No. _____

In the
Supreme Court of the United States

TAKEDA PHARMACEUTICAL COMPANY LIMITED, et al.,

Petitioners,

v.

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

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

PAUL D. CLEMENT
Counsel of Record
ERIN E. MURPHY
MATTHEW D. ROWEN
CAMILO GARCIA*
CLEMENT & MURPHY, PLLC
706 Duke Street
Alexandria, VA 22314
(202) 742-8900
paul.clement@clementmurphy.com

* Supervised by principals of the firm who are members of the Virginia bar

Counsel for Petitioners

November 26, 2025

QUESTIONS PRESENTED

This case involves a multibillion-dollar civil RICO class action covering tens of thousands of third-party payors that reimbursed millions of prescriptions for hundreds of thousands of patients over a ten-year period. As both the district court and the court of appeals admitted, an unknown number of class members were never harmed—by the class's own telling, at least thousands of them. Nevertheless, the Ninth Circuit blessed this sprawling Rule 23(b)(3) class, reaffirming its outlier view that classes with an untold number of unharmed members may be certified, even if the plaintiffs offer no plan for figuring out which class members are properly before the court. In so holding, the court entrenched an acknowledged circuit split on which this Court has twice granted certiorari but has yet to resolve. The Ninth Circuit then made matters even worse, permitting the use of representative evidence to paper over the fundamentally individualized nature of the class claims in a holding that defies this Court's teachings and splits with decisions of other circuits that faithfully follow them.

The questions presented are:

1. 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.

2. Whether a federal court may certify a class action pursuant to Federal Rule of Civil Procedure 23(b)(3) when a class relies on representative evidence to try to prove an individualized reliance issue that is a necessary element of each plaintiff's claim.

PARTIES TO THE PROCEEDING

Petitioners (defendants-appellants below) are Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A. Inc., and Eli Lilly and Company.

Respondents (plaintiffs-appellees below) are Painters & Allied Trades District Council, and 82 Health Care Fund, on behalf of themselves and all others similarly situated, as well as Annie M. Snyder, Rickey D. Rose, John Cardarelli, Marlyon K. Buckner, and Sylvie Bigord.

CORPORATE DISCLOSURE STATEMENT

Takeda Pharmaceutical Company Limited is a publicly held entity traded on the Tokyo Stock Exchange and the New York Stock Exchange and has no parent company. No publicly held company owns 10% or more of its stock. Takeda Pharmaceuticals U.S.A. Inc. is a 100% subsidiary of Takeda Pharmaceuticals Company Limited.

Eli Lilly and Company is a publicly held entity traded on the New York Stock Exchange and has no parent company. No publicly held company owns 10% or more of its stock.

STATEMENT OF RELATED PROCEEDINGS

The following proceedings are directly related to the case within the meaning of Rule 14.1(b)(iii):

- *Takeda Pharm. Corp. Ltd. et al. v. Painters & Allied Trades Dist. Council, 82 Health Care Fund et al.*, No. 23-55742 (9th Cir.), judgment entered on June 16, 2025; petition for rehearing denied on August 8, 2025.
- *Painters & Allied Trades Dist. Council, 82 Health Care Fund et al. v. Takeda Pharm. Corp. Ltd. et al.*, No. 2:17-cv-07223 (C.D. Cal.), certification motion granted on May 24, 2023.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statute and Rules

Other Authorities

PETITION FOR WRIT OF CERTIORARI

This petition presents a question that this Court has twice granted certiorari to answer but has not yet resolved: May a court certify a Rule 23(b)(3) class when the plaintiffs admit that some unknown number of putative class members suffered no Article III injury, but offer no way to separate the injured from the uninjured? That question has long divided the circuits, and this Court has long recognized its importance. This case provides an excellent vehicle for resolving it once and for all.

The answer to the question is plainly no. While some courts have wrestled with how many uninjured class members is too many to preclude certification, it should be common ground that putative class plaintiffs need to provide a viable way of separating the injured-class-member wheat from the uninjured-class-member chaff. But the Ninth Circuit thinks differently, and its extreme view—that plaintiffs need not offer any mechanism for separating out uninjured class members at the class-certification stage, even when everyone agrees that the class includes uninjured members—is incompatible with this Court's teaching, the law in other circuits, and the fundamental limits on Article III courts. If a federal court knows some class members are uninjured, but is left in the dark about which ones and how they can be separated out, then the court has no business certifying the class. Assuming certification does not force the defendant to settle with a payout going to injured and uninjured alike, the court will inevitably find itself unable to award classwide monetary relief. After all, "Article III does not give federal courts the

power to order relief to any uninjured plaintiff, class action or not." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021).

That recurring threshold issue is reason enough to grant certiorari, especially since this case tees up the issue cleanly, without the complications that have frustrated resolution in other cases. But that is not the only way in which the decision below parts with other circuits. The Second Circuit has held that a (b)(3) class essentially identical to the one here cannot be certified, because it is almost unavoidably bogged down by individualized reliance issues.

This case began as two class actions, one brought by consumers and one brought by third-party payors ("TPPs"), both of whom allege that they would not have purchased (patients) or would not have paid for (TPPs) a medicine had its manufacturer not purportedly misled people about its potential risks. The district court correctly recognized that the consumer class could not be certified, because whether a patient and her physician actually relied on the alleged misrepresentations in selecting a course of treatment is an inherently individualized issue that would require thousands upon thousands of mini-trials to adjudicate. Yet the district court nevertheless held that the TPP class could proceed—even though the TPPs' claims turn on the same individualized reliance issues, just one step removed.

The Ninth Circuit blessed the TPP class, positing that general (and highly dubious) statistical evidence that roughly half of prescriptions probably were the product of reliance—meaning roughly half were *not*—sufficed to cure as to the TPP class the same defect

that doomed the consumer class. In doing so, the Ninth Circuit not only blessed certification of a TPP class nearly identical to a putative TPP class the Second Circuit held could *not* be certified due to individualized reliance issues, but departed from the clear teachings of this Court about cases that turn on individualized reliance questions, as well as from decisions from other circuits respecting them.

Each of those issues readily warrants this Court's attention. Indeed, the Court has already recognized the importance of the first issue by granting certiorari to resolve it twice. And the Court has recognized the importance of the second issue by repeatedly intervening when lower courts—including the Ninth Circuit—have tried to use representative evidence to paper over individualized reliance issues. It is particularly critical that the Court intervene again here, as the careful limits this Court and others have imposed on parties seeking to certify classes that turn on reliance issues would be for nought if they could be skirted simply by having a different set of plaintiffs assert essentially the same claims, only one step removed. In short, both issues have divided the lower courts, both are cleanly presented, and both are critical to class-action litigation. The Court should grant review and reverse.

OPINIONS BELOW

The Ninth Circuit's opinion, 2025 WL 1683472, is reproduced at App.1-26; the Ninth Circuit's unpublished order denying rehearing is reproduced at App.27-28. The district court's opinion, 674 F.Supp.3d 799, is reproduced at App.29-100.

JURISDICTION

The Ninth Circuit issued its opinion on June 16, 2025, and denied a petition for rehearing on August 8, 2025. On October 28, 2025, Justice Kagan extended the time to file a petition until December 6, 2025. This Court has jurisdiction under 28 U.S.C. §1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Article III, §§1-2 of the United States Constitution is reproduced at App.149. Federal Rule of Civil Procedure 23 is reproduced at App.149-159.

STATEMENT OF THE CASE

A. Factual and Procedural Background

1. The decision to prescribe a particular medicine to a particular patient is highly individualized and "necessarily reside[s] with the patients and their physicians." App.87. A physician must consider the patient's medical history and current diagnosis, her own knowledge regarding the efficacy and potential side effects of available treatments, what other physicians in the field are prescribing for the ailment, and more. *See UFCW Loc. 1776 v. Eli Lilly & Co.* (*Zyprexa*), 620 F.3d 121, 135 (2d Cir. 2010). Naturally, then, weighing a medicine's risks and benefits lies, first and foremost, with a patient's physician.

Once a physician prescribes a medicine, whether the cost of that medicine will be reimbursed, and who ultimately foots the bill, similarly depend on a host of individualized variables. Third-party payors like respondent Painters, for instance, have the authority to determine which medicines will be covered by their insurance plans. D.Ct.Dkt.127 (2d.Am.Compl.) ¶136.

Painters will reimburse plan members only for prescriptions that are "medically reasonable and necessary for treatment." *Id.* ¶133. And even when a medicine is covered and an individual's claim satisfies the relevant criteria, the costs of a prescription are typically shared among several parties, including TPPs, pharmacy benefit managers, and manufacturers.

2. In 1999, Takeda obtained FDA approval for Actos, a medicine used to treat type-2 diabetes. App.35. Lilly signed a co-promotion agreement, under which it promoted Actos along with Takeda until 2006. App.51. Actos enjoyed exclusivity until 2012, when generic pioglitazone was introduced into the market. CA9.ER.341.

Since it entered the market in 1999, Actos' FDA-approved label has disclosed a potential link—one that petitioners strenuously deny—between use of the medicine and a slightly elevated risk of bladder cancer. CA9.ER.341-42. In 2006, the FDA approved an updated label that reiterated this possible connection based on then-recent studies. CA9.JA.341-42. The FDA undertook a safety review of Actos four years later, and in 2011 it again approved an updated label disclosing a possible association between Actos and an increased risk of bladder cancer for individuals who take it for prolonged periods. CA9.ER.341-42. The FDA, however, has so far found that there is "insufficient data" to make a final determination about this potential risk. CA9.ER.159.

3. In July 2014, Painters and a group of patients who took Actos filed this putative class action as part of a multi-district litigation then pending in the

Western District of Louisiana. App.32. Unlike the other claims consolidated in the MDL, however, these plaintiffs did not claim they developed bladder cancer or suffered any other personal injury from taking Actos. App.32. They instead alleged that patients would not have purchased Actos, and TPPs would not have paid for it, if petitioners had not allegedly concealed information regarding a potentially heightened risk of bladder cancer.

After the parties stipulated to transfer the case out of the MDL to the Central District of California, App.32, plaintiffs filed the operative complaint. The complaint alleges that petitioners caused physicians to overprescribe Actos—which in turn caused TPPs to pay for more prescriptions than they otherwise would have—by concealing an allegedly heightened risk of bladder cancer. The complaint asserts claims under state consumer fraud laws and the Racketeer Influenced and Corrupt Organizations Act. D.Ct.Dkt.127 (2d.Am.Compl.) ¶¶231-357.

4. Plaintiffs moved to certify two classes under Rule 23(b)(3): a class of all TPPs that reimbursed five or more "independent" Actos prescriptions; and a class of all California consumers who purchased Actos beginning in July 1999. App.40-41, 78-79.

In support of their motion, plaintiffs relied on expert evidence to try to prove injury and causation. App.38. Plaintiffs employed an "econometric regression model" to estimate Actos' market share three years *after* the class period ended, even though there was no need to develop such a model because Actos' market share was actually known at this time. App.38. From there, plaintiffs' expert assumed that

the market share generated by his model would have been the same during the class period had the public been "fully informed" about Actos' risks. On that basis, he estimated the percentage of Actos prescriptions that ostensibly would not have been made. App.59-60. That analysis—which assumes (contra reality) that each Actos prescription was entirely independent of all others, and that the supposed misrepresentation was equally likely to drive each prescribing decision—purports to show that roughly 57% of Actos prescriptions would not have been written but for the alleged concealment. App.59. From that, the expert postulated that each TPP in the class has a 98.5% chance of having reimbursed at least one "excess" prescription, i.e., a prescription that would not have been written but for the challenged conduct. App.60; *see also* CA9.ER.367 & n.112.

Plaintiffs did not propose any means, however, of determining which of the millions of prescriptions at issue *in fact* would not have been made, let alone which TPPs paid for each of those prescriptions. And even as to the percentages plaintiffs used to try to mask that problem, their expert report did not perform a regression analysis for the decade actually covered by the putative classes, so it did not purport to analyze whether or to what extent prescription or payment decisions were influenced by other factors, such as drug price changes and the availability of different treatment options.

B. The Class Certification Order

The district court refused to certify the California consumer class, concluding that plaintiffs had not satisfied Rule 23(b)(3)'s predominance requirement

because "a muddled mix of common and individualized evidence would be needed to resolve the elements of causation and reliance." App.85. Some patients, the court explained, had "no other option other than Actos" and accordingly would have taken it with or without the purported misrepresentations. App.87. And in all cases, decisions about how to weigh Actos' many benefits against its potential risks "necessarily reside with" thousands upon thousands of physicians and patients, based on the individualized knowledge of each physician and the individualized circumstances of each patient. App.87. Determining whether the alleged concealment of some risk-related information actually affected "any physician-patient tandem" would therefore require highly individualized inquiries not suitable for class treatment. App.87.

The TPP class is grounded in the very same individualized determinations; indeed, the TPP class is entirely derivative of the consumer class, since it rests entirely on payment for the same prescriptions that members of the consumer class purchased. Yet the district court inexplicably certified the TPP class anyway. The court recognized that an unknown number of class members probably were not injured at all. App.70. The 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. App.70. And the court acknowledged that it was an "open question" whether plaintiffs would be able to deploy their expert's analysis *at all* "without running into the need for individualized analysis." App.70-71. Resisting the

force of its own reasoning, however, the court found that the proposed TPP class met Rule 23's requirements.

Starting with injury—a necessary element not just of a RICO claim, but of any plaintiff's entitlement to recover damages, *TransUnion*, 594 U.S. at 431—the court held that the TPP class could be certified even though plaintiffs offered no way to weed out uninjured TPPs, which all parties agreed were included within the class definition. App.58-66. Relying on plaintiffs' expert's claim that 57% of Actos prescriptions would not have been written in their but-for world, and accepting "at face value" the expert's (demonstrably false) assumption that each Actos prescribing decision is "independent" of all others, the court concluded that any given TPP that reimbursed at least five prescriptions during the class period had a 98.5% chance of having paid for at least one "excess" prescription. App.59-62 & n.88.

From there, the court inferred that petitioners would likely succeed at the end of the day in challenging plaintiffs' injury showing for "about 1.5% of the class" (even though it is always a plaintiff's burden to establish standing). App.60. The court did not purport to identify any common evidence or methodology by which defendants could identify which class members fall within that purported 1.5%. In fact, the court admitted that figuring out which class members land on which side of the injured/uninjured divide would "turn on individualized evidence specific to" each TPP, physician, and patient. App.60. Yet because it viewed 1.5% as a sufficiently small percentage, the court

brushed this defect aside, effectively promising a trial at which petitioners would (somehow) be forced to sift through each and every one of the thousands of TPP class members to find the uninjured ones—a number that, even by plaintiffs' telling, would be many thousands. App.60-62.

Turning to causation, the court acknowledged that petitioners would be entitled to depose thousands of physicians to challenge each TPP's assertion that it suffered financial harm owing to reliance on the alleged concealment. In fact, 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. CA9.ER.31, 63, 67-68. That proved fatal to the California consumer class. When it came to the TPP class, however, the court held that plaintiffs "eke[d] out a victory" on causation, positing that, "if the trial was held" at the time of its decision, they would have had more "common" evidence at the certification stage. App.76-77.

C. The Ninth Circuit Decision

Petitioners moved for permission to file an interlocutory appeal under Rule 23(f), which the Ninth Circuit granted in August 2023. CA9.Dkt.1. Nearly two years later, the Ninth Circuit affirmed the district court's certification of the TPP class, over a dissent from Judge Miller. App.1-26.

The majority did not deny that this case is effectively a fraud-on-the-market RICO class action—which, as Judge Miller pointed out in dissent, App.12, is something this Court has said is "effectively"

impossible to pursue because individual issues would "overwhelm[] the common ones." *Erica P. John Fund, Inc. v. Halliburton Co.*, 563 U.S. 804, 810-11 (2011). But the majority held that the class could be certified anyway because, in its view, "only a de minimis number of TPPs would be uninjured," and both injury and other contested elements could be established via classwide proof—namely, plaintiffs' expert report. App.7.

The majority began by briefly dismissing petitioners' various challenges to the expert report and insisting that the district court conducted a "rigorous analysis" of the objections. In the majority's view, the district court conducted the necessary "rigorous analysis" even though it accepted plaintiffs' expert report "at face value," App.59 n.88, as did the majority, App.5-6. And even though that report opined that 43% of prescriptions—millions of prescriptions in all—still would have been written in the but-for world, the Ninth Circuit nonetheless held that the report's dubious mathematical model still (somehow) sufficed to serve as common evidence that most class members were injured by the alleged fraud. App.7.

The Ninth Circuit next concluded that petitioners' "individualized defenses do not defeat predominance." App.8. According to the majority, deposition testimony from two physicians that they still would have prescribed Actos to many of the very patients on whose prescriptions the TPPs' claims are based, even if the supposedly concealed risks had been on the label, did not "show[] that any TPP lacked civil RICO standing" because "both physicians testified to

decreasing their Actos prescriptions" more generally "because of the bladder cancer disclosure." App.9.

Finally, the court found that "[a]ny challenge of removing uninjured class members … does not defeat predominance." App.9. Relying on Ninth Circuit precedent permitting certification of a class where 94.5% were likely injured, the majority concluded that this class can go forward too because "98.5%" is "greater than … 94.5%." App.10. Doubling down, and going where almost no court of appeals had gone before, the court then held that there was "no need for a trial plan" to identify those uninjured members—which, even accepting the dubious assumption that they comprise only 1.5% of the class, likely number in the thousands. App.10.

Judge Miller dissented. As he explained, "[b]ecause reliance must ordinarily be established with evidence particular to each plaintiff, fraud claims are not normally suitable for class action." App.12. And unlike the majority, Judge Miller saw no reason to deviate from that rule here. After all, "[i]f 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." App.12. Indeed, individual consumer-plaintiffs tried to do exactly that here—and failed. App.89-91. As Judge Miller recognized, the calculus should not change just because "the lawyers who brought this case have tried to circumvent that limitation" by "su[ing] on behalf of third-party payors who reimbursed the cost of drugs that were prescribed and used by others." App.12.

Judge Miller highlighted three objections in particular that show why this class cannot be certified.

First, even taking the plaintiffs' expert report at "face value," the kind of probability analysis it used could not "isolate the causal effect of the bladder cancer risk," and therefore could not supply common proof of causation. App.16-17. Second, even if it did, "plaintiffs lack a feasible method of identifying those class members who suffered no injury." App.19. Finally, even if that report "could show causation and demonstrate that all but a de minimis number of class members were injured, [petitioners] would still be entitled to present and litigate defenses" "based on physicians' prescribing decisions." App.22.

