequence of Petitioners seeking certiorari on an interlocutory appeal.

C. Had a Bladder Cancer Warning Been Issued from the Outset, the Class Would Have, on Average, Paid for 56% Fewer Actos Prescriptions

Dr. William S. Comanor is a Distinguished Professor at the Fielding School of Public Health and Director of the Research Program in Pharmaceutical Economics and Policy at the University of California, Los Angeles. 4-ER-491. He is a pharmaceutical economist, having published over 120 journal articles and chapters on the subject. 4-ER-562–577. Indeed, Dr. Comanor's doctoral work is considered the genesis of the entire field.[6]

Here, Dr. Comanor, along with his colleague Dr. Jon Riddle, prepared econometric regression models to estimate what effect, if any, the concealment of the bladder cancer risk had on Actos utilization. *See* 3-ER-198–261; 4-ER-490–559. After reviewing the peer-reviewed literature on antidiabetic drug utilization and Takeda's and Lilly's internal studies, Dr. Comanor obtained national prescription data and constructed "time series regression models designed to explain the quantities of Actos prescriptions dispensed during the damage periods." 4-ER-520–533. The dependent variable was total Actos prescriptions ("TRx"). *See* 4-ER-593. The explanatory variables were the existence of a bladder cancer warning, the existence of a heart failure warning (added to the

6. In 2015, a prestigious economics journal published a series of articles "Honoring Williams S. Comanor and 50 Years of Pharmaceutical Economics." 2-SER-16. The journal "commemorates a half-century since the opening of the field of pharmaceutical economics with Bill's foundational 1964-1966 publications adapted from his Harvard 1963 doctoral thesis." 2-SER-16.

Actos label in 2007), generic entry of pioglitazone, the total size of the oral anti diabetes drug market each month, the monthly price of Metformin, and the number of competitive drugs in the marketplace in each month. 4-ER-524–525, 4-ER-593–596.

Dr. Comanor's third model, which focuses on the period after the September 2010 bladder cancer alert, yields robust results, with an R^2 value of 99%, i.e., less than 1% of unaccounted variation. 4-SER-530–531. Indeed, as shown in Fig. 7 in Dr. Comanor's report, Model III's predicted Actos volume, while controlling for numerous market variables, closely tracks actual volume during that same period—further indicating its predicative power. 4-SER-551.

Using this regression model, Dr. Comanor estimated the relative market share of Actos at the end of 2013—a point where the market was fully informed about the bladder cancer risk—to create a benchmark. 4-ER-532–533, 553, 599. Using this benchmark, Dr. Comanor estimates "the 'but-for' volumes of Actos prescriptions had the bladder cancer risk been widely known" starting in July 1999 (when Actos first entered the market). 4-ER-533. Overall, Dr. Comanor estimates that, between 1999, i.e., the entry of Actos into the market, and September 2010, i.e., the first bladder cancer alert, on average, 44% of the Actos prescriptions would have still been purchased had the bladder cancer risk been public. 3-ER-256. This estimate is based on a regression of Actos sales following the bladder cancer disclosure. In other words, there would have been, on average, 56% fewer Actos prescriptions had Petitioners not committed fraud.

Importantly, Dr. Comanor also conducted a fourth regression using the entire dataset, encompassing both the pre- and post-bladder cancer warning periods. 3-ER-210–213. That analysis confirmed a statistically significant causal relationship between the concealment of the bladder cancer risk and sales of Actos during the entire class period. 3-ER-211.

Dr. Comanor and his team calculated three damage estimates. *See* 4-SER-515, 3-ER-231–232. The first estimate is the total amount spent by the Class on Actos prescriptions caused by concealment of bladder cancer, i.e., the money that would not have been spent on Actos but-for the RICO violations. 3-ER-258. The second estimate makes the same calculation but reduces the estimate by the cost (at each time period) of the most common therapeutically equivalent medication. 3-ER-259. The third estimate reduces the damage estimate by the average cost at each time point of all other oral antidiabetic drugs ("OADs") on the market. 3-ER-260. Dr. Comanor also applied his damages model to Respondent Painters directly, estimating individual damages using each model. 3-ER-261; 4-ER-559.

II. Procedural History

A. The Multidistrict Litigation Proceeding

In 2011, a multidistrict litigation ("MDL") was formed in the Western District of Louisiana, to address thousands of Actos bladder cancer personal injury claims. In January 2014, the first bellwether case went to trial. After thirty-seven days of trial, including testimony from twenty-nine witnesses, a unanimous jury returned a verdict against

the Petitioners. 2-ER-111. The jury awarded $9 billion in punitive damages—$6 billion against Takeda and $3 billion against Lilly.