In sum, Judge Miller concluded: "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." App.25. Because plaintiffs offered no common way to determine which prescribing decisions were influenced by the alleged fraud, he would have ordered the TPP class decertified. App.25-26.

REASONS FOR GRANTING THE PETITION

This Court has long expressed skepticism about whether a damages class can proceed when it concededly contains class members who suffered no injury, especially when plaintiffs offer no plan for identifying and eliminating uninjured class members. And it has long made clear that a damages class ordinarily cannot proceed when it "require[s] … plaintiffs [to] establish reliance," as "individual reliance issues would overwhelm questions common to the class" in the vast majority of such cases. *Amgen*

Inc. v. Conn. Ret. Plans & Tr. Funds, 568 U.S. 455, 462-63 (2013). Either of those problems should have made certification of this sprawling fraud class a non-starter, as would be the case in most circuits.

That is not speculation; the Second Circuit refused to certify a TPP class virtually identical to this one, recognizing that shifting from a non-certifiable class of patients who purchased a drug to a TPP class of third parties who paid for it did not solve the fundamental problem. Yet the Ninth Circuit blew past *both* of those problems, insisting that class proponents need not offer any plan for separating out concededly uninjured class members, so long as most class members likely have an Article III injury, and that statistical evidence suggesting that roughly 50% of prescriptions were the product of reliance somehow renders the inherently individualized issue of reliance a common one. That result cannot be reconciled with Article III, Rule 23, or the Rules Enabling Act, and it deepens one circuit split and creates another.

First and foremost, the decision below reinforces a deep circuit split that this Court has twice granted certiorari to resolve—to no avail—regarding the propriety of certifying (b)(3) classes that concededly contain uninjured members. Had this case arisen in the Second or Eighth Circuit, class certification would have failed from the get-go: It is undisputed that the TPP class includes at least some uninjured members, and those courts categorically reject certification of classes that are not defined to exclude the uninjured. Had this case arisen in the First, Third, or D.C. Circuit (and likely the Fourth too), class certification would have failed as well: While those courts may allow

damages classes to proceed even when the class definition does not categorically exclude the uninjured, they at least require plaintiffs to supply a plan for identifying and excluding those who lack Article III injuries.

But the Seventh, Ninth, and Eleventh Circuits are undeterred either by the presence of class members without injuries or by the failure of class proponents to supply any plan for identifying and excluding the uninjured save through thousands and thousands of mini (or full-blown) trials—a prospect that should independently preclude certification. In this last group of circuits, unless the uninjured camp constitutes a large percentage of the class, neither their presence nor (at least in the Ninth Circuit) the absence of any mechanism to sift them out is an obstacle to class certification. This Court has twice recognized the importance of this issue, but it has not yet been able to resolve it. Now is the time, and this is the opportune case, to provide a nationwide answer once and for all.

That is not the only circuit split implicated here, as the glaring reliance problems inherent in plaintiffs' claims should have led the Ninth Circuit to conclude that common issues do not predominate over individualized ones. As the district court understood, at heart, plaintiffs allege fraudulent inducement: They claim that physicians would not have prescribed, patients would not have taken, and TPPs would not have paid for Actos, if only they had not purportedly been misled about its risks. Yet plaintiffs offered no common way to determine which physicians in fact relied on that purported deception or which TPPs in

fact paid as a result—presumably because there is none. That reality posed an insuperable obstacle for the consumer class here and likewise led the Second Circuit to deny certification for a virtually identical TPP class.

Undeterred, the Ninth Circuit viewed a regression analysis positing that 57% of Actos prescriptions were likely fraudulently induced—which, of course, means that 43% were not—as sufficient to permit class certification. Even accepting that evidence "at face value," which is pretty much the opposite of the "rigorous analysis" demanded by this Court's precedents, that statistical evidence does not begin to answer the critical questions of *who* was injured by the alleged fraud and *to what extent*. That is why both this Court and others—including the district court as to the consumer class—have long rejected efforts to use such generic statistical evidence to convert reliance into a common issue. By starkly departing from that settled practice, the Ninth Circuit has taken its outlier class-action jurisprudence even further off the rails, and has turned Rule 23 into a mere pleading exercise in this context: Limit a drug-risk-fraud class to TPPs, and anything goes.

The questions presented are recurring and critically important, as evidenced by the facts that this Court has twice granted certiorari to resolve the first one and the circuits are squarely divided on the second one on virtually identical facts. This case is also an excellent vehicle to resolve both questions. Both issues were pressed and passed upon below, and there have been no subsequent developments that change the shape of the case. Thie Court should grant

certiorari on both questions and bring the bring the Ninth Circuit back in line with Article III, Rule 23, and this Court's precedent once and for all.

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

A. The Circuits Are Divided Over Whether and When Courts Can Certify a Damages Class With Uninjured Members.

This Court has twice granted certiorari to resolve the division in the circuits over whether (and, if so, in what circumstances) federal courts may certify class actions when some class members are uninjured. *See Lab'y Corp. of Am. Holdings v. Davis*, 145 S.Ct. 1133, *cert. denied as improvidently granted*, 605 U.S. 327 (2025); *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 460 (2016). The split has not gone away. If anything, it has only gotten more pronounced.

The varying approaches of the circuits can generally be separated into three camps. The Second and Eighth Circuits have held that a damages class cannot be certified if it is clear that the class "contains members lacking Article III standing." *Denney v. Deutsche Bank AG*, 443 F.3d 253, 264 (2d Cir. 2006); *accord Johannessohn v. Polaris Indus., Inc.*, 9 F.4th 981, 988 n.3 (8th Cir. 2021) ("[A] class cannot be certified where it is defined in such a way to include individuals who lack standing."). While those courts do not require absent class members to prove their standing separate and apart from the class representative's standing, *see Hyland v. Navient Corp.*, 48 F.4th 110, 118 n.1 (2d Cir. 2022), they do require class representatives to ensure that a (b)(3)

class is defined "in such a way that anyone within it would have standing." *Denney*, 443 F.3d at 264.

The second camp, which includes the First, Third, and D.C. Circuits, applies a no-injury/no-plan/no-class rule. The courts in this second group admit the possibility of certifying a damages class with a "very small absolute number" of uninjured members swept into its definition. *In re Asacol Antitrust Litig.*, 907 F.3d 42, 53 (1st Cir. 2018). But they strictly enforce Rule 23(b)(3)'s predominance requirement, and thus will not bless certification of such classes unless the plaintiffs can identify a "winnowing mechanism" that is "truncated enough to ensure that the common issues predominate, yet robust enough to preserve the defendants' Seventh Amendment and due process rights." *In re Rail Freight Fuel Surcharge Antitrust Litig.*, 934 F.3d 619, 625 (D.C. Cir. 2019); *accord, e.g.*, *In re New Motor Vehicles Canadian Exp. Antitrust Litig.*, 522 F.3d 6, 28-29 (1st Cir. 2008).[1]

As judges in these circuits have explained, that does not mean that certification should follow as a matter of course if only a relatively small number of putative class members are likely uninjured. After all, class members "do not come pre-identified" as injured or uninjured, and "one does not ordinarily set out to find a needle in a haystack by examining only" a small percentage "of the straw." *Asacol*, 907 F.3d at 61

---

[1] In a recent opinion, the Fourth Circuit appeared to adopt this approach. In *Mr. Dee's Inc. v. Inmar, Inc.*, 127 F.4th 925 (4th Cir. 2025), the court affirmed denial of class certification because nearly a third of the proposed class was potentially uninjured and the circumstances giving rise to harm "varied substantially" and thus were unamenable to "class treatment." *Id.* at 933-34.

(Barron, J., concurring). Plaintiffs in these circuits must instead offer a mechanism at certification that allows uninjured members to be removed through common evidence, and thus prevents individualized inquiries from overwhelming common ones.

In the Seventh, Ninth, and Eleventh Circuits, by contrast, district courts may certify a damages class even if it includes "more than a de minimis number of uninjured class members." *Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC*, 31 F.4th 651, 669 (9th Cir. 2022) (en banc); *accord Kohen v. Pac. Inv. Mgmt. Co.*, 571 F.3d 672, 677 (7th Cir. 2009); *Cordoba v. DIRECTV, LLC*, 942 F.3d 1259, 1277 (11th Cir. 2019). While these circuits use different formulations for the outer bound of how many uninjured class members are too many—a "great many," *Kohen*, 571 F.3d at 677, versus a "large portion," *Cordoba*, 942 F.3d at 1277—all have a know-it-when-you-see-it feel. *See Messner v. Northshore Univ. HealthSystem*, 669 F.3d 802, 805 (7th Cir. 2012) (admitting that "there is no precise measure for 'a great many'"). And in the Ninth Circuit, the class now does not even need to propose a "plan to screen out" uninjured members. App.10. Whether there is any common way to determine which class members have Article III standing is largely irrelevant in these circuits, so long as other issues in the case appear sufficiently common.

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

The decision below not only puts the Ninth Circuit at the extreme end of the spectrum on uninjured

plaintiffs; it also puts that court in a class of its own when it comes to class claims that turn on what all agree are individual reliance issues. Indeed, the Second Circuit rejected a class of TPPs pressing a nearly indistinguishable theory against Lilly, holding that the TPP claims were not susceptible of common proof on a classwide basis because they turned on the same inherently individualized reliance issues as would be present in a class of the underlying patients. The Second Circuit, in contrast to the courts below, rejected the notion that the hopelessly individualized nature of the reliance of individual patients somehow fades away when the focus shifts to TPPs who pay those same claims. And even outside this specific context, other circuits confronting putative classes in which reliance is an individualized issue all have reached the same conclusion: Such classes cannot be certified because "individual reliance issues would overwhelm questions common to the class." *Amgen*, 568 U.S. at 462-63. Once again, then, the Ninth Circuit is on the wrong and short side of a circuit split.

1. In the Second Circuit *Zyprexa* litigation, "unions and insurers who act as third-party payors … brought [a] putative class action" alleging that the manufacturer of Zyprexa misled the public about the drug's "side effects," which caused physicians to prescribe more of the drug than they otherwise would have, which in turn caused the TPPs to "pay[] for … prescriptions that would not have been issued but for the alleged misrepresentations." *Zyprexa*, 620 F.3d at 123. In other words, the TPPs argued that "they paid for Zyprexa prescriptions that would not have been written absent the fraud" alleged. *Id.* at 131. And to try "[t]o prove that doctors had, in

fact, relied on [the alleged] misrepresentations in making their prescription decisions, the plaintiffs" adduced evidence that "the number of Zyprexa prescriptions fell after the drug's weight- and diabetes-related side effects were disclosed by a revision to its label in 2003." *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 89-90 (2d Cir. 2015); *see Zyprexa*, 620 F.3d at 128, 135.

All of that should sound familiar: Plaintiffs here are pressing the same theories, and they have supported them with the same kind of evidence. *See* pp.6-10, *supra*. But that is where the similarities end, as the Second Circuit in *Zyprexa* rejected the TPPs' effort to elide the individual reliance issues that underlie a TPP class through general evidence of likely impact on patients and physicians. Prescriptions for medicine, the court explained, necessarily depend on "the independent actions of prescribing physicians," who consider various factors such as a patient's medical history and the physician's "own experience with prescribing" the medicine. *Zyprexa*, 620 F.3d at 135. And none of that goes away when a class is crafted to include TPPs instead of patients, as there is still no common way to determine, e.g., what (if any) alternatives patients and physicians would have turned to, and whether TPPs would have been better off, in a but-for world (e.g., the alternative may be more expensive). In other words, just as figuring out whether and to what extent any *particular patient* suffered injury is not something that can be done through a spreadsheet or statistical model, neither is answering that question as to TPPs. *Id.* at 135-36.

To be sure, as the Second Circuit later noted, there may be rare cases in which physicians "faced 'the same more-or-less one-dimensional decisionmaking process,' such that the alleged misrepresentation would have been 'essentially determinative' for each plaintiff." *Sergeants*, 806 F.3d at 88 (quoting Richard A. Nagareda, *Class Certification in the Age of Aggregate Proof*, 84 N.Y.U. L. Rev. 97, 121 (2009)). But such cases will be extremely few and far between, for the simple reason that individual reliance is not the kind of issue that is ordinarily susceptible to classwide proof. It is little wonder, then, that such classes so far are 0-for-2 in the Second Circuit.

2. Other circuits have followed the same course in other contexts involving claims grounded in individualized reliance issues. *See, e.g.*, *Vogt v. Progressive Cas. Ins. Co.*, 129 F.4th 1071, 1072-73 (8th Cir. 2025); *Castano v. Am. Tobacco Co.*, 84 F.3d 734, 745 (5th Cir. 1996). The Sixth Circuit's recent en banc opinion in *Speerly v. Gen. Motors, LLC*, 143 F.4th 306 (6th Cir. 2025) (en banc), is illustrative. There, the court rejected efforts to certify a sprawling class action in which consumers alleged that a manufacturer misled them into buying a car with concealed defects. In an opinion authored by Judge Sutton, the court explained why the putative classes could bring neither consumer-fraud nor fraudulent-concealment claims on a classwide basis: Both claims require proof of reliance, which is impossible to prove on a classwide basis when consumers "went to different dealerships, heard different sales pitches, purchased different vehicles, and received different prices." *Id.* at 329-30. As the court put it, "[d]ivining the purchase price of a broken promise" is ultimately a "personal and

individualized matter" not subject to common proof. *Id.* at 330.[2]

3. In stark contrast to those decisions, the Ninth Circuit held that the same kinds of inherently individualized reliance determinations are no barrier to certification of a class of TPPs—even as it recognized that they would doom a class of patients. That is not because plaintiffs here demonstrated that, for the physicians and the patients, "the alleged misrepresentation would have been 'essentially determinative.'" *Sergeants*, 806 F.3d at 88. "Here," just as in *Zyprexa*, "the record shows that individualized prescribing decisions" may *not* have turned on the alleged fraud. App.25 (Miller, J., dissenting). Indeed, even by plaintiffs' own expert's (faulty) estimation, nearly half of Actos prescriptions were *not* the product of reliance. App.61 n.93. Nor is it because plaintiffs came up with some better way of trying to prove reliance on a common basis. They supplied exactly the same kind of evidence as the putative classes in *Zyprexa* and *Sergeants*: evidence that prescriptions dropped after more information about the drug's risk was released. *See* App.37.

---

[2] The First Circuit's decision in *In re Neurontin Marketing & Sales Practices Litigation*, 712 F.3d 60 (1st Cir. 2013), contains some dicta that arguably conflicts with these decisions (and arguably comports with what the Ninth Circuit did here). But the First Circuit notably did not weigh in on the Rule 23 issue in *Neurontin*, *see id.* at 70 ("We express no view as to whether the plaintiffs can, on remand, meet the requirements of Rule 23."), and the court's more recent opinion in *Asacol* casts considerable doubt on whether that court would certify a class like this one, *see Asacol*, 907 F.3d at 53-54 (refusing to certify a class because many members would need to testify to establish injury).

As the district court explained with respect to the proposed consumer class—which was founded on the exact same fraud allegations and would have required the exact same reliance showing (and more)—that evidence cannot begin to overcome the "muddled mix of common and individualized evidence … needed to resolve the elements of causation and reliance." App.85. By allowing the TPP class to go forward on the exact same representative evidence just because the class members are TPPs instead of patients, the Ninth Circuit blessed the exact same maneuver that the Second Circuit easily saw through in *Zyprexa*.

II. The Decision Below Is Deeply Flawed And Contravenes Article III, Rule 23(b)(3), And This Court's Precedents.

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

The threshold problems with this class are the same as in *LabCorp*. Because the class is defined based on whether, not why, TPPs reimbursed Actos prescriptions, everyone agrees that "at least some plaintiffs were uninjured." App.19. That is a problem in and of itself, of course. *See, e.g.*, *Lab'y Corp.*, 605 U.S. at 328 (Kavanaugh, J., dissenting from order dismissing certiorari as improvidently granted) ("I would hold that a federal court may not certify a damages class that includes both injured and uninjured members."). But it is compounded by the fact that the Ninth Circuit did not even require plaintiffs to put forward a mechanism for determining who among them is or is not injured. The class thus has been certified even though there is no assurance

that it will lead to *any* classwide verdict that could be imposed consistent with Article III.

The problems with that outcome follow ineluctably from bedrock standing principles. "Article III does not give federal courts the power to order relief to any uninjured plaintiff, class action or not." *TransUnion*, 594 U.S. at 431. "Every class member must have Article III standing in order to recover individual damages." *Id.* And "a plaintiff must demonstrate standing separately for each form of relief sought," *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 185 (2000), as well as for each claim it presses, *Town of Chester v. Laroe Ests., Inc.*, 581 U.S. 433, 440 (2017). In a case with multiple plaintiffs pressing multiple claims, each monetary award sought by each plaintiff is a separate form of relief for which each plaintiff's Article III standing must be demonstrated. Yet plaintiffs here have not even identified a way to determine which class members suffered *any* injury, let alone how many times each of them did so.

Allowing such a fundamentally defective class to go forward almost certainly means that the district court will end up adjudicating claims over which it has no jurisdiction or, at a bare minimum, that claims that do not belong in the Article III courts at all will be used to leverage a settlement. That is precisely why this Court has long held that "Rule 23's requirements must be interpreted in keeping with Article III constraints." *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 613 (1997). Indeed, the Federal Rules themselves, reflecting the limits of the Rules Enabling Act, declare that they "do not extend … the jurisdiction of the

district courts." Fed. R. Civ. P. 82. Relieving plaintiffs of their obligation to prove standing just because they are part of a class would not only violate that shall-not command, but plainly violate Article III, as would allowing a federal court to order a defendant to pay money to plaintiffs who have not proven that they suffered any injury. So if a class cannot assure the court that it has a common means of identifying who among its members was injured, then the proceeding is not "a proper case or controversy" under Article III, and the federal courts "have no business deciding it" at all. *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 341-42 (2006).

Nor would such a class pass muster under Rule 23. To satisfy Rule 23(a), all members of a class must "have suffered the same injury"; otherwise, commonality is lacking. *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 349-50 (2011); *accord Amchem Prods.*, 521 U.S. at 623-24; *see* Fed. R. Civ. P. 23(a)(2). This Court has held that variation in the *type* of injury suffered by class members precludes certification. *See, e.g.*, *Wal-Mart*, 564 U.S. at 350. Variation in the *fact* of injury precludes certification, *a fortiori*.

That is particularly obvious when it comes to damages classes. Under Rule 23(b)(3), it is not enough for there to be common questions of law or fact; those common questions must predominate over individualized ones. Rule 23(b)(3) thus imposes a "far more demanding" standard of sameness than Rule 23(a). *Amchem Prods.*, 521 U.S. at 624; *accord Comcast Corp. v. Behrend*, 569 U.S. 27, 34 (2013). And that burden is insurmountable when class members do not share a common injury.

The Ninth Circuit tried to gloss over these principles by positing that Rule 23(b)(3) requires only that common issues predominate over individual ones, "including individualized questions about injury." App.58; *see Olean*, 31 F.4th at 669. But predominance requires courts to look not only at the number of common issues, but at *which* issues are common; after all, "[a]ny competently crafted class complaint literally raises common questions." *Wal-Mart*, 564 U.S. at 349. And when the irreducible minimum of Article III standing cannot be proven without resort to thousands and thousands of mini (or full-blown) trials, a class cannot be certified under Rule 23(b)(3) no matter how many other common issues there may be. *See Tyson Foods*, 577 U.S. at 453.[3]

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

To the extent the Ninth Circuit tried to suggest that this case really *can* be resolved based on common evidence, that claim is even more plainly foreclosed by this Court's precedent. Plaintiffs' claims turn on the theory that physicians would not have prescribed, patients would not have taken, and TPPs would not have paid for Actos if they had not purportedly been misled about its risks. On top of that, plaintiffs must

---

[3] Rule 23(b)(3) also requires superiority, Fed. R. Civ. P. 23(b)(3) ("the court [must] find[] … that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy"), and there is nothing permissible, let alone superior, about a class action that adjudicates the claims of class members with no Article III injury or uses those uninjured class members to drive a settlement.

prove whether and when reimbursement actually caused each TPP a financial injury—something that would not be true if, say, a physician would have prescribed a more expensive treatment in a world where the physician was less likely to prescribe Actos to some or all patients.

As the district court recognized, such claims would be dead on arrival if brought by a class of patients who purchased Actos. Yet for some reason the court thought, and the Ninth Circuit agreed, that shifting the focus to the TPPs who paid for the medicine alters the equation. It does not. The TPP class is no more able than the patient class to divine some common way of proving reliance or injury.

Far from helping plaintiffs' case, their expert report proves the point. By their expert's own telling, this is *not* a case where the alleged misrepresentation would have been one-dimensionally determinative for each prescription (let alone each TPP). Indeed, their expert readily admitted that at least 43% of Actos prescriptions were likely *not* owing to the alleged misrepresentations, and instead would have been made with or without them. *See* App.38. Yet he identified no common way for determining which ones fell into which camp. That does not begin to provide a basis for ordering classwide relief, as it would be utterly arbitrary—not to mention a blatant violation of Article III—to award classwide damages based on a statistical estimate of how likely conduct is to have injured *someone*, without determining whether and when it actually injured any of the class members.

In allowing the class to go forward anyway, the Ninth Circuit committed essentially the same mistake

this Court corrected in *Wal-Mart*. There, the Court rejected another Ninth Circuit decision that allowed the use of statistical evidence that would have been insufficient, if not inadmissible, to establish liability in individual cases to be the basis for class-wide proceedings. As the Court explained, even assuming that evidence could support an inference of a general pattern of discrimination, it would not prove that any particular adverse employment action was in fact the product of discrimination. The answer to that question turned on the choices of thousands of supervisors influenced by potentially different factors, only some of which may have been actionable. 564 U.S. at 355-56. The Court thus found no reason to believe that those claims could be "productively … litigated at once." *Id*. at 350; *see also Tyson Foods*, 577 U.S. at 458 (explaining that the proposed class in *Wal-Mart* failed because "representative evidence" could not be used to establish liability when "the employees were not similarly situated").[4]

Plaintiffs' effort to flatten the differences among class members here through a combination of artful pleading and an economic study is simply a rehash of *Wal-Mart*. Plaintiffs are once again trying to create the appearance of commonality through purportedly representative evidence that probably would not even

---

[4] While the Court did allow representative evidence to be used in *Tyson Foods*, that was not a case involving reliance, let alone a case in which the district court conceded that reliance was an individualized issue. It was instead the rare case where each class member *could* have relied on the representative evidence to prove with his or her individual claim, because the employer failed to keep records of donning and doffing time. *See* 577 U.S. at 456.

be admissible, let alone dispositive, in individual cases. Whether each prescription would have been written (and ultimately reimbursed) but for the alleged fraud is "the essential question on which [plaintiffs'] theory … depends." *Wal-Mart*, 564 U.S. at 354. And the answer to that question depends on highly individualized prescribing decisions made by hundreds of thousands of physicians across the country.

Just as in *Wal-Mart*, then, there is no reason to believe that question "can productively be litigated at once," *id.* at 350—as plaintiffs' expert implicitly recognized when he estimated that nearly half of Actos prescriptions likely were *not* a product of the alleged misrepresentations. *See* App.38. Indeed, that is precisely why the district court (correctly) refused to certify the patient class, and it is precisely why the Second Circuit refused to certify the virtually identical TPP class in the *Zyprexa* litigation. By allowing the TPP class to go forward here, the Ninth Circuit has created a very real risk of enlarging class members' substantive rights and abridging defendants', in violation of the Rules Enabling Act, 28 U.S.C. §2072(b). In short, this class is the prototypical case in which the central issues of liability and damages cannot be solved in "one stroke." *Wal-Mart*, 564 U.S. at 350. It thus could not satisfy Rule 23(b)(3) even if it were at least ostensibly confined to TPPs who actually suffered some Article III injury.

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

Both issues presented merit this Court's review. The first has captured this Court's attention twice

already without resolution and is, in the Court's own words, of "great importance." *Tyson Foods*, 577 U.S. at 461. So is the second. Rule 23(b)(3) is already "the most adventuresome" exception to individual litigation. *Amchem Prods.*, 521 U.S. at 614 (citation omitted). This Court has ensured that 23(b)(3)'s "predominance criterion" remains particularly "demanding" to keep this innovation within statutory and constitutional limits. *Id.* In the Ninth Circuit, however, this adventure has gone off the rails. All that is needed there to certify a class and force a defendant "to settle even if they have meritorious defenses" is a reasonably competent expert (or at least one who appears competent). *Olean*, 31 F.4th at 685-89 (Lee, J., dissenting). Plaintiffs' expert purported to estimate market share at a period after the alleged fraud became public and assumed that it would been the same in the but-for world. *See* App.17-18 (Miller, J., dissenting). Rule 23 demands far more.

The stakes implicated by the questions here are high, as class certification is "often, if not usually, the prelude to a substantial settlement by the defendant because the costs and risks of litigating further are so high." *Amgen*, 568 U.S. at 485 (Scalia, J., dissenting). Certifying classes without a plan for weeding out uninjured class members or avoiding thousands of individualized inquiries into reliance heightens those risks and "substantially raise[s] the costs of doing business." *Lab'y Corp.*, 605 U.S. at 333 (Kavanaugh, J., dissenting). And those costs are already sky-high: Last year, the cost of *defending* class actions—not the cost of losing and having to pay classwide relief; just defending against them—topped $4 billion. Carlton Fields, *2025 Carlton Fields Class Action Survey*, at 6

(2025), https://perma.cc/7UTZ-ZTPH. To the extent those costs are inflicted in the name of individuals who do not belong in the Article III courts at all, the dynamic is even more troubling.

As this case illustrates, whether a fraud class can be certified based on general proof consistent with Article III or Rule 23(b) is literally a multibillion-dollar question. On the basis of its anything-goes approach, the Ninth Circuit affirmed the certification of an unwieldy civil RICO class seeking billions in damages, based on generic evidence that most members likely suffered some injury. That approach creates a pathway for enterprising plaintiffs' lawyers to seek treble damages on claims that, by their nature, are almost never susceptible to common proof. Indeed, if a class is certified that cannot be practically tried, settlement becomes almost inevitable. Even when a common adjudication is efficient and feasible, the pressure to settle is overwhelming, as defendants facing "even a small chance of" such a "devastating loss" will "be pressured into settling questionable claims." *AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 350 (2011). But when the alternative to settlement is a class action that will entail a costly morass of individualized proceedings to ascertain which class members were injured and, if so, to what degree, the pressure to settle even truly frivolous claims mounts higher still. And defendants will be forced to "pass on those costs to consumers in the form of higher prices; to retirement account holders in the form of lower returns; and to workers in the form of lower salaries." *Lab'y Corp.*, 605 U.S. at 333 (Kavanaugh, J., dissenting).

Unless this Court steps in, district courts in the Ninth Circuit will become even stronger magnets for the 10,000+ class actions filed annually. *See Olean*, 31 F.4th 686 (Lee, J., dissenting). It is hard to imagine a putative class plaintiff (or plaintiffs' lawyer) who would not take advantage of the Ninth Circuit's uber-permissive approach to try to extract "blackmail settlements." Henry J. Friendly, *Federal Jurisdiction: A General View* 120 (1973). After all, if plaintiffs can get around issues as individualized as reliance by offering an expert whose opinion that most plaintiffs likely suffered some injury will be taken "at face value," App.60-61, then there is nothing stopping a class comprising thousands of disparate fraud, consumer-protection, or employment claims from being certified.

This case is an excellent vehicle to resolve the questions presented. The two previous times this Court granted certiorari on the first question, it was prevented from deciding it for procedural reasons. *See Lab'y Corp.*, 605 U.S. 327; *Tyson Foods*, 577 U.S. at 460-61. This case suffers from no such defects. The issues raised here were preserved below, and the district court has done nothing since to alter the class definition, the fact that it contains uninjured members, or the fact that the class's case depends on whether it can really prove highly individualized elements via "representative" proof. Furthermore, because this case arises from the grant of a Rule 23(f) interlocutory appeal, it is unburdened by post-verdict issues; the Court can focus on certification alone.

In short, "[t]he Ninth Circuit's decision is incorrect under Rule 23 and this Court's precedents,

and it will generate serious real-world consequences." *Lab'y Corp.*, 605 U.S. at 333 (Kavanaugh, J., dissenting). The Court should grant review to resolve the deep circuit splits this case implicates and to bring the Ninth Circuit back in line with this Court's caselaw once and for all.

CONCLUSION

For the foregoing reasons, this Court should grant the petition.

Respectfully submitted,

PAUL D. CLEMENT
Counsel of Record
ERIN E. MURPHY
MATTHEW D. ROWEN
CAMILO GARCIA*
CLEMENT & MURPHY, PLLC
706 Duke Street
Alexandria, VA 22314
(202) 742-8900
paul.clement@clementmurphy.com

* Supervised by principals of the firm who are members of the Virginia bar

Counsel for Petitioners

November 26, 2025

APPENDIX

TABLE OF APPENDICES

Appendix A

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 23-55742

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.

Argued & Submitted: Nov. 14, 2024
Submission Deferred: June 2, 2024
Resubmitted: June 6, 2025
Filed: June 16, 2025

Before: S.R. Thomas and Miller, Circuit Judges, and Rosenthal, District Judge.

MEMORANDUM OPINION

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 classwide 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.

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.

---

[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.

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

---

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

---

[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).

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.

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

[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.

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.

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 timeseries 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.

Appendix B

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 23-55742

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.

Filed: Aug. 8, 2025

Before: S.R. Thomas and Miller, Circuit Judges, and Rosenthal,* District Judge.

ORDER

The panel has voted to deny the petition for panel rehearing. Judge Miller would grant the petition for panel rehearing.

---

* The Honorable Lee H. Rosenthal, United States District Judge for the Southern District of Texas, sitting by designation.

The full court has been advised of the petition for rehearing en banc, and no judge of the court has requested a vote on whether to rehear the matter en banc. *See* Fed. R. App. P. 40.

The petition for panel rehearing and the petition for rehearing en banc (Docket Entry No. 85) are denied.

Appendix C

UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA

No. 17-cv-07223

PAINTERS & ALLIED TRADES DISTRICT COUNCIL 82 HEALTH CARE FUND, third-party healthcare payor fund; et al.,

Plaintiffs,

v.

TAKEDA PHARMACEUTICAL COMPANY LIMITED, a Japanese Corporation; et al.,

Defendants.

Filed: May 24, 2023

MEMORANDUM OPINION AND ORDER ON MOTION FOR CLASS CERTIFICATION

Before the Court is the motion of Plaintiff Painters and Allied Trades District Council 82 Health Care Fund ("Painters") and Plaintiff Annie M. Snyder (jointly, "Plaintiffs") for the following relief:

- to certify two classes—a National Third-Party Payer ("TPP") Class and a California Consumer Class;
- to appoint Painters and Snyder as representatives of those two classes, respectively;

- to appoint attorneys R. Brent Wisner, Michael L. Baum, and Christopher L. Coffin as Class Counsel; and
- to direct Class Counsel to propose a comprehensive notice plan for each class.[1]

Defendant Takeda Pharmaceuticals USA, Inc. and its parent company Defendant Takeda Pharmaceutical Company Limited (jointly, "Takeda") oppose Plaintiffs' Motion to Certify.[2] Defendant Eli Lilly & Company ("Lilly") filed a joinder to Takeda's Opposition.[3] After conducting a hearing and considering the voluminous papers filed in support and in opposition,[4] the Court

---

[1] Mot. for Class Certification (the "Motion to Certify") [ECF No. 229]; *see also* Unredacted Mot. for Class Certification (the "Sealed Motion to Certify") [ECF No. 234].

[2] Takeda's Opp'n to Pls.' Motion (the "Opposition") [ECF No. 247]; Takeda's Unredacted Opp'n to Pls.' Motion (the "Sealed Opposition") [ECF No. 248].

[3] Lilly's Joinder in the Opposition (the "Joinder") [ECF No. 239]; Lilly's Unredacted Joinder in the Opposition (the "Sealed Joinder") [ECF No. 251].

[4] The Court considered the documents of record in this case, including the following (as well as their attachments):

- Second Am. Compl. (the "Amended Complaint") [ECF No. 127];
- Motion to Certify;
- Sealed Motion to Certify;
- Opposition;
- Sealed Opposition;
- Joinder;
- Sealed Joinder;
- Pls.' Reply in Supp. of the Motion (the "Reply") [ECF No. 257];

orders that the Motion is **GRANTED** with respect to the National TPP Class and **DENIED** with respect to the California Consumer Class, for the reasons set forth herein.

- Pls.' Unredacted Reply in Supp. of the Motion (the "Sealed Reply") [ECF No. 260-1];
- Pls.' Reply to the Joinder (the "Reply to Joinder") [ECF No. 261-1];
- Pls.' Unredacted Reply to the Joinder (the "Sealed Reply to Joinder") [ECF No. 271-1];
- Pls.' Suppl. Brief Regarding Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC ("Plaintiffs' Supplemental Brief") [ECF No. 310];
- Defs.' Suppl. Brief in Opp'n to Class Certification ("Defendants' Supplemental Brief") [ECF No. 311];
- Pls.' Not. of Suppl. Authority ("Plaintiffs' Notice") [ECF No. 315];
- Defs.' Response to Plaintiffs' Notice ("Defendants' Response") [ECF No. 316];
- Pls.' [Second] Not. of Suppl. Authority ("Plaintiffs' Second Notice") [ECF No. 317];
- Defs.' Response to Plaintiffs' Second Notice ("Defendants' Second Response") [ECF No. 318];
- Pls.' [Third] Not. of Suppl. Authorities ("Plaintiffs' Third Notice") [ECF No. 321];
- Defs.' Response to Plaintiffs' Third Notice ("Defendants' Third Response") [ECF No. 322];
- Defs.' Not. of Suppl. Authority ("Defendants' Notice") [ECF No. 323]; and
- Pls.' Response to Defendants' Notice ("Plaintiffs' Response") [ECF No. 324].

I. Background

A. Procedural History

This putative class action was originally filed as part of a multi-district litigation pending in the Western District of Louisiana, MDL No. 6:11-md-2299 (the "MDL Court"). The MDL Court consolidated various claims asserted across the country related to the drug Actos.[5] This case differs from the MDL cases because Plaintiffs here do not assert personal injury or product liability claims. Rather, they allege that Takeda and Lilly conspired to market Actos fraudulently by concealing the association between its use and its users' subsequent development of bladder cancer.[6] In September 2017, the MDL Court ordered this case transferred to this district.[7] Three months later, Plaintiffs filed the presently operative pleading—the Amended Complaint—in which they assert claims for relief under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §§ 1961-1968 ("RICO"), and state consumer fraud laws.[8]

In February 2018, the Court dismissed the case, finding that Plaintiffs had not adequately pleaded causation.[9] That decision was reversed by the Ninth Circuit in *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co. Ltd.*, 943 F.3d 1243 (9th Cir. 2019), *cert. denied*, 141 S. Ct. 86 (2020)

---

[5] ACTOS is a registered trademark of Takeda Pharmaceutical Company Limited, Reg. No. 2307686.

[6] *See generally* Amended Complaint.

[7] Order on Mot. To Transfer Case [ECF No. 55].

[8] *See* Amended Complaint ¶¶ 55-74.

[9] *See* Order Partially Granting Mot. To Dismiss [ECF No. 140].

("*Painters & Allied Trades*"). The Ninth Circuit held that Plaintiffs adequately alleged proximate causation to support their civil RICO claim, and it remanded the case to this Court for further proceedings. *Id.* at 1260.

In August 2020, Takeda again moved to dismiss.[10] Lilly filed a joinder[11] in which it adopted the contentions in Takeda's Motion to Dismiss and raised additional arguments specific to Lilly. In February 2021, this Court denied both motions.[12]

In July 2021, Plaintiffs moved to certify the National TPP Class and the California Consumer Class.[13] Takeda opposed two months later, and Lilly joined.[14] Plaintiffs replied in support of the Motion to Certify in November 2021 and submitted a corrected response to Lilly's joinder shortly thereafter.[15] After several stipulated continuances, the Court conducted a lengthy hearing on the Motion to Certify in March 2022.

About a month after that hearing, the Ninth Circuit issued an *en banc* decision in *Olean Wholesale*

---

[10] Takeda's Mot. to Dismiss Under Rules 12(b)(6) and 9(b) and/or Mot. to Strike Class Allegations Under Rule 12(f) (the "Motion to Dismiss") [ECF No. 173].

[11] Lilly's Joinder in the Motion to Dismiss (the "Joinder to the Motion to Dismiss") [ECF No. 174].

[12] Order on the Motion to Dismiss and Joinder to the Motion to Dismiss [ECF No. 206].

[13] *See generally* Motion to Certify.

[14] *See generally* Opposition & Joinder. Initially Takeda filed its Opposition as ECF No. 238 on the docket but refiled on September 29 as ECF No. 247. The Court refers to only the latest filing.

[15] *See generally* Reply; Reply to Joinder.