Upholding the verdict, the district court presiding over the multi-month trial and multi-year MDL explained:

> Beyond merely failing to warn, Plaintiffs presented evidence Takeda and Lilly obfuscated and worked to conceal relevant information from the scientific and medical communities, the FDA, the public, ... concerning an association between Actos use and an increased risk of bladder cancer—again, all in the pursuit of profits ... [T]his intentional conduct reflects the Defendants' deliberate choice, in effect, to sacrifice an identifiable group of individuals in pursuit of profit ... [P]rescribing physicians were denied the information necessary to make a medically-informed decision as to whether it was medically prudent for someone ... to take Actos ... [N]either of Mr. Allen's doctors would have prescribed Actos to Mr. Allen had they known of the risks that Takeda and Lilly knew ... diabetics fighting for control over their disease had other viable alternatives ... Takeda and Lilly acted to protect their sales and profits at the expense of Mr. Allen's, and others like him, health and life, with wanton and reckless disregard of the effects of their actions.

Actos I, 2014 WL 12776173, at *37. Ultimately, the district court reduced the punitive damage award, but confirmed that Takeda's and Lilly's conduct was "grievously

reprehensible." *In re Actos (Pioglitazone) Prods. Liab. Litig.*, No. 6:11-MD-2299, 2014 WL 5461859, at *27 (W.D. La. Oct. 27, 2014). The personal injury claims settled shortly thereafter for $2.4 billion.

B. This Lawsuit

Respondents assert a quantity-effect theory of liability, i.e., that because of the Petitioners' RICO violations, Takeda and Lilly were able to sell greater quantities of Actos. This lawsuit was initially filed in the MDL in 2014 and, in 2017, was transferred, by agreement, to the Central District of California. The RICO claims were originally dismissed with prejudice following a Rule 12(b) motion, but the Ninth Circuit reversed. *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharms. Co. Ltd.*, 943 F.3d 1243 (9th Cir. 2019), *cert. denied*, 141 S. Ct. 86 (2020); *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharms. Co. Ltd.*, 796 F. App'x 919 (9th Cir. 2019). On remand, Petitioners' second motion to dismiss was denied. *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co. Ltd.*, 520 F. Supp. 3d 1258, 1263 (C.D. Cal. 2021).

Following a year of class discovery—again, by agreement—Respondents moved to certify a RICO class of TPPs and a class of California consumers. At the same time, Takeda and Lilly filed motions to exclude the expert opinions of Respondents' econometric experts under *Daubert*. In March 2022, the district court held a day-long hearing on the motions. 1-ER-6. On May 22, 2023, the district court denied the Petitioners' motion to exclude Dr. Comanor's expert opinion. 1-SER-2–12. A few days later, on May 24, 2023, the district court issued an order

certifying the RICO Class and denying certification of the California consumer class. Pet. App. 29. Petitioners filed a Rule 23(f) petition seeking interlocutory relief of the certification order, which the Ninth Circuit granted. Following full briefing and oral argument, the Ninth Circuit affirmed the district court's class certification order. *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co. Ltd.*, No. 23-55742, 2025 WL 1683472, at *1 (9th Cir. June 16, 2025); Pet. App. 1. Petitioners moved for rehearing and/or *en banc* review, which was denied. Pet. App. 27. This petition for writ of certiorari followed.

III. Misstatements in Petition

Petitioners make several misstatements. Pursuant to Rule 15(2), Respondents address those misstatements.

Statement	**Why it is false**
"Since it entered the market in 1999, Actos' FDA-approved label has disclosed a potential link ... between use of the medicine and a slightly elevated risk of bladder cancer." Pet. 5.	The initial label mentioned bladder tumors in a rat study but disavowed any link to humans. 3-SER-334. The 2006 label continued to disavow any link to humans. In 2011, a legitimate bladder cancer warning was added, 2-SER-131, and the current label contains a clear warning on the first page. 3-SER-416.

"[T]heir expert report did not perform a regression analysis for the decade actually covered by the putative classes[.]" Pet. 7.	This is factually incorrect. Dr. Comanor did prepare a model which performed a regression on the entire dataset, and included a variable for pre- and post-bladder cancer alert, i.e., for the period "actually covered by the putative classes." 3-ER-210–213. The bladder cancer alert demonstrated a statistically significant negative effect on Actos utilization, "indicating there is a direct association between the bladder cancer risk announcements and Actos utilization." 3-ER-211.

The district court "also acknowledged that it was hard to see how plaintiffs could prove causation via common proof when petitioners would be entitled to depose the hundreds of thousands of physicians who wrote the millions of prescriptions that class-member TPPs reimbursed." Pet. 8.	The district court never stated this; indeed, the district court openly questioned whether taking individual depositions would even be possible. Specifically, the district court stated that "Takeda or Lilly could still depose individual prescribing physicians to contest Plaintiffs' theory of but-for causation[.]" Pet. App. 73. But, the district court noted that "[i]t is not clear that Takeda or Lilly will—*or even can*—avail themselves of a TPP-by-TPP causation defense using doctor-by-doctor testimony. To sustain an affirmative defense, a defendant must have evidence." Pet. App. 74 (emphasis added). The district court, lacking any evidence to support Petitioners' claim that class members were uninjured, refused to engage in "conjecture." *Id.*