Grocery Coop., Inc. v. Bumble Bee Foods LLC, 31 F.4th 651 (9th Cir. 2022) ("*Olean*"). Because the parties' initial briefing relied on the previously vacated decision in *Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC*, 993 F.3d 774 (9th Cir. 2022),[16] the Court ordered supplemental briefing,[17] which the parties filed in April 2022.[18] Four months later the parties *sua sponte* filed supplemental briefs regarding a decision issued by a court in the Northern District of California, *In re Juul Labs, Inc., Marketing Sales Practices and Products Liability Litigation*, 2022 WL 2343268 (N.D. Cal. June 28, 2022).[19] Plaintiffs contend that *Juul Labs* supports their position in support of certification of the California Consumer Class, and Takeda and Lilly disagree. In November 2022, Plaintiffs alerted the Court that the Supreme Court denied a petition for *certiorari* in *Olean*, and Takeda and Lilly responded a few days later by again arguing that *Olean* is substantively different from the instant case.[20] In February 2023, Plaintiffs provided the Court with notice of two recent orders in which district courts addressed motions for class certification—*Turrey v. Vervent, Inc.*, 2023 WL 163200 (S.D. Cal. Jan. 11, 2023), and *In re National Football League's Sunday Ticket Antitrust Litig.*, 2023 WL 1813530 (C.D. Cal. Feb. 7, 2023)—and Takeda and

---

[16] *See, e.g.*, Sealed Motion to Certify 5:3-7, 28:21, & 31:9-11; Sealed Opposition 7:25-28 & 11:27-28.

[17] *See* Order Regarding Suppl. Briefing [ECF No. 309].

[18] *See generally* Plaintiffs' Supplemental Brief & Defendants' Supplemental Brief.

[19] *See* Plaintiffs' Notice; Defendants' Response.

[20] *See* Plaintiffs' Second Notice; Defendants' Second Response.

Lilly provided their response a week later.[21] Finally, in March 2023, Takeda and Lilly invited the Court's attention to *Van v. LLR, Inc.*, 61 F.4th 1053 (9th Cir. 2023), in which the Ninth Circuit vacated and remanded a district court's order granting class certification.[22] Plaintiffs responded that *Van* actually supports their instant Motion to Certify.[23]

B. Factual Summary

Takeda and Lilly developed and marketed a diabetes drug called Actos. *Painters & Allied Trades*, 943 F.3d at 1246. Takeda obtained Food and Drug Administration ("FDA") approval for Actos in 1999. *Id.* Plaintiffs "allege that despite learning through multiple studies over the next several years that Actos increased a patient's risk of developing bladder cancer, Defendants refused to change Actos's warning label or otherwise inform the public of such risk." *Id.*

Plaintiffs contend that Takeda and Lilly misled the FDA regarding the risk of bladder cancer by generating false studies, manipulating study results, and controlling the messaging about Actos to conceal aspects of the drug's mechanism that could have raised concerns.[24] Plaintiffs also allege that Takeda and Lilly misled prescribing physicians, consumers, and third-party payors into believing that Actos did

---

[21] *See* Plaintiffs' Third Notice; Defendants' Third Response.

[22] *See* Defendants' Notice.

[23] *See* Plaintiffs' Response.

[24] *See, e.g.*, Amended Complaint ¶¶ 29-35, 48-50, 59-63, 70-87, & 95.

not create an increased risk of bladder cancer.[25] According to Plaintiffs, Takeda and Lilly had reason to know about the increased bladder cancer risk, but they chose not to disclose that risk in order to increase their profits from the sale of Actos.[26]

After the bladder cancer risk became known, a group of patients who developed bladder cancer—along with their families—sued Takeda and Lilly, asserting personal injury and wrongful death claims. Those claims were consolidated before the MDL Court in the Western District of Louisiana. *See Painters & Allied Trades*, 943 F.3d at 1246.[27] The MDL Court conducted a 37-day bellwether trial in 2014, and the jury returned a verdict in favor of those patients and their families.[28] The MDL Court concluded, among other things, that "the Plaintiffs presented evidence that the Defendants were aware of the risk of death by way of bladder cancer associated with Actos® use and that they chose to conceal and obfuscate those risks in order to sell more product and to increase their profit."[29] *In re Actos (Pioglitazone) Prod. Liab. Litig.*, 2014 WL 12776173, at *36 (W.D. La. Sept. 5, 2014).

---

[25] *See, e.g.*, *id.* at ¶¶ 1, 44, 45, 60-62, 67, 79, 85-87, 100, 134, & 135.

[26] *See, e.g.*, *id.* at ¶¶ 25-28, 36, & 95.

[27] *See also id.* at ¶¶ 121-26.

[28] *Id.* at ¶ 124. The parties later "agreed to a global settlement program for all eligible personal injury claimants who used Actos before December 1, 2011 and had been diagnosed with bladder cancer." *Painters & Allied Trades*, 943 F.3d at 1246 (citing *In re Actos (Pioglitazone) Prods. Liab. Litig.*, 274 F. Supp. 3d 485, 503 (W.D. La. 2017)).

[29] Amended Complaint ¶ 126.

The instant action was filed by Painters, a third-party payor, and five individual patients.[30] The individual patients allege that neither they nor their physicians knew that Actos use increased the risk of bladder cancer, and they aver that they would not have purchased Actos if they had known of its risks.[31] As a result of the "fraudulent concealment of the bladder cancer risk," Painters says that it "reimbursed a significant number of claims at potentially elevated prices for Actos" that would not have been reimbursed "but for the fraud."[32]

That theory of causation is known as the "quantity effect theory." *Painters & Allied Trades*, 943 F.3d at 1247. In support of their theory, Plaintiffs offer evidence of emails, testimony, and internal marketing studies, some dating back to 1999, that suggest that Takeda and Lilly were aware that language linking Actos to bladder cancer would reduce sales of Actos.[33] If true, that foresight was prescient, because sales of Actos began to decline in 2010 when the FDA announced that it would investigate Actos for bladder cancer risk. Sales dropped even more precipitously after a bladder cancer warning was added to the Actos label in August 2011.[34] Plaintiffs provide evidence of reports studying the causal relationship between the use of Actos and bladder cancer taken from internal Takeda researchers and external academic

---

[30] Amended Complaint ¶¶ 2-7.

[31] *Id.* at ¶¶ 139-205.

[32] *Id.* at ¶ 138.

[33] Sealed Motion to Certify 19:2-22:19.

[34] *Id.* at 22:22-23:23.

researchers.[35] Lastly, Plaintiffs introduce an econometric regression model from their expert, Dr. William S. Comanor.[36] His analysis found—with an R2 value of 99%—that, had a bladder cancer warning been issued from the beginning, TPPs would have paid for 56% fewer Actos prescriptions during the class period.[37]

II. Legal Standard

The class action is "an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only." *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 348 (2011) (internal quotations omitted). To certify a class, "plaintiffs 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.

Rule 23(a) imposes the following requirements for the certification of a class: (1) the class is so numerous that a joinder of all members is impracticable (numerosity); (2) there are questions of law or fact common to the class (commonality); (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class (typicality); and (4) the representative parties will fairly and adequately protect the interests of the class (adequacy). *See* Fed. R. Civ. P. 23(a). "A plaintiff seeking class certification bears the burden of affirmatively demonstrating through evidentiary

---

[35] *Id.* at 23:24-27:10.

[36] *Id.* at 28:9-17.

[37] *Id.* at 29:8-30:7.

proof that the class meets the prerequisites of Rule 23(a)." *Sali v. Corona Reg'l Med. Ctr.*, 909 F.3d 996, 1003-04 (9th Cir. 2018) (internal quotations omitted).

In addition, at least one element of Rule 23(b) must be satisfied for a court to certify a class. *See* Fed. R. Civ. P. 23(b). Here, Plaintiffs focus on the third element—*i.e.*, predominance and superiority[38]—which would allow this Court to certify a class where:

> the court finds 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. The matters pertinent to these findings include:
>
> > (A) the class members' interests in individually controlling the prosecution or defense of separate actions;
> >
> > (B) the extent and nature of any litigation concerning the controversy already begun by or against class members;
> >
> > (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and
> >
> > (D) the likely difficulty in managing a class action.

Fed. R. Civ. P. 23(b)(3). With respect to the predominance element, what matters is not merely "the raising of common questions," but, rather, "the

---

[38] *See generally id.*

capacity of a class-wide proceeding to generate common answers apt to drive the resolution of the litigation." *Dukes*, 564 U.S. at 350 (internal quotations omitted).

Lastly, the Court observes that its decision on this Motion to Certify is preliminary in nature, because an "order that grants or denies class certification may be altered or amended before final judgment." Fed. R. Civ. P. 23(c)(1)(C).

III. The Amended National TPP Class

Plaintiffs seek to certify a nationwide class of TPPs for Plaintiffs' civil RICO claims against Takeda and Lilly.[39] In view of issues raised in Takeda's briefs, Plaintiffs amended their definition of the putative National TPP Class from what appears in the Amended Complaint.[40] Plaintiffs now define that class as:

> All third-party payers ("TPPs") in the United States and its territories, that purchased, paid for, and/or reimbursed all or any portion of the price for Actos, ActosPlus MET, ActosPlus MET XR, Duetact, and/or Oseni, for 5 or more independent prescriptions, between July 1, 1999 and September 17, 2010, for purposes other than resale.

---

[39] Amended Complaint ¶¶ 127 & 239-51 (alleging that (1) Takeda and Lilly conducted an enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c) and, additionally and in the alternative, (2) Takeda and Lilly conspired to conduct or participate in the conduct of an enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d)).

[40] Sealed Reply 1:26-28.

> Excluded from this class are any TPPs that have released claims covered by this lawsuit.[41]

As discussed below, Plaintiffs' proposed National TPP Class easily satisfies the four mandatory requirements under Rule 23(a). Plaintiffs also succeed in showing that the class action form is superior, thereby satisfying one of two prongs of Rule 23(b)(3). The heart of the dispute over the certification of the National TPP Class is the final prong of Rule 23(b)(3): do common questions of law and fact predominate over Plaintiffs' RICO claims? The Court answers that question in the affirmative.

A. Rule 23(a) Requirements

"Rule 23(a) ensures that the named plaintiffs are appropriate representatives of the class whose claims they wish to litigate." *Dukes*, 564 U.S. at 349.

1. Numerosity

Takeda's documents reveal that there are hundreds, if not thousands, of TPPs in the United States that reimbursed Actos prescriptions.[42] That finding alone would satisfy the numerosity requirement. *See, e.g.*, *Ochinero v. Ladera Lending, Inc.*, 2021 WL 2295519, at *9 (C.D. Cal. Feb. 26, 2021) ("Typically, courts have found that the numerosity requirement is satisfied when the proposed class includes at least forty members."). Neither Takeda nor Lilly disputes that finding or raises challenges to

---

[41] *Id*. at 2:1-3; *see also* Amended Complaint ¶ 222.

[42] *See* Motion to Certify, Ex. 6 [ECF No. 229-7].

numerosity,[43] so the Court concludes that numerosity is satisfied.

2. Commonality

"[C]ommonality requires that the class members' claims 'depend upon a common contention' such that 'determination of its truth or falsity will resolve an issue that is central to the validity of each claim in one stroke.'" *Abdullah v. U.S. Sec. Assocs., Inc.*, 731 F.3d 952, 957 (9th Cir. 2013) (quoting *Dukes*, 564 U.S. at 350). Here, Takeda and Lilly stipulated to the notion that the existence of an alleged RICO enterprise between Takeda and Lilly would qualify as a common question for all class members at any given point in time.[44] Because the Court agrees with that proposition, and neither Takeda nor Lilly raises any other issues concerning commonality,[45] the Court concludes that Rule 23(a)(2) is satisfied.

3. Typicality

"To demonstrate typicality, Plaintiffs must show that the named parties' claims are typical of the class." *Ellis v. Costco Wholesale Corp.*, 657 F.3d 970, 984 (9th Cir. 2011) (citing Fed. R. Civ. P. 23(a)(3)). "The test of typicality 'is whether other members have the same or similar injury, whether the action is based on conduct which is not unique to the named plaintiffs, and whether other class members have been injured by the

---

[43] *See generally* Sealed Opposition; Sealed Joinder.

[44] Sealed Motion to Certify 7:7-11; *see generally* Sealed Opposition (making no objection); *see also* Sealed Joinder 4:9-25 (acknowledging the stipulation but qualifying its reach with respect to liability).

[45] Sealed Reply 2:7.

same course of conduct.'" *Hanon v. Dataproducts Corp.*, 976 F.2d 497, 508 (9th Cir. 1992) (quoting *Schwartz v. Harp*, 108 F.R.D. 279, 282 (C.D. Cal. 1985)). The Rule 23(a) standard is "permissive," and it requires only that the representative's claims are "reasonably co-extensive with those of absent class members." *Rodriguez v. Hayes*, 591 F.3d 1105, 1124 (9th Cir. 2010) (citation omitted).

Plaintiffs argue that Painters is typical of the National TPP Class for two reasons. First, Painters' injuries—*i.e.*, payments for excess prescriptions—are based upon the same legal theories as those of the absent TPPs.[46] And second, the manner in which Painters administers its benefits—*i.e.*, via a pharmacy benefit manager—mirrors the approach of TPPs across the country.[47] According to Plaintiffs' expert Dr. Peter Penna, the relationship between Painters and its pharmacy benefit manager—Prime Therapeutics—"is typical of such relationships in the United States," and it includes "usual and customary services."[48]

Takeda does not dispute either point. Rather, Takeda argues that Painters' claims are atypical because they are subject to "unique defenses relating to [Painters'] failure to preserve relevant documents."[49] Specifically, Takeda accuses Painters of spoilation by failing to ensure that Prime Therapeutics preserved relevant documents, as

---

[46] Sealed Motion to Certify 7:24-27.

[47] *Id.* at 8:16-21.

[48] *Id.* at 8:28-9:3.

[49] Sealed Opposition 37:15-16.

Painters did not preserve documents on its own.[50] Takeda also says that Prime Therapeutics testified that it did not receive a litigation hold notice, so it has documents and formularies reaching back to only 2009.[51]

When a class representative destroys evidence, the Court may deem her claim to be atypical if that conduct threatens to become the focus of the litigation. *See Doyle v. Chrysler Grp. LLC*, 2014 WL 7690155, at *3 (C.D. Cal. Oct. 9, 2014), *rev'd and remanded on different grounds*, 663 F. App'x 576 (9th Cir. 2016). However, the Court concludes that Painters cannot be accused of spoilation because ***it*** did not destroy or dispose of any documents—Prime Therapeutics did. Painters provides evidence of its diligent efforts to preserve its documents, to notify Prime Therapeutics of the lawsuit (when Takeda, ironically, did not), and even to subpoena Prime Therapeutics.[52]

Moreover, Takeda gives little if any explanation for why the lost documents—specifically, Prime Therapeutics' drug formularies from 2005 to 2009—even matter.[53] Painters claims that it has the data showing how much it paid for Actos prescriptions, rendering the information in the formularies duplicative.

---

[50] *Id.* at 37:23-38:4; Sealed Motion to Certify 8:16-17.

[51] Sealed Opposition 38:3-10.

[52] Sealed Reply 2:25-3:16.

[53] *See* Sealed Opposition 38:5-10 (asserting that the loss of formularies has impacted the litigation, without identifying the impact or explaining why that information matters).

Therefore, the Court is doubtful that the lost formularies would become the focus of the lawsuit. In fact, if that information was so important, the Court would have expected the issue to arise during the hearing on the Motion to Certify. It did not. Thus, the Court is not persuaded that the lost formularies render Painters' claims atypical. Rule 23(a)(3) is satisfied with respect to typicality.

4. Adequacy

Rule 23(a)(4) requires that the class representative "fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). Takeda makes two arguments why Painters is an inadequate class representative.

First, Takeda contends that Painters has abandoned allegedly viable claims because (1) it narrowed the period of the class by amending the end date to September 2010; and (2) it declined to appeal its excess price theory of damages.[54] Because those "tactical decisions potentially jeopardize the rights of absent class members," says Takeda, "class certification should be denied."[55]

Takeda's argument is weak and easily surmounted. "A strategic decision to pursue those claims a plaintiff believes to be most viable does not render her inadequate as a class representative." *Todd v. Tempur-Sealy Int'l, Inc.*, 2016 WL 5746364, at *5 (N.D. Cal. Sept. 30, 2016). Takeda offers no compelling reason why narrowing the class definition—as Painters did here—jeopardizes the

[54] *Id.* at 35:23-36:4.

[55] *Id.* at 36:5-6.

rights of absent class members.[56] If anything, the new timeframe better aligns with the data unearthed in discovery, which undergirds Plaintiffs' theory. Pruning unviable elements from one's case is a hallmark of competence, not inadequacy.[57]

Moreover, Takeda moved to dismiss the excess price theory with prejudice and ***won***.[58] Takeda now asserts that Plaintiffs' failure to revive that theory on appeal renders Painters an inadequate representative,[59] but Takeda offers no authority for the proposition that declining to appeal constitutes abandonment rather than an exercise of discretion.[60] *Cf. In re Conseco Life Ins. Co. LifeTrend Ins. Sales & Mktg. Litig.*, 270 F.R.D. 521, 532 (N.D. Cal. 2010) ("Plaintiffs are permitted to press a theory of contract liability that affords them the best chance of certification and of success on behalf of the class" in view of "changes occasioned by the issuance of the regulatory settlement."). Indeed, the facts here are distinguishable from the cases that Takeda cites, in which the class representative took some affirmative action to waive or abandon certain claims. *See, e.g.*, *Clark v. Experian Info. Sols., Inc.*, 2001 WL 1946329,

---

[56] *See generally id.*

[57] Sealed Reply 5:22-25.

[58] In Chambers Order Partially Granting Mot. to Dismiss [ECF No. 140] 2.

[59] Sealed Opposition 35:25-27.

[60] *See id.* at 34:25-35:22 (where none of the cases that Takeda cites stands for the proposition that failing to appeal a claim dismissed with prejudice constitutes abandonment for the purposes of determining adequate representation under Rule 23(a)(4)).

at *3 (D.S.C. Mar. 19, 2001) (the plaintiffs abandoned their claims); *Thompson v. Am. Tobacco Co.*, 189 F.R.D. 544, 550 (D. Minn. 1999) (the plaintiffs tried to "reserve" personal injury and damage claims); *Drimmer v. WD-40 Co.*, 2007 WL 2456003, at *3 (S.D. Cal. Aug. 24, 2007), *aff'd*, 343 F. App'x 219 (9th Cir. 2009) (the plaintiff's "own conduct militates against finding that he adequately represents the class" when he "refuses to seek all available remedies even for himself").

Second, Takeda lambasts Painters as "stunningly unaware of what has been happening in this litigation since it was filed."[61] But in support of that accusation, Takeda can cite only a lapse of memory by Painters' fund counsel during a live deposition regarding certain details of the litigation.[62] While mildly unflattering for Painters, it is too much of a stretch for Takeda then to equate that circumstance to a case in which the class representative "ceded all control to his counsel."[63] *Azoiani v. Love's Travel Stops & Country Stores, Inc.*, 2007 WL 4811627, at *2 (C.D. Cal. Dec. 18, 2007).

Crucially, Takeda does not assert that Painters' interests are misaligned with those of the other class members. *See, e.g.*, *Crawford v. Honig*, 37 F.3d 485, 487 (9th Cir. 1994), *as amended on denial of reh'g* (Jan. 6, 1995) (adequacy depends on the qualifications

---

[61] *Id.* at 36:21-22.

[62] *See, e.g.*, *id.*, Ex. G. Dep. Tr. of Rule 30(b)(6) Designee Roger Stelljes [ECF No. 248-4] 38:20-25 (where the fund's counsel could not remember if the class was shortened from September 2010 or 2011).

[63] Sealed Opposition 36:22-37:12.

of the representative, "an absence of antagonism, a sharing of interests between representatives and absentees, and the unlikelihood that the suit is collusive") (internal quotations and citations omitted). The Court therefore concludes that the adequacy requirement is satisfied. *See* Fed. R. Civ. P. 23(a)(4).

In summary, each of the requirements under Rule 23(a) is met for the National TPP Class.

B. Rule 23(b) Requirements

The proposed class must also meet one of three prongs set forth in Rule 23(b). Plaintiffs focus on the third prong, which requires both that a class action is the superior method of adjudication and that common issues of law or fact predominate over individualized issues. *See* Fed. R. Civ. P. 23(b)(3).

1. Superiority

Plaintiffs argue that a class action is superior because it would be uneconomical to litigate many of the claims for individual TPPs separately, in view of the staggering costs of litigation and the barriers to access the IQVIA data needed to establish causation.[64] Takeda responds that trial will be unmanageable if the Court certifies the class, given the myriad witnesses and volume of evidence involved. Takeda points to the five-week trial in *In re Neurontin Mktg. & Sales Pracs. Litig.*, 2011 WL 3852254, at *2 (D. Mass. Aug. 31, 2011), as a benchmark.[65]

Notwithstanding the enormous logistical hurdles of a five-week trial, the alternative would be far less

---

[64] Sealed Motion to Certify 36:9-18.

[65] Sealed Opposition 33:21-34:18.

efficient. With thousands of TPPs, there could be hundreds or thousands of individual lawsuits. Even if each of those trials is short, the cumulative amount of time and resources expended on all of those proceedings—by both the judicial system and the parties—would be greater in the aggregate. One supposed "nightmare" trial is preferable to many hundreds of shorter ones.[66] The class action form is far superior here. *See* Fed. R. Civ. P. 23(b)(3).

2. Predominance

In this lawsuit, the battle over certification is waged in the trenches of the second prong of Rule 23(b)(3): predominance. In view of the quantity of briefing on this topic and the complexity of the factual matters involved, the Court will proceed claim by claim, element by element, endeavoring to conduct a "rigorous analysis" to determine whether common questions of law and fact predominate over Plaintiffs' claims. *See Comcast Corp. v. Behrend*, 569 U.S. 27, 35 (2013).

The predominance inquiry tests "whether proposed classes are sufficiently cohesive to warrant adjudication by representation." *Amchem Prod., Inc. v. Windsor*, 521 U.S. 591, 623 (1997). "Considering whether questions of law or fact common to class members predominate begins, of course, with the elements of the underlying cause of action." *Erica P. John Fund, Inc. v. Halliburton Co.*, 563 U.S. 804, 809 (2011) (internal quotations omitted).

For the National TPP Class, Plaintiffs assert civil RICO claims against Takeda and Lily under 18 U.S.C.

---

[66] *Id.* at 34:16.

§ 1962(c) and derivatively under § 1962(d).[67] To establish those claims, Plaintiffs must show (1) that a RICO violation occurred; and (2) that the class members have standing. *Painters & Allied Trades*, 943 F.3d at 1248.

After those issues have been characterized as common or individual, "courts then loosely compare the issues subject to common proof against the issues subject solely to individualized proof to assess whether the common issues predominate." 2 W. Rubenstein, *Newberg on Class Actions* § 4:50 (5th ed. 2021) ("Rubenstein"). That final step "is more of a qualitative than quantitative analysis." *Id.* One indication that common issues predominate is if adding more plaintiffs to the class only minimally affects the amount of evidence to be introduced. *See id.* Another indication is if individual factual determinations "can be accomplished using computer records, clerical assistance, and objective criteria." *Id.* But if the resolution of an issue "breaks down into an unmanageable variety of individual legal and factual issues leading to an inordinate number of evidentiary hearings," then common questions do not predominate. *Kristensen v. Credit Payment Servs.*, 12 F. Supp. 3d 1292, 1306 (D. Nev. 2014).

a. Civil RICO Violation

To demonstrate a civil RICO violation, "a plaintiff must prove that the defendant engaged in (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." *Painters & Allied Trades*, 943 F.3d at 1248 n.5.

---

[67] Amended Complaint ¶¶ 231-259.

i. Conduct

Plaintiffs argue that questions of conduct are common to the class because evidence of conduct all stems from the behavior of Takeda and Lilly.[68] The Court agrees. "Proving the first element of a RICO violation in this case would involve common questions about the activities" of Takeda and Lilly and whether they "participated or engaged in conduct" with each other. *In re Ins. Brokerage Antitrust Litig.*, 579 F.3d 241, 269 (3d Cir. 2009). Such evidence would not necessarily vary based upon the number of TPPs in the class. Even if including some TPPs in the class (and not others) would force Plaintiffs to extend the timeframe of the class period,[69] the locus of the evidence would nonetheless be Takeda and Lilly. Thus, common questions predominate with respect to the first element of a civil RICO violation.

Lilly suggests that the evidence will not bear out Plaintiffs' allegations regarding its conduct (as opposed to Takeda's conduct), especially in the years after 2006, when Lilly stopped promoting Actos.[70] But that concern is immaterial at this stage of the litigation. Whether the evidence will support Plaintiffs' claims is a matter for trial or summary judgment; it is peripheral to the question of whether (or not) the issue is common to the class.[71] *See Amgen*

---

[68] Sealed Motion to Certify 11:9-12.

[69] Imagine, for example, some cluster of TPPs started reimbursing for Actos prescriptions only at the end of the class period, rather than continuously throughout the period.

[70] *See* Sealed Joinder 5:1-15.

[71] Sealed Reply to Joinder 1:16-27. Additionally, the MDL Court found that Lilly "continued to collect a residual fee based

Inc. v. Connecticut Ret. Plans & Tr. Funds, 568 U.S. 455, 459 (2013) (holding that "Rule 23(b)(3) requires a showing that *questions* common to the class predominate, not that those questions will be answered, on the merits, in favor of the class") (emphasis in original); *Olean*, 31 F.4th at 667 (observing that district courts are "limited to resolving whether the evidence establishes that a common question is *capable* of class-wide resolution, not whether the evidence in fact establishes that plaintiffs would win at trial") (emphasis original).

ii. Enterprise

Plaintiffs contend that the second element of a RICO violation—the existence of an enterprise—also involves common evidence.[72] *See In re Ins. Brokerage Antitrust Litig.*, 579 F.3d at 269-70. Under the RICO statute, an enterprise is defined as "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4). On its face, it appears that the question of whether Takeda or Lilly was "part of an association-in-fact enterprise operating an alleged scheme to defraud the class members" is one that "can be resolved on a class-wide basis." *Negrete v. Allianz*

---

upon the scope and success of its efforts during the official term of the Co-Promotion Agreement" for three years after Lilly ceased actively to promote Actos. *In re Actos (Pioglitazone) Prod. Liab. Litig.*, 2014 WL 46579, at *9 (W.D. La. Jan. 6, 2014). Plaintiffs contend that such a finding illustrates how they would succeed on the merits for the element of conduct. *See* Sealed Reply to Joinder 2:1-19.

[72] Sealed Motion to Certify 11:12-15.

Life Ins. Co. of N. Am., 287 F.R.D. 590, 610 (C.D. Cal. 2012); *see also Just Film, Inc. v. Buono*, 847 F.3d 1108, 1122 n.3. (9th Cir. 2017) (whether the defendants were "part of an enterprise" was an issue to be "resolved on a classwide basis").

In response, Takeda and Lilly assert that their evolving relationship from 1999 through 2010 precludes Plaintiffs from using common proof to establish that a RICO enterprise existed.[73] But that argument muddies the inquiry. Even if Takeda and Lilly's relationship changed over time, the evidence needed to prove the existence of an enterprise would not vary by TPP—it would remain common to the class. Common evidence need not be evidence that holds true or applies equally across periods of time; it can refer to any or all evidence that answers a question common to the class. *See Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 453 (2016) (observing that a common question is one where the same evidence will suffice for each member to make a *prima facie* showing ***or*** the issue is susceptible to generalized, class-wide proof); *see also Does I v. Gap, Inc.*, 2002 WL 1000073, at *7 (D. N. Mar. I. May 10, 2002) (holding that common issues predominate in a claim for a civil RICO violation where "common evidence" could prove the existence of a RICO enterprise). Thus, common questions of law and fact predominate over the second element of a civil RICO violation.[74]

---

[73] Sealed Opposition 30:9-10; Sealed Joinder 4:9-25.

[74] Additionally, the parties dispute whether Takeda and Lilly's prior stipulation, *see* Motion to Certify, Ex. 9 [ECF No. 229-10], means that they conceded the argument that the existence of an enterprise is one common to the class. *Compare* Sealed Motion to

iii. Pattern of Racketeering Activity

Lastly, Plaintiffs argue that the third and fourth elements of a RICO violation "would encompass common questions . . . including whether activities that constitute racketeering were taking place through the enterprise . . . and whether these racketeering activities were recurring such that a pattern could be established."[75] *In re Ins. Brokerage Antitrust Litig.*, 579 F.3d at 270. The alleged racketeering activity involves mail fraud and wire fraud under 18 U.S.C. § 1341 and § 1343, respectively.[76]

Takeda and Lilly attack this contention from two angles. First, they argue that proving racketeering by means of mail and wire fraud would require common evidence showing that they intended to "deceive *and* cheat."[77] *United States v. Miller*, 953 F.3d 1095, 1101 (9th Cir. 2020) (emphasis original). Takeda and Lilly say that the evidence against them of fraud and deception varies depending on the time-period because their product labels changed.[78] That nuance

---

Certify 11:12-15 *with* Sealed Opposition 30:24-31:2 *and* Sealed Joinder 4:9-25. Whether Takeda and Lilly conceded that point is moot because the Court concludes that common issues predominate over the first and second elements of a civil RICO violation.

[75] Sealed Motion to Certify 11:15-19.

[76] Amended Complaint ¶ 239.

[77] Sealed Opposition 9:28-10:5; *see also* Sealed Joinder 3:16-27.

[78] Sealed Opposition 28:7-8; *see also id.* at 27:19-22 ("Simply put, the evidence as to whether Defendants committed a RICO violation (and Defendants' defenses to such allegations) is not

matters because statements are false and misleading only if such is the case "***at the time they were made***, as required in a civil RICO action based on mail and wire fraud." *United Food & Com. Workers Cent. Pennsylvania & Reg'l Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255, 257 (9th Cir. 2010) (emphasis added).

Takeda and Lilly's argument is unpersuasive. While the product labels for Actos may have changed from 1999 to 2011, they would have changed for all members of the class at the same time. That fact distinguishes the circumstances here from the case that Takeda cites,[79] in which the defendant allegedly violated New York consumer protection laws by, *inter alia*, failing to disclose certain fees, terms, and conditions on the various websites through which it sold video games. *See Williams v. Oberon Media, Inc.*, 2010 WL 8453723, at *1 (C.D. Cal. Apr. 19, 2010), *aff'd*, 468 F. App'x 768 (9th Cir. 2012). There, "the content and format of those websites varie[d] from website to website." *Id.* at *9. As a result, the district court determined that it would need to engage in a customer-by-customer inquiry to determine which

---

common for all class members, but varies based on when the underlying Actos prescription was filled.").

[79] *Id.* at 28:14-17. Takeda cites two other cases, but the Court also finds them distinguishable. *See id.* at 28:17-29:1 (citing *Reitman v. Champion Petfoods USA, Inc.*, 830 F. App'x 880, 881 (9th Cir. 2020) (affirming the district court's denial of class certification where each bag of the defendant's dog food contained different information depending on the packaging), and *Cabral v. Supple LLC*, 608 F. App'x 482, 483 (9th Cir. 2015) (vacating certification where the defendant made different statements about its product through different advertising channels)).

disclosures any individual class member read. *Id.* In contrast, Takeda and Lilly have not explained why Actos product labels would differ from TPP to TPP. If, for certain periods of time, the product labels were deemed not false or misleading, then that would hold true for all TPPs purchasing Actos in that timeframe, effectively shortening or redrawing the class period eligible for damages. But that scenario would not require individualized hearings. The evidence needed to resolve the inquiry would remain "a common body of evidence," even if the evidence may implicate individual TPPs (or temporal clusters of TPPs) differently. *Olean*, 31 F.4th at 666.

Second, Takeda argues that the changing state of scientific knowledge precludes Plaintiffs from establishing the element of scienter with common proof.[80] Takeda cites *Sanneman v. Chrysler Corp.*, 191 F.R.D. 441, 453 (E.D. Pa. 2000), and *In re Ford Motor Co. Vehicle Paint Litig.*, 182 F.R.D. 214, 220 (E.D. La. 1998), for support.[81] Again, the Court concludes that evidence of scienter would involve common elements because Takeda and Lilly's scientific knowledge would not vary by individual TPP. Evidence of scienter would necessarily focus on what Takeda and Lilly knew, not what the individual TPPs knew.[82] *See, e.g.*, *Broomfield*

---

[80] *Id.* at 29:2-8.

[81] *Id.* at 29:9-18.

[82] Furthermore, neither *Sanneman* nor *Ford Motor Co. Vehicle Paint Litig.* provides any reasoning or explication regarding how a defendants' changing scienter over time means that common questions do not predominate. If anything, a defense that Takeda lacked scienter in 2000, but had it in 2004, would necessarily rely

v. Craft Brew All., Inc., 2018 WL 4952519, at *13 (N.D. Cal. Sept. 25, 2018) (holding that the question of the defendant's "state of mind is . . . common to the class"); *cf. In re Bofl Holding, Inc. Sec. Litig.*, 2021 WL 3742924, at *4 (S.D. Cal. Aug. 24, 2021) (holding, in the context of securities fraud, that "the defendant's scienter [is an] issue[] that would require the same proof for any class member"); *Takiguchi v. MRI Int'l, Inc.*, 2016 WL 1091090, at *7 (D. Nev. Mar. 21, 2016) (holding that evidence of scienter is "clearly susceptible to classwide proof"). Thus, common evidence would predominate over the third and fourth elements of a RICO violation and any respective defenses put forward by Takeda or Lilly.

In conclusion, common questions of fact predominate over each element of the civil RICO violation.

b. Civil RICO Standing

To allege civil RICO standing under 18 U.S.C. § 1964(c), a "plaintiff must show: (1) that his alleged harm qualifies as injury to his business or property; and (2) that his harm was by reason of the RICO violation." *Canyon County v. Syngenta Seeds, Inc.*, 519 F.3d 969, 972 (9th Cir. 2008) (internal quotations omitted). The Supreme Court has interpreted the phrase "by reason of" in 18 U.S.C. § 1964(c) to require both proximate and but-for causation. *See Holmes v. Sec. Inv. Prot. Corp.*, 503 U.S. 258, 268 (1992).

---

on evidence common to a class of TPPs that purchased Actos in that time frame.

i. Injury

To satisfy the element of injury, Plaintiffs must show that "'damages are capable of measurement on a classwide basis,' in the sense that the whole class suffered damages traceable to the same injurious course of conduct underlying the plaintiffs' legal theory." *Just Film, Inc.*, 847 F.3d at 1120 (citing *Comcast Corp.*, 569 U.S. at 34). But the presence of individualized variation in the damages does not, by itself, defeat certification. *See Leyva v. Medline Industries Inc.*, 716 F.3d 510, 514 (9th Cir. 2013). The Court must determine whether common questions "predominate[] over any individual questions, including individualized questions about injury or entitlement to damages." *Olean*, 31 F.4th at 669.

Takeda argues that the National TPP class definition includes some uninjured TPPs and that their presence is a reason to reject certification, as their inclusion in the class generates the need for individualized analysis.[83] *See Ruiz Torres v. Mercer Canyons Inc.*, 835 F.3d 1125, 1138 (9th Cir. 2016) (noting that the class should not be "defined so broadly as to include a great number of members who for some reason could not have been harmed by the defendant's allegedly unlawful conduct") (internal citations omitted). Specifically, Takeda highlights three "types" of uninjured TPPs.[84] The Court reviews each in turn.

---

[83] *See* Sealed Opposition 10:10-15:11.

[84] *Id.* at 11:11.

(a) Inevitable Actos Prescriptions

The first type of uninjured class members are those TPPs that paid for Actos prescriptions that would have been written anyway, fraud be damned.[85] Takeda pounces on the remarks of Plaintiffs' expert witness—Comanor—when he states that "a good number of Actos prescriptions were dispensed that would have occurred even in the absence of the Defendants' misconduct."[86] In fact, Comanor estimates that around 40% of the Actos prescriptions would have still been written (and, thus, would have been reimbursed), even if there was full awareness of the bladder cancer risks.[87]

Plaintiffs seek to overcome that criticism by including only those TPPs in the class that paid for at least five Actos prescriptions during the class period. In his report, Comanor concluded that 56.77% of Actos prescriptions during the class period were fraudulently induced.[88] Taking Comanor's analysis at

---

[85] *Id.* at 11:12-13 & 12:2-13:20.

[86] *Id.* at 12:4-6 (quoting Motion to Certify 31:20-22).

[87] Sealed Opposition 19:4-7.