"All parties agreed [uninjured class members] were included within the class definition." Pet. 9.	No uninjured class member has been identified and, based on simple probability, it is highly unlikely that there is any uninjured class member. Every class member has, at minimum, a 98.5% likelihood of being injured, assuming they have the requisite five independent prescriptions to be part of the Class.
Petitioners "produced at the certification stage depositions of two physicians who prescribed Actos to individual representatives of the patient class, both of which showed that additional disclosures would not have altered their prescribing decisions."	Both of the physicians testified that the bladder cancer warnings altered their prescribing decisions. 2-SER-26; 2-ER-63. Indeed, the Ninth Circuit found that "both physicians testified to ***decreasing*** their Actos prescriptions because of the bladder cancer disclosure." Pet. App. 9 (emphasis added).

The district court "accepted plaintiffs' expert report 'at face value[.]'" Pet. 11.	The district court conducted a careful *Daubert* analysis of Dr. Comanor's report and held that it was reliable and admissible under Rule 702. 1-SER-5. The "face value" reference by the district court referred to the fact that it had, previously, determined that the econometric modeling was admissible and reliable and, thus, could be considered as part of the Rule 23 inquiry. Importantly, the district court's *Daubert* ruling is not subject to this appeal. So, for this appeal, the Court must accept that econometric modeling as admissible and reliable.

WHY THE PETITION SHOULD BE DENIED

I. This Case Is Not the Proper Vehicle to Resolve Any Purported Circuit Split Related to Whether a Class May Contain Uninjured Class Members Because There Are No Uninjured Class Members Here

Petitioners argue that this case presents the same question as *LabCorp*: "Whether a federal court may

certify a class action pursuant to Federal Rule of Civil Procedure 23(b)(3) when some members of the proposed class lack any Article III injury." *Lab'y Corp. of Am. Holdings v. Davis*, 145 S. Ct. 1133, 1134 (2025); Pet. 24.[7] It does not. The preponderance of the evidence indicates that the RICO Class does not include any uninjured members. Indeed, after eleven years of litigation, Petitioners have yet to identify a single uninjured class member.

The class is limited to those TPPs that purchased "5 or more independent prescriptions" of Actos.[8] Pet. App. 40–41. According to Dr. Comanor's analysis, approximately 56% of Actos prescriptions were fraudulently induced. Pet. App. 38; 3-ER-256. This means, if a TPP purchased a *single* Actos prescription, it is more likely than not (56%) that the Actos prescription was fraudulently induced. However, if a TPP has five independent prescriptions—which is the *minimum* required to be in the class—the likelihood of being injured is 98.5%. 3-ER-220; see, e.g., *see In re Celexa & Lexapro Mktg. & Sales Pracs. Litig. ("Celexa & Lexapro")*, 915 F.3d 1, 13 (1st Cir. 2019) ("[I]f Painters paid for as few as five independent prescriptions, there would be a 98% chance that at least one was the result of off-label marketing ... So the odds that Painters was not harmed if the drugs were, indeed, ineffective was likely infinitesimal[.]").

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7. Here, Petitioners style their first question presented as follows: "Whether a federal court may certify a class action pursuant to Federal Rule of Civil Procedure 23(b)(3) when some members of the proposed class lack any compensable injury in fact." Pet. 1.

8. An "independent" prescription is a non-refill prescription. Pet. App. 62.

For class members with more than five independent prescriptions—which is the overwhelming majority of the class—"their chance of having at least one fraudulent prescription increases with each additional prescription." Pet. App. 10. Thus, for those class members that have hundreds or thousands of independent Actos prescriptions, there are "infinitesimal chances of being uninjured." *Id.* For example, if a TPP reimbursed ten independent Actos prescriptions, the chance that none of the ten were induced by fraud would be 0.023%[9]—or, put another way, there is 99.77% that the TPP was injured. If a TPP reimbursed 100 independent prescriptions, the probability of that TPP being uninjured is 0.00000000000000000000000000000000000004%.[10]

At the class certification stage, Article III standing is assessed against the preponderance of the evidence standard. *DZ Rsrv. v. Meta Platforms, Inc.*, 96 F.4th 1223, 1240 (9th Cir. 2024), *cert. denied*, 145 S. Ct. 1051 (2025); *see Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992) (Article III standing established by "the degree of evidence required at the successive stages of the litigation."). Here, where the likelihood of injury for the most-likely-to-be-uninjured class member is 98.5%, there is no reason to believe, by a preponderance of the evidence, that *any* class member is uninjured. Thus, this case does not present a situation where there is any real probability of there being an uninjured class member—indeed, on this record, for any class member, the evidence supports that they were economically injured, i.e., paid for at least

9. $(1—0.5677)^{10} \approx 0.00023$

10. $(1—0.5677)^{100} \approx 0.00000000000000000000000000000000000004$

one fraudulently-induced Actos prescription, sufficient to meet Article III standing.

Against this math, it is no wonder Petitioners are *unable to identify a single uninjured class member* after eleven years of litigation. Instead, Petitioners present depositions of two prescribers—neither of whom belong to the class—and who both testified that their Actos use *decreased* because of the bladder cancer disclosure in 2011. Specifically, the first prescriber testified that she prescribes *less* Actos because of the bladder cancer risk and that she has observed "similar decreases in use" among her colleges "at Kaiser following the bladder cancer risk disclosure." 2-SER-26. The second prescriber testified that, once she learned of the bladder cancer risk, she stopped using it altogether with certain patients (men over 60 who smoke). 2-ER-63. Both depositions *confirm* that Actos utilization decreased because of the bladder cancer risk—the exact opposite of what Takeda and Lilly must prove to conjure an uninjured class member. The Ninth Circuit agreed, noting that the proffered testimony "*shows causation and injury*, not a lack of causation and injury." Pet. App. 9 (emphasis added).

Almost three years ago, the district court stated that Petitioners "could still depose individual prescribing physicians to contest [Respondents'] theory of but-for causation[.]" Pet. App. 73. But, to date, Petitioners have *not* done this and there is no evidence in this record. *See, e.g.*, *Kohen v. Pac. Inv. Mgmt. Co. LLC*, 571 F.3d 672, 679 (7th Cir. 2009) (affirming certification where defendant could still "depose a random sample of class members to determine how many ... were not injured," but it "has not done this"). As the district court explained in certifying

the class, "[w]hile the Court could speculate whether Takeda or Lilly will depose (or even can depose) many prescribing physicians, it is not this Court's role to make decisions on conjecture." Pet. App. 76. The district court, thus, refused to "speculat[e on] whether the dearth of physician testimony is the result of a tactical decision or a matter of unavailability." *Id.*

As the tally stands, there is admissible evidence—characterized by the district court as "a mountain of evidence," *id.*, that each class member is, more likely than not, injured; and there is no *evidence* to the contrary. On this record, Petitioners' assertion that there are uninjured class members in the certified class is little more than supposition. Absent such a showing, this case does not present the factual predicate necessary to resolve any purported circuit split concerning classes that include uninjured members.

Petitioners might reply that their lack of evidence proves their point—that it is difficult to separate "the injured-class-member wheat from the uninjured-class-member chaff[.]" Pet. 1. But, again, there is no evidence to support this argument—indeed, the record directly contradicts it. For one, it is undisputed that Petitioners, like the defendant in *Kohen*, did not even try to "depose a random sample of class members to determine how many ... were not injured[.]" *Kohen*, 571 F.3d at 679. Moreover, it is undisputed that Petitioners' expert economist, Dr. James Hughes, and Dr. Comanor were *each* able to identify class members using plan-level data and limit their analyses to plans with at least five new prescriptions with ease: "the IQVIA plan-level data provided by the Defendants permits the tabulation of total

new prescription by plan and month[.]" 3-ER-221; *see also* 3-ER-467 (Dr. Hughes focused on plans that "have ... at least five new prescriptions over the course of the data."). The district court held that both experts "successfully used the same IQVIA plan-level data to screen out TPPs that did not fall within the class definition when filtering for independent prescriptions." Pet. App. 62. That each side's experts were able to perform these analyses with relative ease confirms that Petitioners possess the tools necessary to test their affirmative defense. They just either failed to do so or, more likely, as the math suggests, there is simply no chaff in this wheat.

II. The Interlocutory Posture of This Case Warrants Denial of Certiorari

Petitioners' certiorari bid is further undermined by this case's interlocutory posture. This Court has frequently noted that the interlocutory posture of a case is sufficient to warrant denying certiorari. *See*, *e.g.*, *Kennedy v. Bremerton Sch. Dist.*, 139 S. Ct. 634, 635–36 (2019) (statement of Alito, J., respecting the denial of certiorari); *Brotherhood of Locomotive Firemen & Enginemen v. Bangor & Aroostook R.R.*, 389 U.S. 327, 328 (1967) (per curiam); *see also Virginia Military Inst. v. United States*, 508 U.S. 946, 946 (1993) (opinion of Scalia, J., respecting the denial of certiorari).

Denying certiorari review of an interlocutory decision promotes judicial efficiency and allows the Court to consider claims based on a full factual record and comprehensive presentation of the legal issues. As litigation progresses, the lower courts may also engage in different legal analyses and reach different legal conclusions—which

should inform this Court's consideration of the issues. Denying certiorari of an interlocutory decision enables additional arguments asserted at different stages of the proceeding to be consolidated into a single petition. *See Major League Baseball Players Ass'n v. Garvey*, 532 U.S. 504, 508 n.1 (2001) (per curiam).