[88] The Court takes Comanor's report at face value and does not prejudge its accuracy. *See* Expert Report of William S. Comanor (the "Comanor Report") [ECF No. 234-6]. While the Court found his testimony to be admissible for the purpose of class certification, it is up 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. Importantly, Takeda and Lilly do not provide a competing regression analysis. Instead, Takeda and Lilly offer arguments and expert testimony why they believe that Comanor's analysis is flawed. *See, e.g.*, Defs.' Mot. to Exclude William S. Comanor [ECF No. 249]; *see*

face value, the odds that any given prescription, plucked randomly out of the class period, was induced by fraud would be 56.77%.[89] As a result, any TPP that paid for at least five Actos prescriptions has, statistically, a 98.5% chance of suffering an injury from Takeda and Lilly's alleged concealment of the bladder cancer risks.[90] While it is not known at this time which specific TPPs managed to avoid paying for any fraudulently induced prescriptions entirely,[91] one would expect—statistically speaking—that Takeda and Lilly could dispute injury upon that basis for only about 1.5% of the class. And even though those disputes would likely turn on individualized evidence specific to those TPPs, common evidence of injury would still be expected to apply to the other 98.5% of the class. "That the defendant might attempt to pick

---

also Expert Report of James W. Hughes on Class Certification (the "Hughes Report") [ECF No. 248-5] (critiquing the Comanor Report methodologically, but refraining from offering a competing analysis). Comanor's probability scores are the only ones that the Court has before it.

[89] The Court notes that 56.77% is the ***average*** probability of a fraudulently induced prescription across the class period. Plaintiffs acknowledge that the probability changes over time. *See* Not. of Lodging of Pls.' PowerPoint for Hr'g on Pls.' Motion to Certify [ECF No. 305] 67. The probability ranges from as low as 11.7% in the year 2000 to as high as 70.6% in 2010. *See* Comanor Report 64 (providing a table of the share of "fully informed" prescriptions for Actos and Actos combinations).

[90] Sealed Reply 9:28-10:9. The math is relatively straightforward. Taking Comanor's summary statistics as valid, the chance that a TPP paid for five Actos prescriptions—and that ***none*** was induced by fraud—would be (1 - 0.5677)5, or about 1.5%.

[91] *See* Defendants' Supplemental Brief 9:22-10:8.

off the occasional class member here or there through individualized rebuttal does not cause individual questions to predominate." *Olean*, 31 F.4th at 668.

This conclusion is valid even when taking into account the temporal variations in Comanor's probability scores, since the years when the odds of fraudulently induced prescriptions were lowest also tended to be the years when total volumes of prescriptions were the lowest.[92] For example, for 2000, Comanor estimated that 88.3% of Actos prescriptions and Actos combination treatments were fully informed of the bladder cancer risks, and, thus, they would have still been prescribed.[93] That year there were 4,459,950 total Actos prescriptions and Actos combination treatments, of which 3,938,256 (or 88.3%) were therefore fully informed. But those 3.9 million prescriptions represent only about 3% of the total number of Actos prescriptions and Actos combination treatments reimbursed during the class period. Moreover, the data shows that Actos prescriptions grew steadily each year. So even though the odds were better that a TPP was uninjured from prescriptions arising from the early years of the class period, those years saw fewer total prescriptions. Thus, the number of uninjured TPPs appears to be *de minimis* even when temporal variations are considered, and it is

---

[92] *See* Comanor Report 64.

[93] It is worth noting that 88.3% is the highest probability (and, thus, the least favorable probability to Plaintiffs) of any given year that a prescription was deemed "fully informed." *Id*. The average probability of a fully informed prescription during the class period is about 43% (that is, one minus 57%—the average chance that the prescription was due to fraud).

more likely than not that common questions of fact would predominate over individualized ones when it comes to injury.[94]

Takeda tries to throw another wrench into the probability analysis by arguing that individualized data would be needed to determine whether any individual TPP's five (or more) payouts were for "independent" prescriptions or merely for refills.[95] While that theory has some superficial appeal, it does not survive scrutiny. Plaintiffs point out that both their experts and Takeda's expert—Dr. James W. Hughes—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.[96] Because the IQVIA data facilitates individual determinations, Plaintiffs' approach is a textbook example of how the use of "computer records, clerical assistance, and objective criteria" can obviate the need for an evidentiary hearing on each claim. Rubenstein § 4:50. The Court is persuaded that common questions of fact still predominate.

---

[94] Even if the number of uninjured class members was more than *de minimis*, *Olean* clarified that that defect is not necessarily a bar to certification. *Olean*, 31 F.4th at 669 (rejecting the argument "that Rule 23 does not permit the certification of a class that potentially includes more than a de minimis number of uninjured class members").

[95] Sealed Opposition 13:8-20; Defendants' Supplemental Brief 10:8-15.

[96] *See* Sealed Reply 11:14-21; *see also* Plaintiffs' Supplemental Brief 10:1-9.

(b) More Costly Alternatives

A second type of uninjured TPPs is those "that would have paid more for an alternative treatment, had they not reimbursed for Actos."[97] After all, there are patients who switched from Actos to another drug, and, in some instances, those patients' doctors prescribed more expense alternatives.[98] Understanding whether a patient would have moved from Actos to a different drug, says Takeda, is an analysis "necessarily unique to each TPP, based on the individual patient prescription decision that underlies the TPP's claims data."[99]

Close scrutiny reveals cracks in that argument. Although Takeda implies that this offset issue is rampant throughout the class, Takeda never identifies how many TPPs are (or would be) affected.[100] Takeda only regurgitates the number from the Hughes Report identifying how many ***patients*** switched from Actos to another regimen[101]—about

---

[97] Sealed Opposition 14:1-2.

[98] For context, Actos is often understood as a second-line treatment drug. That is, patients usually start with a different drug, like Metformin, before trying Actos. *See* Reporter's Tr. of Mot. Proceedings (the "Hearing Transcript") [ECF No. 312] 11:8-12:4 & 40:7-15.

[99] Sealed Opposition 15:3-5.

[100] *Id*. at 15:6-11.

[101] *Compare id*. 15:7-8 (citing the Hughes Report: "more than 30% of patients paid more for their diabetes treatment after they stopped using Actos") *with* Hughes Report ¶ 158 (observing that "26.1 percent of all Actos patients switched to an alternative branded monotherapy, and an additional 4.5 percent of patients switched to a combination therapy").

30%.[102] But that 30% figure says nothing about the number of ***TPPs*** affected by higher alternative costs. And in fact, the Court has reason to believe that switching costs may affect only a *de minimis* number of TPPs. Hughes estimated that only 14.4% of the patients who switched treatments from Actos chose a new treatment equal to or greater in cost than their prior Actos prescription.[103] Doing the math, 14.4% of 30.6% of patients is about 4% of total patients in the sample population. In other words, only about 4% of the patients switched from Actos to an equally or more expensive drug.

How those patients are distributed across the class of TPPs is unknown to the Court at this time. But the answer 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). The Court reviews each scenario in turn.

(1) Distribution Across the TPPs

In the first scenario, it appears extremely unlikely that ***any*** TPP would count as uninjured (when those TPPs were likely reimbursing many other patients' fraudulently induced prescriptions at the same time), thus directly undermining Takeda's argument that individualized questions of injury would overwhelm

---

[102] Sealed Opposition 15:7.

[103] Hughes Report ¶ 160 (stating that, of the patients who transitioned from Actos to alternative treatments, only 14.4% paid for new regimens that were "equally or more expensive for the TPP")

common ones. Moreover, any variance in the distribution of those patients would be a factor to consider only in calculating ***damages***, which does not disturb predominance. *See* Rubenstein § 4:54 (observing that "courts in every circuit have uniformly held that the 23(b)(3) predominance requirement is satisfied despite the need to make individualized damage determinations").

(2) Concentration in a Few TPPS

In the second scenario, common questions of fact would still predominate, since the evidence would—at most—give Takeda the ability to "pick off the occasional class member here or there," which "does not cause individual questions to predominate."[104] *Halliburton Co.*, 573 U.S. at 276. That ability to pick off a few class members, of course, also assumes that the avoidance of ***economic loss*** is sufficient to render a TPP uninjured. Plaintiffs directly challenge that assumption, arguing that the act of paying for fraudulently induced prescriptions—even when the alternatives are more expensive—is an injury in and of itself.[105] The Court agrees. "To the extent that class members were relieved of their money by [defendant's] deceptive conduct—as Plaintiffs allege—they have suffered an 'injury in fact.'" *Mazza v. Am. Honda*

---

[104] The Court hypothetically referred to this scenario as the Kansas City example during the hearing. Hearing Transcript 49:20-51:22. For instance, if all of those patients and prescribers lived in one city, and all of those prescriptions were reimbursed by one TPP, then Takeda will have succeeded in removing only that one TPP from the class.

[105] *See* Sealed Reply 12:9-13:3.

Motor Co., 666 F.3d 581, 595 (9th Cir. 2012), *overruled on other grounds by Olean*, 31 F.4th at 682 n.32 (9th Cir. 2022). Again, whether the net economic loss is zero (or negative) is a question of ***damages***, not injury. *See Olean*, 31 F.4th at 679; *Painters & Allied Trades*, 943 F.3d 1251 n.7 (describing that question as a "damages question for another day"). Therefore, the presence of more costly alternative medicines is not a reason, in this case, to believe that individualized questions predominate over the element of injury.

(c) TPPs That Settled

A third and final type of uninjured TPPs is those that already settled.[106] While the Court can understand how their inclusion could have raised individualized issues, the issue is now moot. Plaintiffs have amended the putative National TPP class definition to exclude those TPPs.[107]

In summary, Takeda fails to persuade the Court that the question of injury cannot be resolved through Plaintiffs' common body of evidence. Furthermore, because class damages can be calculated formulaically in a manner consistent with Plaintiffs' theory of liability, Plaintiffs have met their burden to demonstrate predominance. *See Comcast Corp.*, 569

---

[106] Sealed Opposition 11:24-12:1.

[107] *See* Sealed Reply 1:26-2:3 (amending the National TPP class to exclude those TPPs that had already settled their claims). At the hearing, counsel for Plaintiffs averred that roughly 15 to 20 TPPs settled, which would not disturb the numerosity requirement discussed in Part III.A.1 above. Hearing Transcript 6:13-20.

U.S. at 35; *see also* Rubenstein § 4:54 (discussing individual damages versus common liability).

ii. Causation

(a) Proximate Causation

Although the causation analysis includes both but-for and proximate causation, *see Holmes*, 503 U.S. at 268, neither Takeda nor Lilly challenges the idea that common issues predominate proximate causation.[108] Instead, Takeda and Lilly attack the idea that common issues of law and fact predominate over but-for causation. Accordingly, the Court regards Rule 23(b)(3)'s predominance requirement as satisfied with respect to the element of proximate causation.

(b) But-For Causation

To establish but-for causation under the "quantity-effect theory," *see Painters & Allied Trades*, 943 F.3d at 1247, Plaintiffs need to prove that Takeda and Lilly's fraudulent concealment of Actos's bladder cancer risk caused TPPs to pay for additional quantities of the drug—more than they would have otherwise paid, had they known the risks. As evidence, Plaintiffs offer Comanor's regression analysis, as well

---

[108] *See generally* Sealed Opposition; Sealed Joinder; *see also* Sealed Reply 9:18-19. As the Ninth Circuit already reasoned, if a TPP can establish that Takeda and Lilly engaged in racketeering to conceal the risk of bladder cancer and that the TPP purchased at least one additional Actos prescription because of that conduct (*i.e.*, but-for causation), then the injury is sufficiently "direct" to satisfy proximate causation. Sealed Motion to Certify 32:28-33:4 (citing *Painters & Allied Trades*, 943 F.3d at 1251).

as direct evidence of internal company emails, marketing studies, and other testimony.[109]

Plaintiffs point to several out-of-circuit cases for the proposition that a statistical regression, like Comanor's analysis, can establish but-for causation for a civil RICO claim, especially when used in tandem with other circumstantial or direct evidence.[110] *See, e.g.*, *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21, 30 (1st Cir. 2013) ("*Neurontin I*") (affirming a jury verdict and bench trial where a regression analysis determined that "three out of ten Neurontin prescriptions written by neurologists for migraine would not have been written or filled but for the alleged misconduct"); *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 51, 57 (1st Cir. 2013) ("*Neurontin II*") (holding that the statistical evidence that "Aetna presented on but-for causation—that in the absence of Pfizer's alleged fraud, Aetna would have paid for fewer off-label prescriptions of Neurontin—survives summary judgment"); *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 60, 68 (1st Cir. 2013) ("*Neurontin III*") (holding that the "plaintiffs need not prove causation through the testimony of individual doctors" and that the "combination of the aggregate evidence and the circumstantial evidence" was enough to overcome summary judgment).

In 2019, the First Circuit reaffirmed the approach that it forged in the *Neurontin* cases to establish but-

---

[109] Sealed Motion to Certify 19:4-22:19.

[110] *Id.* at 12:21-16:10.

for causation.[111] *See In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 915 F.3d 1, 14 (1st Cir. 2019) (reversing the district court's entry of summary judgment) ("*Celexa*"). In *Celexa*, Painters sued Forest Laboratories and Forest Pharmaceuticals for a civil RICO violation regarding sales of Celexa and Lexapro. *See id*. at 5. Painters sued on behalf of itself and a putative class of nationwide TPPs. *See id*. at 7. While the case was before the district court, Painters' expert, Dr. Meredith Rosenthal, conducted the same regression analysis from the *Neurontin* cases "to examine whether the fraudulent, off-label promotion in this case caused physicians to write additional offlabel prescriptions." *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 315 F.R.D. 116, 126 (D. Mass. 2016), *aff'd*, 915 F.3d 1 (1st Cir. 2019). At the time, the district court expressed doubts about the ability of Rosenthal's causation analysis to satisfy Rule 23(b)(3)'s predominance requirement.[112] *See id*. at 127. The district court ultimately denied class certification, in part because it determined that individualized questions predominated over issues of causation. *See id*. at 128. But importantly, the district court also denied certification for reasons relating to the statute of limitations. *See id*. at 129-30.

---

[111] *Id*. at 16:1-17:14.

[112] Importantly, the district court directed its skepticism toward an assumption embedded in Rosenthal's model. *See Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 315 F.R.D. at 127. That assumption is not relevant here, because Rosenthal was modeling the relationship between promotional spending and sales. *See id*. at 126.

On appeal, the First Circuit affirmed the district court's denial of class certification, but, only narrowly—on statute of limitation grounds. *See Celexa*, 915 F.3d. at 14-17. In *dicta*, the First Circuit remarked that it was "not clear why those issues to which the district court pointed would preclude certification of such a class" when "Painters' clinical and statistical evidence, if believed, could establish causation and injury at least for any TPP who paid for more than a handful of different patients' prescriptions." *Id.* at 14.

Lastly, Plaintiffs discuss *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71 (2d Cir. 2015) ("*Sergeants*"), in which the Second Circuit noted in *dicta* that "it may be possible for a class of plaintiffs to prove the causation element of a pharmaceutical fraud claim such as this one with generalized proof," even though the plaintiffs "failed to offer such proof" in that case. *Id.* at 74-75.

Celexa, *Sergeants*, and the *Neurontin* cases give the Court confidence that evidence common to the class—*e.g.*, a regression model, academic papers, internal corporate studies, and emails from Takeda's and Lilly's employees—can be used to establish but-for causation under a quantity-effect theory for a single TPP or even for a class of them. But whether common evidence can ***establish*** but-for causation is a separate issue from whether common questions of fact ***predominate*** over that same inquiry. It remains an open question whether a class of TPPs may successfully leverage common evidence of the kind offered here (and discussed in *Celexa* and in the *Neurontin* cases) without running into the need for

individualized analysis—or, at least, without running into so much individualized analysis that individual questions of fact begin to overwhelm the common ones.

Of the *Neurontin* cases, only *Neurontin III* considered a motion to certify a class. *See Neurontin III*, 712 F.3d at 63. There, the district court initially denied class certification. *See In re Neurontin Mktg. & Sales Pracs. Litig.*, 2011 WL 1882870, at *5 (D. Mass. May 17, 2011) (holding that a class action would be "unmanageable" where "a factfinder would have to perform a granular doctor-by-doctor analysis" in order "to differentiate those prescriptions that were caused by fraud from those that were attributable to non-fraudulent off-label marketing or other independent factors"). The First Circuit vacated the denial of class certification, but only because the district court rested its decision on the belief that a statistical regression analysis "could not provide proof of causation or damages." *Neurontin III*, 712 F.3d at 70. Neither *Celexa* nor *Neurontin III* concluded that common questions predominated over Plaintiffs' approach to but-for causation. Vacating a denial of certification is not tantamount to an endorsement of Plaintiffs' view.[113] The same goes for *dicta* that offers only glimmers of hope.[114] *See, e.g.*, *Celexa*, 915 F.3d. at 14; *Sergeants*, 806 F.3d at 74-75.

---

[113] Intriguingly, after the First Circuit remanded the case, the district court hinted that it would likely grant the motion for class certification. *See* Motion to Certify, Ex. 10 [ECF No. 229-11] 35:19-25. But the parties settled before the district court could issue its ruling. *See* Motion to Certify, Ex. 3 [ECF No. 229-4].

[114] Sealed Opposition 16:12-16 (remarking on Plaintiffs' reliance on *dicta*).

Takeda marshals its own authority regarding but-for causation, citing *UFCW Loc. 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 135-36 (2d Cir. 2010) ("*Zyprexa*").[115] The Second Circuit declined to certify a class of nationwide TPPs based upon the quantity-effect theory[116] where the district court had noted that "the evidence showed that at least some doctors were not misled by Lilly's alleged misrepresentations, and thus would not have written 'excess' prescriptions as identified by the plaintiffs." *Id.* at 136. The Second Circuit concluded that the independent actions of physicians made "general proof of but-for causation impossible." *Id.*

Although the First Circuit and Ninth Circuit have subsequently spurned the idea expressed in *Zyprexa* that a plaintiff needs individual proof of physicians' decision-making,[117] *Zyprexa* nevertheless unearths a

---

[115] *Id.* at 18:1-19:11.

[116] For context, the Second Circuit in *Zyprexa* also reversed the district court's certification of a class of TPPs based upon the "excess price theory," which posits that the TPPs overpaid for Zyprexa prescriptions because the manufacturer's misrepresentations artificially inflated the price of the drug.