Here, the Ninth Circuit affirmed a class-certification order taken on appeal pursuant to Rule 23(f), entered well before any ruling on the merits, summary judgment, trial, or final judgment. No damages have been awarded, no liability has been established, and no determination has been made that any class member—named or absent—is entitled to recover or is uninjured. Rule 23(c)(1)(C) expressly provides that a class-certification order "may be altered or amended before final judgment," and the district court retains full authority to decertify the class, refine its scope, or address any standing, manageability, or proof-related issues that may arise as the case proceeds. For example, if Petitioners finally identify an uninjured class member, the district court may, at that point, reconsider whether certification is appropriate. Intervening now, however, while the evidentiary record continues to develop, would require the Court to speculate about how injury, defenses, and remedies *might* be litigated in the future. Because of the interlocutory nature of this appeal,[11] this case is simply not the proper vehicle for resolving any issues—real or imagined—on appeal.

11. Indeed, there is a pending motion for summary judgment on a potentially dispositive issue before the district court that is, in turn, awaiting a ruling by the Ninth Circuit. D. Ct. Dkt. No. 421, 2:2017-cv-07223 (C.D. Cal.). Should Petitioners prevail on that motion, this case, and this appeal, will cease to exist, and there would be no grounds for any review of the certification order.

III. The Court Should Not Grant Certiorari on the "But-For" Causation Question Because There is No Circuit Split that This Case Could Address

Petitioners next contend that certiorari is warranted to resolve a supposed circuit split concerning class claims that purportedly turn on but-for causation (referred to as "reliance") issues. Pet. 19–24. That argument rests almost entirely on a single decision of the Second Circuit—*UFCW Local 1776 v. Eli Lilly & Co. ("Zyprexa")*, 620 F.3d 121 (2d Cir. 2010). One case, however, does not a circuit split make, especially given that *Zyprexa* turned on the facts specific to the certification sought in that case, not a transposable rule of law. *See*, *e.g.*, Sup. Ct. R. 10 ("A petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law.").

A genuine circuit split worthy of certiorari review requires a "real and embarrassing conflict of opinion and authority between the Circuit Courts of Appeals" on the same legal question, not merely an apparent or superficial disagreement. *Rice v. Sioux City Memorial Park Cemetery*, 349 U.S. 70, 79 (1955) (quoting *Layne & Bowler Corp. v. Western Well Works, Inc.*, 261 U.S. 387, 393 (1923). Petitioners identify no such division here. No court of appeals—including the Second Circuit—has adopted a categorical rule barring TPPs from proving civil RICO but-for causation through common evidence, and no court has held that physician decision-making always defeats predominance in pharmaceutical fraud cases. To the contrary, the Second Circuit has specially recognized that causation may be susceptible to common proof when plaintiffs present evidence capable of showing that

defendants' conduct distorted the market or prescribing environment in a uniform way.

A. The Second Circuit is in Harmony with the Ninth Circuit on RICO But-For Causation

Zyprexa is not the silver bullet that Petitioners wish it to be. There, the Second Circuit held in *dicta*[12] that "general proof of but-for causation" was "impossible" because prescribing doctors may have reacted differently to the same fraudulent conduct. *Zyprexa*, 620 F.3d at 135–36. But the Second Circuit backtracked any absolute rule of law.

In *Sergeants*—a case decided after *Zyprexa*—the Second Circuit held that, far from "impossible," "it *may be possible* to demonstrate class-wide RICO causation in a case such as this one by adducing generalized proof from which a reasonable jury could conclude that only some prescriptions paid for by each class member were written based on the defendant's alleged misrepresentations." *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 94, 97 (2d Cir. 2015) (emphasis added). The Second Circuit went on to explain that but-for causation could be susceptible to common proof "so long as at least some of the prescriptions for which it paid were written in reliance on those misrepresentations." *Id.* at 94. The Second Circuit suggested that this could be established using a regression model: "Regression models are a well-known and widely

12. Plaintiffs had abandoned the quantity effect theory, but the Second Circuit chose to explain why it was doomed for failure anyway. *See Zyprexa*, 620 F.3d at 135.

accepted tool of economic analysis, and while they 'cannot explicitly determine causation or prove causality between variables,' they can strongly support a causal relationship between two variables (here, safety disclosures and sales) by ruling out or limiting the influence of other variables, or by demonstrating that those other variables are themselves merely a function of one of the first two." *Id*. at 96. However, because plaintiffs did not provide a regression in *Sergeants*, it "distinguishe[d] th[e] case from the First Circuit's decision in *In re Neurontin Marketing & Sales Practices Litigation*[.]" *Id*. (citing *In re Neurontin Mktg. & Sales Pracs. Litig. ("Kaiser")*, 712 F.3d 21, 27–28 (1st Cir. 2013)).

Collectively, *Kaiser*, along with the other First Circuit cases in the *Neurontin* litigation—*In re Neurontin Mktg. & Sales Pracs. Litig. ("Aetna")*, 712 F.3d 51 (1st Cir. 2013) and *In re Neurontin Mktg. & Sales Pracs. Litig. ("Harden")*, 712 F.3d 60 (1st Cir. 2013)—hold that a TPP can establish but-for causation in a quantity effect pharmaceutical RICO case using a combination of regression and persuasive common evidence. The First Circuit reaffirmed this analysis in *Celexa & Lexapro*, 915 F.3d at 6.[13]

13. Petitioners claim that the First Circuit's *Asacol* decision "casts considerable doubt on whether that court would certify a class like this one[.]" Pet. 23 (citing *In re Asacol Antitrust Litig.*, 907 F.3d 42, 53–54 (1st Cir. 2018)). That is simply not the case. For one, *Asacol* is not a civil RICO case. But, more crucially, *Asacol* was a case "in which any class member may be uninjured" and where there were apparently "thousands who in fact suffered no injury." *Asacol*, 907 F.3d at 53. Again, Petitioners have failed to identify a single uninjured class member, and will likely struggle to do so given the infinitesimal probabilities at play.

The Ninth Circuit's decision below does not conflict with *Zyprexa*; rather, it follows the exact approach outlined by the Second Circuit in *Sergeants*, one exemplified by the First Circuit in *Neurontin* and *Celexa & Lexapro*. Here, as the First and Second Circuits signaled was possible, plaintiffs presented extensive expert, documentary, and testimonial evidence—including econometric analysis and internal company materials—capable of showing that Petitioners' concealment of the bladder cancer risk distorted prescribing behavior in a classwide manner. Applying settled Rule 23 principles, the Ninth Circuit held that the district court did not abuse its discretion in concluding that this common proof was sufficient to satisfy predominance. That fact-bound determination does not create a circuit split, let alone one warranting this Court's intervention. It merely reflects the application of an agreed-to legal principle—shared by all circuits—related to whether but-for causation can be proven with common evidence as applied to different factual patterns in *Zyprexa*, *Sergeants*, *Kaiser*, *Aetna*, *Harden*, *Celexa & Lexapro*, and, now, here. At most, Petitioners identify routine inter-circuit variation in the application of Rule 23 to differing factual and evidentiary records—precisely the sort of case-specific divergence that does not justify certiorari. *See* Sup. Ct. R. 10.

B. Petitioners' Other Cases Are Not Relevant

Petitioners also try to argue that decisions from the Eighth, Fifth, and Sixth Circuits demonstrate that their purported reliance split extends beyond *Zyprexa*. A review of those cases, however, confirms the opposite: each turned on materially different facts, involved fundamentally different theories of injury, or rejected

certification for reasons wholly independent of any categorical rule concerning causation in pharmaceutical RICO cases.

In *Vogt v. Progressive Casualty Insurance Co.*, the Eighth Circuit affirmed denial of class certification where a consumer brought fraud and negligence claims against the seller of a used van. 129 F.4th 1071, 1072 (8th Cir. 2025). On its face, this case has nothing to do with RICO or pharmaceutical fraud; accordingly, it is difficult to see how this has any applicability to the purported certification ruling here and whether but-for causation or reliance can be established using common proof. This is confirmed by *Custom Hair Designs by Sandy v. Central Payment Co., LLC*, 984 F.3d 595 (8th Cir. 2020), where the Eighth Circuit specifically addressed RICO and made clear that Petitioners "arguments about reliance misstate current RICO law[.]" *Id.* at 602 (citing *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 652 (2008). This is because "[a]lthough reliance is required for common law fraud, RICO's predicate is mail or wire fraud, which did not exist at common law." *Id.* The Eighth Circuit went on to affirm certification of the civil RICO class at issue. *Id.* at 605.

Castano v. American Tobacco Co. is even further afield. 84 F.3d 734 (5th Cir. 1996). That case involved an unprecedented attempt to certify a nationwide class of smokers asserting a sweeping array of state-law claims based on nicotine addiction, spanning dozens of jurisdictions with materially divergent legal standards. The Fifth Circuit reversed certification primarily because the district court failed to grapple with overwhelming variations in state law and had not articulated a workable trial structure. *Id.* at 741–44. Again, the case did not

concern RICO, a key distinction the Fifth Circuit, like the Eighth Circuit, recognizes in light of *Bridge*: "mail fraud and its place in the RICO framework are different from a case alleging common-law fraud, and one of the differences is the lack of a reliance requirement." *Allstate Ins. Co. v. Plambeck*, 802 F.3d 665, 676 (5th Cir. 2015) (citing *Bridge*, 553 U.S. at 653); *see also Torres v. S.G.E. Mgmt., L.L.C.*, 838 F.3d 629, 636–37, 646 (5th Cir. 2016) (affirming certification of civil RICO class and recognizing effect of *Bridge*).