[117] *See Neurontin I*, 712 F.3d at 45 (noting that a tort plaintiff need not prove a series of negatives); *Neurontin III*, 712 F.3d at 68 (holding that the "plaintiffs need not prove causation through the testimony of individual doctors"); *Painters & Allied Trades*, 943 F.3d at 1257 (expressing concern that manufacturers could "hide behind prescribing physicians and pharmacy benefit managers" if prescribing physicians' and pharmacy benefit managers' decisions constituted an intervening cause to sever the chain of proximate cause); *see also id.* at 1258 (crediting allegations of survey data showing that 75% of responding physicians lost considerable interest in an oral anti-diabetic drug once they learned that it carried a risk of bladder cancer).

key flaw with Plaintiffs' predominance argument. Namely, Takeda or Lilly could still depose individual prescribing physicians to contest Plaintiffs' theory of but-for causation, as those physicians might testify that they would have continued to prescribe Actos, notwithstanding the bladder cancer risk. And even if Plaintiffs present evidence that such testimony is "unreliable," a trier of fact could nonetheless rely on the physicians' testimony to qualify, discredit, or reject Plaintiffs' common evidence of but-for causation (*e.g.*, Comanor's regression analysis). *See Neurontin I*, 712 F.3d at 29. Since the number of testifying physicians would likely increase with the number of TPPs in the class, and that testimony would be linked to specific TPPs, such evidence would constitute individualized evidence. With so many individual TPPs in the class, a real and significant risk exists that individualized factual determinations would swamp common ones on the question of but-for causation.[118]

Plaintiffs gloss over that issue by repeatedly insinuating that they must prove only a *prima facie* case with common evidence,[119] but the predominance question is not limited merely to Plaintiffs' case-in-chief. Affirmative defenses, too, must be considered. *See Dukes*, 564 U.S. at 367 (holding that a class cannot be certified on the premise that a defendant "will not be entitled to litigate its statutory defenses to individual claims"); *see also Tyson*, 577 U.S. at 457 (noting that the petitioner's reliance on the

---

[118] Sealed Opposition 21:27-22:4.

[119] *See, e.g.*, Sealed Motion to Certify 3:1-4, 10:23-25, 11:21-22, 12:2-4, & 32:15-17; Sealed Reply 14:20-15:4 & 15:20-22.

respondents' representative evidence "did not deprive petitioner of its ability to litigate individual defenses"). Moreover, the *Neurontin* cases do not come to the rescue, since they concluded that doctor-by-doctor testimony was best left for the trier of fact to weigh and decide.[120] *See, e.g.*, *Neurontin I*, 712 F.3d at 45-46; *Neurontin II*, 712 F.3d at 58; *Neurontin III*, 712 F.3d at 69. In other words, rather than eschewing individualized evidence like testimony from the prescribing physicians, the *Neurontin* cases reserved it for the jury to consider.

At this point, one might conclude that individualized questions of fact predominate over common questions—at least, when it comes to but-for causation. But that conclusion is premature. It 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. Transitively, then, the availability of evidence matters for the purposes of determining predominance. For example, in *Tyson*, the Supreme Court noted that:

> respondents sought to introduce a representative sample to fill an evidentiary gap created by the employer's failure to keep adequate records. If the employees had proceeded with 3,344 individual lawsuits, each employee likely would have had to introduce Mericle's study to prove the hours he or she worked. Rather than absolving the employees from proving individual injury, the

[120] Sealed Opposition 21:11-27.

> representative evidence here was a permissible means of making that very showing. Reliance on Mericle's study did not deprive petitioner of its ability to litigate individual defenses. Since there were no alternative means for the employees to establish their hours worked, petitioner's primary defense was to show that Mericle's study was unrepresentative or inaccurate. That defense is itself common to the claims made by all class members.

Tyson, 577 U.S. at 456-57. Implicit in that reasoning is the idea that the question of predominance did not hinge on what evidence was ***theoretically*** available, but instead on what evidence was ***actually*** adduced to support the parties' claims and defenses. *Accord Huntsman v. Sw. Airlines Co.*, 2021 WL 391300, at *11 (N.D. Cal. Feb. 3, 2021) (synthesizing *Tyson* and other authorities to hold that the mere existence of an affirmative defense does not defeat class certification); *see also* Rubenstein § 4:55 (observing that the general rule, "regularly repeated by courts in many circuits," is that courts traditionally have been "reluctant to deny class action status under Rule 23(b)(3) simply because affirmative defenses may be available against individual members").

In reviewing the docket, the Court notes that most of the evidence related to the element of but-for causation (from either party) is common to the class. Excerpts of two depositions, each of a prescribing physician, constitute the only exception.[121] Those

---

[121] *See* Opposition, Ex. D. Dep. of Bolanle T. Oyeyipo, MD (the "Oyeyipo Deposition") [ECF No. 247-5]; *see also* Opposition,

excerpts are the only individualized evidence that Takeda or Lilly submitted in relation to the element of but-for causation on the Motion to Certify. In contrast, Plaintiffs supply a mountain of evidence regarding but-for causation that is common to the class; *e.g.*, Comanor's regression model, internal email conversations, academic studies, data regarding physician information requests, and the results of Takeda's internal investigations.[122] As the tally stands, individualized issues would not predominate over but-for causation if the trial was held today. While 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. The Court conducts a "rigorous analysis" of the issues and evidence as they stand to determine whether Rule 23 has been satisfied. *Gen. Tel. Co. of Sw. v. Falcon*, 457 U.S. 147, 161 (1982). It refrains from speculating whether the dearth of physician testimony is the result of a tactical decision or a matter of unavailability. Accordingly, the Court concludes that Plaintiffs have shown, by the preponderance of the evidence, that common questions of fact predominate over the element of but-for causation.

Ex. E. Remote Video Dep. of Cathy Stotz (the "Stotz Deposition") [ECF No. 247-6].

[122] *See* Sealed Motion to Certify 19:2-31:7 (describing common evidence on causation); *see also* Sealed Reply 15:5-18 (highlighting common evidence of internal marketing surveys and evidence of increases in physician information requests).

C. Conclusion for the National TPP Class

The Court is persuaded that the National TPP Class can be certified. Plaintiffs easily satisfy the four requirements of Rule 23(a). Plaintiffs also satisfy the superiority prong of Rule 23(b)(3). When it comes to predominance under Rule 23(b)(3), Plaintiffs handily show, by a preponderance of the evidence, that common questions of law and fact predominate over five of the seven underlying elements to their civil RICO claims. *Olean*, 31 F.4th at 665. Only two elements provoke any trepidation, and both relate to civil RICO standing: injury and but-for causation. 18 U.S.C. § 1964(c). Nonetheless, this Court concludes that Plaintiffs eke out a victory on both.

With respect to injury, the Court is persuaded that common questions are more likely to predominate than not for three reasons. First, the way that Plaintiffs define the class statistically limits the number of uninjured TPPs to a *de minimis* level. Second, the data from the regression model (which appears highly unique to this case) shows that variations in the probability of fraudulently induced prescriptions are still unlikely to generate large clusters of uninjured TPPs, given their timing with prescription volumes. And third, as even Takeda and Lilly acknowledge,[123] the Ninth Circuit foreclosed their argument that the presence of uninjured class members is a *per se* reason to deny certification. *See Olean*, 31 F.4th at 669.

Lastly, with respect to but-for causation, the Court recognizes and considers the possibility that an

---

[123] Defendants' Supplemental Brief 8:27-28.

individualized but-for causation analysis could overwhelm a common analysis. But in view of the sparse rebuttal evidence in the record animating that defense, the Court refrains from giving undue weight to the theoretical at the expense of the concrete. Thus, predominance for Rule 23(b)(3) is established for each element of Plaintiffs' civil RICO claims. And even if individualized questions of fact did outnumber common ones on the question of but-for causation, the bulk of the questions raised by Plaintiffs' civil RICO claims would be resolved with common evidence. On balance, the Court finds it appropriate to **GRANT** Plaintiffs' Motion to Certify as it relates to the National TPP Class. Painters is an appropriate class representative, and its counsel of record have demonstrated their competence to serve as Class Counsel.

IV. The California Consumer Class

Plaintiffs also seek to certify a class of California consumers, with Snyder named as the putative class representative. Plaintiffs define that class as:

> All consumers and entities in the State of California, who paid or incurred costs for the drug Actos, for purposes other than resale, between 1999, i.e., when the drug was approved, and the present. Excluded from the California Consumer Class are employees of Takeda, including its officers or directors, the Court to which this case is assigned, and those consumers who are presently seeking a

> personal injury claim arising out of their use of Actos.[124]

On behalf of the California Consumer Class, Plaintiffs assert three claims against Takeda and Lilly: (1) a claim seeking relief under California's Consumer Legal Remedies Act (the "CLRA"), *see* Cal. Civ. Code §§ 1750, *et seq.*; (2) a claim for remedies pursuant to California's Unfair Competition Law (the "UCL"), *see* Cal. Bus. & Prof. Code §§ 17200, *et seq.*; and (3) a claim seeking remedies under California's False Advertising Law (the "FAL"), *see* Cal. Bus. & Prof. Code §§ 17500, *et seq*.[125]

As discussed below, Takeda and Lilly make a weak typicality challenge. *See* Fed. R. Civ. P. 23(a)(3). Otherwise, Takeda and Lilly concede that Plaintiffs satisfy the Rule 23(a) requirements. Like the National TPP Class discussed in Part III above, the battle over certification largely turns on the issue of predominance. *See* Fed. R. Civ. P. 23(b)(3).

A. Rule 23(a) Requirements

1. Numerosity, Commonality, and Adequacy

Plaintiffs assert that there are "hundreds of thousands, if not millions, of consumers who purchased Actos within the State of California between July 1, 1999 and September 17, 2010."[126] And Snyder herself declares that she has no conflict of

---

[124] Amended Complaint ¶ 223.

[125] *Id.* at ¶¶ 260-88. Those claims are pled as Counts III, IV, and V, respectively.

[126] Sealed Motion to Certify 37:5-14.

interest with any of those putative members of the California Consumer Class.[127] Additionally, Plaintiffs argue that there are issues of law and fact common to the putative California Consumer Class regarding Takeda and Lilly's alleged violations of California consumer protection laws.[128]

Takeda and Lilly do not contest any of those arguments or averments.[129] In view of those concessions, the Court concludes that the numerosity, commonality, and adequacy elements satisfied. *See* Fed. R. Civ. P. 23(a)(1), (2), & (4).

2. Typicality

Plaintiffs allege that Snyder sustained the injury of purchasing Actos without a full and accurate knowledge of its risks.[130] Snyder herself declares that she would "never have purchased and ingested the drug" had she known that Actos was associated with an increased risk of bladder cancer.[131] For those reasons, Plaintiffs suggest that Snyder—and the injury that she sustained—are typical of the class. *See* Fed. R. Civ. P. 23(a)(3); *see also Ellis*, 657 F.3d at 984 (reiterating that the test of typicality "is whether other members have the same or similar injury, whether the action is based on conduct which is not unique to the named plaintiffs, and whether other class members

---

[127] *Id.* at 38:12-15.

[128] *Id.* at 37:15-28.

[129] *See generally* Sealed Opposition & Sealed Joinder.

[130] Sealed Motion to Certify 38:1-3.

[131] Decl. of Annie Snyder (the "Snyder Declaration") [ECF No. 229-50] ¶ 9.

have been injured by the same course of conduct") (internal citations and quotations omitted).

Writing separately, Lilly argues that Snyder is not typical of the class for two reasons. First, Lilly observes that Snyder began purchasing Actos in May 2009—three years after Lilly stopped promoting the drug.[132] Lacking unilateral control to change the labels and to cure any omissions after the co-promotion ended,[133] Lilly insinuates that Snyder faces "additional, unique legal hurdles in pursuing claims against Lilly as compared to putative class members who paid for Actos during the term of the copromotion agreement."[134] But that argument is a red herring because Snyder alleges liability under the CLRA, UCL, and FAL based upon a decades-long conspiracy, for which Lilly received royalties after its co-promotion with Takeda ended.[135]

Second, Lilly points out that Snyder's physician, Dr. Cathy Stotz, testified that she believed that Actos was the right medical choice for Snyder.[136] But that argument is yet another red herring: Stotz's *post hoc* beliefs regarding the propriety of the treatment are immaterial to the typicality of Snyder's injury.[137] If

---

[132] Sealed Joinder 8:15-18.

[133] *Id.* at 9:1-10.

[134] *Id.* at 9:11-13. Curiously, though, Lilly does not identify what those unique legal hurdles might be. *See generally id.*

[135] Sealed Reply to Joinder 6:5-24.

[136] Sealed Joinder 9:13-19.

[137] It also strikes the Court that ***many*** physicians would be reluctant to reverse their earlier recommendations, *see, e.g.*,

Snyder had known about the bladder cancer risks, Snyder avers that she would not have pursued the treatment, notwithstanding her physician's recommendation.[138] *See Guido v. L'Oreal, USA, Inc.*, 284 F.R.D. 468, 479 (C.D. Cal. 2012), *on reconsideration*, 2012 WL 2458118 (C.D. Cal. June 25, 2012) (finding typicality satisfied when the named plaintiff "testified that she would not have purchased Serum or would have paid less for Serum had she known it had flammable characteristics").

In summary, Snyder meets the typicality requirement as a putative class representative. *See* Fed. R. Civ. P. 23(a)(3). Other California consumers ostensibly would have been injured by the same omissions from Takeda and Lilly. Neither the timing nor Snyder's physician's belief is a bar to that finding.

B. Rule 23(b) Requirements

Like they did with the National TPP class, here Plaintiffs elect to meet the mandates of Rule 23(b) by attempting to show that the California Consumer Class satisfies the third prong; *i.e.*, superiority and predominance. *See* Fed. R. Civ. P. 23(b)(3).

1. Superiority

Plaintiffs argue that it would be "unrealistic to expect millions of California consumers to engage in a multiyear litigation against Takeda and Lilly to recover a meager refund."[139] Takeda and Lilly wisely

---

Neurontin I, 712 F.3d at 29 (discussing the phenomenon), which, ironically, would make Snyder's experience even more typical.

[138] *See* Sealed Reply to Joinder 7:1-6 (citing Snyder Declaration ¶¶ 7-9).

[139] Sealed Motion to Certify 45:6-8.

concede the point. As with the National TPP class, the Court finds that the class action form would be superior to alternative methods in this instance.

2. Predominance

Plaintiffs argue that their CLRA, UCL, and FAL claims focus on Takeda and Lilly's misconduct, and, thus, common issues predominate. Specifically, Plaintiffs contend that Takeda and Lilly made material omissions about Actos's bladder cancer risk, which caused the members of the California Consumer Class to sustain economic injuries.[140] The Court evaluates predominance for each of those claims. *See Comcast Corp.*, 569 U.S. at 35.

a. CLRA

The CLRA makes unlawful various "unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or which results in the sale . . . of goods . . . to any consumer." Cal. Civ. Code § 1770(a). Here, Plaintiffs allege that Takeda and Lilly's omission of Actos's bladder cancer risk constituted two such proscribed practices under the CLRA: namely, misrepresenting the "certification" of safety in violation of Cal. Civ. Code § 1770(a)(2) and misrepresenting the "standard, quality, or grade" of the drug in violation of Cal. Civ. Code § 1770(a)(7).[141]

Relief under the CLRA is "limited to '[a]ny consumer who suffers any damage as a result of the use or employment by any person of a method, act, or

---

[140] *Id.* at 38:18-45:2.

[141] Amended Complaint ¶ 264.

practice' unlawful under the act." *Massachusetts Mut. Life Ins. Co. v. Superior Ct.*, 97 Cal. App. 4th 1282, 1292 (2002), *as modified on denial of reh'g* (May 29, 2002) (citing Cal. Civ. Code § 1780(a)). Thus, Plaintiffs must "show not only that a defendant's conduct was deceptive but that the deception ***caused*** them harm." *Id*. (emphasis added). In other words, the California Consumer Class must have relied on Takeda or Lilly's omissions. Additionally, Plaintiffs must demonstrate an "actual injury as to each class member." *Steroid Hormone Prod. Cases*, 181 Cal. App. 4th 145, 155 (2010), *as modified on denial of reh'g* (Feb. 8, 2010) ("*Steroid*"). "[B]oth the named plaintiff and unnamed class members must have suffered some damage caused by a practice deemed unlawful under Civil Code section 1770." *Id.* at 156. Accordingly, the Court evaluates whether common questions predominate over the elements of causation and Plaintiffs' reliance, Plaintiffs' injury, and Takeda or Lilly's obligation to disclose the risks—*i.e.*, their deceptive conduct.[142]

---

[142] Where, as here, Plaintiffs' CLRA claim is premised on an "omission," the omission must be either: (1) "contrary to a representation actually made by the defendant"; or (2) "an omission of a fact the defendant was obliged to disclose." *Daugherty v. Am. Honda Motor Co.*, 144 Cal. App. 4th 824, 835 (2006). An obligation to disclose exists for the purposes of a CLRA claim based upon "failure to disclose a fact" in any of "four circumstances": "(1) when the defendant is the plaintiff's fiduciary; (2) when the defendant has exclusive knowledge of material facts not known or reasonably accessible to the plaintiff; (3) when the defendant actively conceals a material fact from the plaintiff; [or] (4) when the defendant makes partial representations that are misleading because some other material fact has not been disclosed." *Collins v. eMachines, Inc.*, 202 Cal. App. 4th 249, 255 (2011), *as modified* (Dec. 28, 2011).

i. Deceptive Conduct

The Court begins with the easiest element to evaluate. Similar to the element of a civil RICO violation that the Court considered in connection with the National TPP Class, *see supra* Part III.B.2.a.i, the Court agrees with Plaintiffs that questions of deception are ones susceptible to common class-wide proof for the California Consumer Class, since the inquiry turns on evidence of what Takeda and Lilly knew and what they failed to disclose. *See Tait v. BSH Home Appliances Corp.*, 289 F.R.D. 466, 481 (C.D. Cal. 2012) (holding that evidence of the defendant's senior management's desire "to eliminate references to odor problems" in its product's labeling constituted common evidence that could establish deceptive conduct). Thus, common evidence would resolve this element—predominance is established.

ii. Causation and Reliance

In contrast, a muddled mix of common and individualized evidence would be needed to resolve the elements of causation and reliance. Causation "may be established" on a class-wide basis ***if*** a material misrepresentation or omission has been made to the entire class. *In re Vioxx Class Cases*, 180 Cal. App. 4th 116, 129 (2009) ("*Vioxx*"); *see also Stearns*, 655 F.3d 1022 (noting that the rule applies to cases regarding omissions) (citing *McAdams v. Monier, Inc.*, 182 Cal. App. 4th 174, 184 (2010)). "That the defendant can establish a lack of causation as to a handful of class members does not necessarily render the issue of causation an individual, rather than a common, one." *Vioxx*, 180 Cal. App. 4th at 129.