The Sixth Circuit's recent decision in *Speerly v. General Motors LLC*, another case Petitioners cite, likewise does not concern RICO. 143 F.4th 306 (6th Cir. 2025) (en banc). And, like the other Circuits, the Sixth Circuit recognizes the effect of *Bridge*. *Brown v. Cassens Transport Co.*, 546 F.3d 347, 357 (6th Cir. 2008); *see also Compound Prop. Mgmt. LLC v. Build Realty, Inc.*, 343 F.R.D. 378, 407 (S.D. Ohio 2023) (certifying civil RICO class and holding that plaintiffs need not prove reliance in light of *Bridge*).

In short, none of the additional cases Petitioners cite supports the existence of a circuit split on causation in civil RICO cases, let alone any split on reliance warranting this Court's review. To the extent those decisions denied class certification, they did so in non-RICO contexts, on materially different records, or based on individualized issues unrelated to the principles governing RICO claims in pharmaceutical fraud cases after *Bridge*. Where courts of appeals have addressed civil RICO directly, including in the Eighth, Fifth, and Sixth Circuits, they have consistently recognized that reliance is not an element of RICO liability and that causation may, in appropriate

cases, be established through common proof. The decision below is fully consistent with that settled understanding, and Petitioners' effort to recast fact-bound certification rulings from unrelated contexts into a "reliance split" fails to identify any conflict this Court needs to resolve.

IV. The Decision Below Is Consistent with This Court's Precedent

Petitioners next try to argue that, substantively, the decision below is not consistent with Article III, Rule 23, and this Court's precedents. Pet. 24–30. In so doing, they claim that the Ninth Circuit did not "require plaintiffs to put forward a mechanism for determining who among them is or is not injured." Pet. 24. But, as discussed above, Respondents have put forward such a mechanism—only TPPs that have at least five independent Actos prescriptions, which can be tabulated using claims data, can be part of the Class. Using this simple process, injured and uninjured TPPs can be quickly and easily classified. And, indeed, given the probability analysis undergirding Respondents' class definition and illustrated by the math above, each class member, more likely than not, has Article III standing by virtue of being a class member.[14] *See*, *e.g.*

14. Importantly, other courts embrace the use of probability for this purpose: "probability analysis provides a plausible method for determining—across the classes—the number of class members who may not have sustained injury from defendants' purported conduct." *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, No. 17-MD-2785-DDC-TJJ, 2020 WL 1180550, at *33 (D. Kan. Mar. 10, 2020); *see Celexa & Lexapro*, 915 F.3d at 13; *In re Niaspan Antitrust Litig.*, 464 F. Supp. 3d 678, 717 (E.D. Pa. 2020) (using probability to conclude class did not include uninjured TPP class members); *In re Loestrin 24 FE Antitrust Litig.*, 410 F. Supp. 3d 352, 405 (D.R.I. 2019).

Perry v. Village of Arlington Heights, 186 F.3d 826, 829 (7th Cir. 1999) (noting that the existence of standing need only be proven be a preponderance of the evidence*)*.

Moreover, contrary to Petitioners' claims, the Ninth Circuit's decision faithfully applies this Court's settled Rule 23 jurisprudence, particularly *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442 (2016)—a case heavily relied on by Respondents, the district court, and the Ninth Circuit. A class representative can demonstrate predominance under Rule 23(b)(3) for an element if, using only common evidence, there exists a triable issue of fact regarding that element: a "permissible method of proving classwide liability is by showing that each class member could have relied on that sample to establish liability if he or she had brought an individual action." 577 U.S. at 455. The Ninth Circuit expressly recognized this holding in the decision below. Pet. App. 3. The appeals court also, following *Wal-Mart Stores, Inc. v. Dukes*, considered Petitioners' affirmative defenses. Pet. App. 3. (citing *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 367 (2011)). And, in affirming certification, the Ninth Circuit hewed to these precedents—scrutinizing the robust evidentiary record mustered at the class certification stage and considering Petitioners' challenges—ultimately holding that the district court did not abuse its discretion by finding predominance. Pet. App. 3.

Indeed, the "mountain of evidence regarding but-for causation that is common to the class" (Pet. App. 76) supplied by Respondents at certification included:

- Numerous admissions by Takeda and Lilly employees, corporate representatives, and

their expert admitting the concealment of the bladder cancer risk caused excess Actos prescriptions to issue, *see*, *e.g.*, 2-SER-309–09; 4-SER-702; 2-SER-301; 2-SER-293;

- Internal marketing surveys showing that physician interest in an OAD like Actos would dramatically decline if there were a bladder cancer risk associated with product, *see*, *e.g.*, 2-SER-283–84; 2-SER-205;

- Testimony from actual prescribers that they stopped or reduced prescribing Actos because of the bladder cancer risk, including one of the plaintiffs' prescribers, 2-SER-26; 2-ER-63;

- Data showing a systematic and dramatic decline of Actos use following the bladder cancer risk disclosures in 2010 and 2011, *see*, *e.g.*, 4-ER-547; 3-ER-244–248; 4-ER-545–552;

- Internal studies and admissions by Takeda that the bladder cancer risk was causing decreased utilization in 2010 and 2011, *see*, *e.g.*, 2-SER-126; 4-SER-545; 4-SER-548; 4-SER-557–566; 4-SER-568; 4-SER-540;

- Multiple peer-reviewed and independent studies confirming the effect of the bladder cancer risk disclosure on Actos utilization in the United States and around the world, *see*, *e.g.*, 2-SER-103; 2-SER-83; 2-SER-68; 2-SER-59;

- Evidence of a dramatic increase of physician information requests concerning bladder cancer once the risk was disclosed, *see*, *e.g.*, 2-SER-52; 2-SER-52; 2-SER-34; 2-SER-36–50; and

- A robust economic regression confirming that the bladder cancer risk did, in fact, have a causal impact on Actos use during the class period, *see*, *e.g.*, 3-ER-256.[15]

This is all *common* evidence that, when considered together, would allow an individual TPP to make out a *prima facie* case of but-for causation, i.e., that it, more likely than not, paid for at least one fraudulently induced Actos prescription.

In short, the decision below recognizes that Article III demands a showing of injury by a preponderance of the evidence, not certainty; that Rule 23(b)(3) demands predominance of common questions, not individualized proof of liability; and that probabilistic and statistical evidence may be used where appropriate. Because the

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15. *Tyson Foods* also held that: "In many cases, a representative sample is "the only practicable means to collect and present relevant data" establishing a defendant's liability." 577 U.S. at 455 (citing the Manual of Complex Litigation § 11.493, p. 102 (4th ed. 2004)). The Court went on to state that "[i]n a case where representative evidence is relevant in proving a plaintiff's individual claim, that evidence cannot be deemed improper merely because the claim is brought on behalf of a class. To so hold would ignore the Rules Enabling Act's pellucid instruction that use of the class device cannot 'abridge ... any substantive right.' 28 U.S.C. § 2072(b)." *Id.*

Ninth Circuit faithfully applied those settled principles to a robust evidentiary record, its decision is fully consistent with this Court's precedents.

V. Petitioners' Policy Concerns Do Not Provide a Basis for Certiorari

With the law against them, Petitioners raise "tort reform" policy concerns about settlement pressure. Pet. 31–34. This Court has rejected such arguments before. *See Amgen Inc. v. Conn. Ret. Plans & Tr. Funds*, 568 U.S. 455, 474–77 (2013) (dismissing policy arguments about "in terrorem settlements"). But Petitioners' suggestion that this case represents an unfair or disproportionate exposure to liability disregards this case's undisputed economic context.

For the decade Takeda and Lilly actively concealed the bladder cancer risk, they exposed "more than 10 million" Americans to a carcinogen without their consent and *netted $24 billion* in the process. 2-SER-412–413. By violating RICO, Takeda and Lilly made staggering profit, selling more Actos than they ever would have had they been honest. TPPs around the country footed much of that bill. This lawsuit attempts, in part, to correct the impact of this fraud by recovering a portion of the money they obtained from TPPs. This fraud is no remote and trivial matter; it is, according to the MDL court that presided over Actos litigation for over five years, "a concerted, long-term effort to conceal and obfuscate information about the true risk of bladder cancer ... all in the blind pursuit of profit." *Actos II*, 2014 WL 5461859, at *24.

There has been no flood of civil RICO class action litigation in the Ninth Circuit in the wake of the certification order here; no parade of horribles. Pet. 33. This is because the decision below does not create a new cause of action, relax the elements of civil RICO, or dispense with proof of injury. It applies settled Rule 23 principles to a highly developed factual record involving a "mountain of evidence" of long-term concealment of serious safety risks tied to a single, massively profitable pharmaceutical product. Pet. App. 76. The denial of class certification to the consumer class in the same case underscores the narrowness of the ruling and the continued rigor of Rule 23 scrutiny. Far from opening the floodgates, the decision confirms that certification remains dependent on the particular evidence and theories presented. In short, nothing in Petitioners' policy discussion identifies a concrete, recurring problem, let alone one that requires this Court's intervention on an interlocutory appeal.

CONCLUSION

The petition seeks this Court's intervention not to resolve a genuine conflict or correct a departure from settled law, but to relitigate a fact-bound class-certification decision entered after years of litigation and careful review. Petitioners have not identified a single uninjured class member, have not demonstrated a meaningful circuit split on causation, and have not shown that the decision below conflicts with this Court's precedents. Even if Petitioners had done these things, this interlocutory appeal does not present a suitable vehicle for addressing the questions Petitioners pose, especially in light of the interlocutory nature of the case and a continued development of the evidentiary record in the district court.

Because the Ninth Circuit faithfully applied governing law and because this case raises no issue warranting certiorari, the petition for a writ of certiorari should be denied.

Respectfully submitted,

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