Materiality is "generally judged by a reasonable man standard." *Steroid*, 181 Cal. App. 4th at 157 (internal quotations omitted). "[H]owever, if the issue of materiality or reliance is a matter that would vary from consumer to consumer, the issue is not subject to common proof, and the action is properly not certified as a class action." *Vioxx*, 180 Cal. App. 4th at 129 (citing *Caro v. Procter & Gamble Co.*, 18 Cal. App. 4th 644, 668 (1993) (affirming denial of class certification where the materiality of the defendant's representations regarding the freshness of its orange juice varied from consumer to consumer, since not all consumers believed the defendant's statements and thus were not induced "to alter [their] position to [their] detriment")).

To their credit, Plaintiffs offer some compelling common evidence of materiality; *e.g.*, the wave of physician information requests ("PIRs") came in the wake of the bladder cancer risk disclosures and Lilly's concession that bladder cancer risks would be a "serious thing" for a healthcare professional.[143]

But as Lilly argued at the hearing, the materiality of that bladder cancer risk to patients' diabetes prognoses is highly individualized. Moreover, some medicines and treatment regimens would be

---

[143] *See* Sealed Motion to Certify 42:24-43:2 (pointing out that Lilly conceded that bladder cancer risks would be a "serious thing" for a healthcare professional and noting a wave of PIRs that came in the wake of the disclosures). While PIRs in aggregate serve as common evidence, PIRs could also serve as individualized evidence: many physicians expressed concerns, but others did not, and even more would not have changed their prescription.

ineffective; some patients would have no other option other than Actos, notwithstanding the bladder cancer risks.[144] Those determinations necessarily reside with the patients and their physicians. Even Comanor recognized that reality.[145] Therefore, the question of whether Takeda or Lilly's omissions were material to the choices of any physician-patient tandem is an individualized one. And unlike the National TPP Class—where Plaintiffs could establish a *prima face* case with extant common evidence (before even considering Takeda's or Lilly's possible affirmative defenses)—the Court struggles to see how Plaintiffs can circumvent that individualized, case-by-case materiality analysis for the California Consumer Class.[146]

---

[144] Hearing Transcript 123:3-127:18 (using the case of the named class representative as an example, wherein her physician testified that there was no other option but to choose Actos).

[145] *See, e.g.*, Ex. A. Remote Video Dep. of Dr. William S. Comanor [ECF No. 248-2] 109:20-23 (observing that the decision to prescribe lies with the physician and patient) & 192:18-193:6 ("Q: Okay. As you sit here, you can't say what an individual physician would do with respect to any particular patient and their prescribing diabetes medications? A: That is obviously correct.").

[146] Important here to the Court's decision is the relative quantum of evidence. Whereas Plaintiffs adduced mountains of common evidence for the National TPP class, they fail to do so for the California Consumer Class. For example, Plaintiffs do not have large numbers of consumers who were surveyed regarding their opinions, nor do Plaintiffs have evidence of a large number of consumers seeking refunds. The quantum of evidence on each side with respect to this class is far closer to parity.

Plaintiffs also rely heavily on the "presumption" of reliance.[147] *See Davis-Miller v. Auto. Club of S. California*, 201 Cal. App. 4th 106, 125 (2011), *as modified* (Nov. 22, 2011) (noting that, unlike the UCL and FAL, the CLRA requires "an additional showing of reliance"). But that presumption does not necessarily apply here. In *Vioxx*, the plaintiffs sought to certify a class upon the basis of alleged misrepresentations and omissions in "Merck's direct-to-consumer advertisements," which "did not address the cardiovascular risks at all." *Vioxx*, 180 Cal. App. 4th at 123. In view of the individualized issues regarding Vioxx's effectiveness and safety, the trial court concluded that the plaintiffs could not establish materiality and reliance with respect to the CLRA on a classwide basis. *See id*. at 126. The California Court of Appeals affirmed:

> [P]hysicians consider many patient-specific factors in determining which drug to prescribe, including the patient's history and drug allergies, the condition being treated, and the potential for adverse reactions with the patient's other medications—in addition to the risks and benefits associated with the drug. When all of these patient-specific factors are a part of the prescribing decision, the materiality of any statements made by Merck to any particular prescribing decision cannot be presumed. All of this evidence supports the trial court's conclusion that whether Merck's misrepresentations were material, and therefore induced reliance, is a

[147] *See* Sealed Reply 22:24-25.

> matter on which individual issues prevailed over common issues, justifying denial of class certification with respect to the CLRA claim

Vioxx, 180 Cal. App. 4th at 134. The cardiovascular risks in *Vioxx* and the bladder cancer risks here both strike the Court as serious considerations—ones that most reasonable physicians and patients would evaluate before choosing an appropriate healthcare regimen.

But materiality is found only where the omission of those risks "would have been important to the decision-making process." *Krueger v. Wyeth, Inc.*, 2011 WL 8971449, at *9 (S.D. Cal. Mar. 30, 2011) ("*Krueger I*"); *see also In re Vioxx Consolidated Class Action*, 2009 WL 1283129 (Cal. Super. Apr. 30, 2009) ("[t]o determine whether the cardiac risks posed by Vioxx were material to any given class member requires an examination of the member's medical needs and history"). That aspect of materiality implicates a further individualized analysis. As Stotz's testimony illustrates,[148] medical decisions are unique. Some risks may not be all that important to the decision-making process when a patient faces a debilitating and life-threatening disease. The Court is loath to insert itself into the doctor's office and impose its judgment onto physicians and their patients, blanketly concluding on behalf of all "reasonable persons" that some risks matter (*i.e.*, bladder cancer risk) and that some do not (*i.e.*, untreated or mismanaged diabetes). After all, *sola dosis facit venenum*—the dose makes the poison. *See* Lothar

[148] *See generally* Stotz Deposition; *see also* Oyeyipo Deposition.

Determann, *Healthy Data Protection*, 26 Mich. Tech. L. Rev. 229, 277-78 n.245 (2020) ("Pracelsus [*sic*, Paracelsus] said, 'Sola dosis facit venenum' (all things are poison and nothing is without poison; only the dose makes a thing not a poison) (citation omitted)). And indeed, Comanor's own model suggests that 40% of Actos purchases would have been made even if full information of the risks was known.[149] Forty percent is not a trivial amount, even post- *Olean*.

For the same reasons as the court in *Vioxx*, the Court here concludes that individualized questions of fact predominate over causation and reliance with respect to Plaintiffs' CLRA claim. *See also Stearns*, 655 F.3d at 1024 (affirming the denial of class certification for a CLRA claim where there were "myriad reasons" why a consumer might not have been misled by an omission on the defendant's website, and yet "all of those people would have been swept willy-nilly into the class"); *cf. Steroid*, 181 Cal. App. 4th at 159-60 (distinguishing *Vioxx* by asserting that "there is no impediment to establishing reliance on a classwide basis for the CLRA claim in this case because it can be established by showing that the alleged misrepresentation—that the androstenediol products were legal—was material").[150]

---

[149] Sealed Opposition 42:23-25.

[150] Plaintiffs also rely on *Krueger I*, but that case is distinguishable on the facts. The court there explained that "the drug in Vioxx ultimately performed as advertised, but with an undisclosed side effect," whereas in *Krueger I*, the drug "did not perform as advertised." *Krueger I*, 2011 WL 8971449, at *8. Here, Plaintiffs say that Actos performed as advertised but that it

iii. Actual Injury

"A CLRA claim warrants an analysis different from a UCL claim because the CLRA requires each class member to have an actual injury caused by the unlawful practice." *Stearns*, 655 F.3d at 1022. Injury is conflated, though, with the reliance inquiry. *See Steroid*, 181 Cal. App. 4th at 156-57. As discussed above, individualized questions predominate over the question of reliance. Therefore, individualized questions predominate over the element of injury as well.

b. UCL and FAL

The UCL proscribes unfair competition, described as "unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising." Cal. Bus. & Prof. Code § 17200. "Thus, there are three varieties of unfair competition: practices which are unlawful, unfair or fraudulent." *Daugherty v. Am. Honda Motor Co.*, 144 Cal. App. 4th 824, 837 (2006), *as modified* (Nov. 8, 2006). Plaintiffs allege violations of all three varieties, although each allegation arises from essentially the same deceptive and misleading conduct.[151]

Similarly, the FAL prohibits the dissemination of any advertising "which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading." Cal. Bus. & Prof. Code § 17500. Consistent with their UCL claim, Plaintiffs allege that Takeda and Lilly

---

posed an undisclosed risk of bladder cancer. That allegation makes this case closer to *Vioxx* than *Krueger I*.

[151] *See* Amended Complaint ¶¶ 271-81.

advertised on its packaging and through various media outlets in a manner that misstated Actos's bladder cancer risk.[152]

To state a claim under either the UCL or the FAL, "it is necessary only to show that 'members of the public are likely to be deceived.'" *Kasky v. Nike, Inc.*, 27 Cal. 4th 939, 951 (2002). Whereas a "fraudulent deception must be actually false, known to be false by the perpetrator and reasonably relied upon by a victim who incurs damages," none of those elements is required to state a claim for relief under the UCL or the FAL. *Day v. AT & T Corp.*, 63 Cal. App. 4th 325, 332 (1998). While the UCL focuses "on the defendant's conduct, rather than the plaintiff's damages, in service of the statute's larger purpose of protecting the general public against unscrupulous business practices," *In re Tobacco II Cases*, 46 Cal. 4th 298, 312 (2009), predominance is not necessarily automatic in every UCL or FAL case. "For example, it might well be that there was no cohesion among the members because they were exposed to quite disparate information from various representatives of the defendant." *Stearns*, 655 F.3d at 1020.

Takeda first challenges the idea that common evidence predominates over the California Consumer Class members' exposure to its omissions. Takeda argues that it is unlikely that each member of the California Consumer Class viewed the product label, especially when the labels are often directed at physicians.[153] To wit, Snyder testified that she read

---

[152] *Id.* at ¶ 285.

[153] Sealed Opposition 41:3-15.

labels sometimes, but not every time.[154] Plaintiffs counter by asserting that the fraud lasted a decade, thus making the facts here analogous to the tobacco industry's decades-long deceptive advertising campaign.[155] *See Tobacco II*, 46 Cal. 4th at 324-27. But while the duration of Takeda's alleged malfeasance shares an order of magnitude with that of the tobacco industry in *Tobacco II* (*i.e.*, decades rather than months or years), product labels for a specific oral antidiabetic medication do not share the same level of ubiquity as cigarette advertisements. *See id.* at 327 (describing the tobacco industry's technique of "saturation advertising"); *see also Mazza*, 666 F.3d at 596 ("In the absence of the kind of massive advertising campaign at issue in *Tobacco II*, the relevant class must be defined in such a way as to include only members who were exposed to advertising that is alleged to be materially misleading.").

Furthermore, Plaintiffs cannot simply assume that every patient who took Actos was instantly exposed to misleading statements, especially when Plaintiffs' own expert's model accounts for a lag in the time it takes for information to be disseminated.[156] That empirical fact suggests that Plaintiffs are not entitled to a presumption. Indeed, "*Tobacco II* does not stand for the proposition that a consumer who was never exposed to an alleged false or misleading advertising or promotional campaign is entitled to restitution." *Pfizer Inc. v. Superior Ct.*, 182 Cal. App.

---

[154] Opposition, Ex. I [ECF No. 238-10] 63:3-24.

[155] Sealed Reply 22:25-23:12.

[156] *See* Sealed Opposition 42:9-18.

4th 622, 632 (2010). The availability of some common evidence—which at best indicates that some physicians were aware of the omission[157]—does not obviate the need for individualized evidence.

Second, Takeda contends that the materiality of the misleading omissions would also vary patient by patient.[158] As discussed earlier, *see supra* Part IV.B.2.a.ii, the Court agrees that individualized issues are likely to predominate, especially when at least 40% of the class would have continued to purchase Actos after being fully informed of the bladder cancer risks, according to the Plaintiffs' expert.

Third, Takeda argues that the modification of the class period—back to 2010—triggers statute-of-limitation issues for Plaintiffs' CLRA and FAL claims.[159] *See Yumul v. Smart Balance, Inc.*, 733 F. Supp. 2d 1117, 1130 (C.D. Cal. 2010) (explaining that CLRA and FAL claims are subject to a three-year statute of limitations and that UCL claims are subject to a four-year statute of limitations). Those issues, says Takeda, raise "substantial individual questions that vary among class members." *O'Connor v. Boeing N. Am., Inc.*, 197 F.R.D. 404, 414 (C.D. Cal. 2000). Plaintiffs reply that the "discovery rule" applies here, which has the effect of postponing the accrual of the claims.[160] *See Clemens v. DaimlerChrysler Corp.*, 534

---

[157] Sealed Motion to Certify 40:2-9 (discussing Takeda's studies and interviews of prescriber awareness of bladder cancer risks).

[158] Sealed Opposition 42:19-43:11.

[159] *Id.* at 44:21-45:22.

[160] Sealed Reply 25:4-10.

F.3d 1017, 1024 (9th Cir. 2008) (citing *Norgart v. Upjohn Co.*, 21 Cal. 4th 383, 397 (1999)).

"In order to invoke this special defense to the statute of limitations, the plaintiff must specifically plead facts which show (1) the time and manner of discovery and (2) the inability to have made earlier discovery despite reasonable diligence." *Saliter v. Pierce Bros. Mortuaries*, 81 Cal. App. 3d 292, 297 (1978). Since this case was filed on July 23, 2014,[161] Plaintiffs would need to invoke the discovery rule for any California Consumer Class member who discovered (or could have discovered) the misleading omissions prior to July 23, 2011—at least with respect to the CAL and CLRA claims.[162]

While the Court need not now adjudicate the merits of this defense, it must consider whether evidence common to the class, or evidence particular to individual class members, would predominate in resolving the inquiry. Ironically, Takeda and Lilly appear more likely to avail themselves of evidence common to the class to overcome the discovery rule defense—*e.g.*, the FDA's announcement on September 17, 2010, that it was conducting an on-going safety review of Actos for bladder cancer risk;[163] the American Diabetes Association's publication of studies of pioglitazone use and bladder cancer on April

---

[161] *See* Compl. [ECF No. 1].

[162] The parties acknowledge that the UCL claim is not at issue here. *See* Sealed Opposition 45:20-22; Sealed Reply 25:28. Given the UCL's four-year limitations period, the cutoff date would be July 23, 2010.

[163] Second Amended Complaint ¶ 94.

22, 2011;[164] the European Medicines Agency's June 9, 2011, announcement that it was suspending Actos;[165] and the FDA's June 15, 2011, safety announcement informing the public of the links between Actos use and bladder cancer.[166] On the other hand, individualized evidence—such as patient or prescriber testimony— would likely be needed to show that any given California Consumer Class member "was not negligent in failing to make the discovery sooner" in view of those announcements or that they "had no actual or presumptive knowledge of facts sufficient to put [them] on inquiry." *Bedolla v. Logan & Frazer*, 52 Cal. App. 3d 118, 129 (1975). While Plaintiffs make clear that they intend to point to the August 2011 Actos product label's inclusion of the bladder cancer risk (which is common evidence),[167] the Court is skeptical that individual testimony could be entirely avoided, should Plaintiffs avail themselves of the discovery rule.

c. Damages

If Plaintiffs prevail on their claims for the California Consumer Class, then they would be entitled to only those damages resulting from their theory of liability—in this case, restitution. *See Comcast Corp.*, 569 U.S. at 35. "It follows that a model purporting to serve as evidence of damages in this class action must measure only those damages attributable to that theory." *Id.* Calculations "need not

---

[164] *Id.* at ¶ 96.

[165] *Id.* at ¶ 97.

[166] *Id.* at ¶ 99.

[167] *See* Sealed Reply 25:12-22.

be exact," so long as they are "consistent" with Plaintiffs' liability case. *Id.* "And for purposes of Rule 23, courts must conduct a 'rigorous analysis' to determine whether that is so." *Id.* (citing *Dukes*, 564 U.S. at 351).

Plaintiffs presented a model for the National TPP Class, but they do not do so for the California Consumer Class. Rather, Plaintiffs merely allude to a methodology described in another case. Plaintiffs say that Comanor is ready and willing to perform an analysis using the methodology similar to the one performed in *Krueger v. Wyeth, Inc.*, 396 F. Supp. 3d 931 (S.D. Cal. 2019) ("*Krueger II*").[168] But that analysis remains a mere proposal.[169]

While the methodologies described in *Krueger II* appear sound in principle, the Court is skeptical that Plaintiffs have met their burden here. Plaintiffs cite no authority suggesting that they may provide merely a ***proposal*** for a model calculating damages.[170] The Court cannot conduct a rigorous analysis of a plan written, so to speak, on a paper napkin. Comanor would need to apply the methodologies to the facts and data in this case to show that they are consistent with Plaintiffs' theory of liability. *See Pulaski & Middleman, LLC v. Google, Inc.*, 802 F.3d 979, 989 (9th Cir. 2015) (requiring that damages be computed even if only an approximation for the purposes of

---

[168] *Id.* at 24:8-25:2.

[169] Hearing Transcript 69:23-70:20 (emphasizing that Comanor "proposes" following the methodology of Rosenthal in *Krueger II*, not that Comanor performed it).

[170] *See* Sealed Motion to Certify 43:9-5:2 & Sealed Reply 24:7-25:2.

restitution under California law). In other words, Plaintiffs are obligated to show that their damages ***are*** measurable, not that they ***could be***. *See Daniel F. v. Blue Shield of California*, 305 F.R.D. 115, 128 (N.D. Cal. 2014). That burden may be easy to satisfy, but it nonetheless remains Plaintiffs' burden to satisfy, as the movant for class certification. Because Plaintiffs have not done so, the Court must decline to certify the California Consumer Class. *See Kim v. Benihana, Inc*, 2022 WL 1601393, at *12 (C.D. Cal. Mar. 25, 2022) (denying class certification where the plaintiff did not present a damages model).

C. Conclusion for the California Consumer Class

Like the National TPP Class discussed in Part III above, the Court is persuaded that the California Consumer Class easily meets the four requirements of Rule 23(a). The California Consumer Class also satisfies the superiority prong of Rule 23(b)(3). But when it comes to predominance, the role of individualized evidence appears far more prominent, even though it varies slightly from claim to claim.

A mix of common and individualized evidence would likely come into play with respect to materiality, exposure, and the statute of limitations. Saying ***exactly*** how much, though, is unclear. With far less evidence submitted to the Court with respect to the California Consumer Class, predicting the precise proportions of individual and common evidence needed to resolve the inquiries appears especially challenging. But at a minimum, the importance of materiality to the element of reliance—which traverses the CLRA, UCL, and FAL claims—

transitively amplifies the importance of any evidence related to that inquiry. On that element, the Court foresees a potentially far greater need for individualized testimony, should Takeda and Lilly be able to marshal it.

The California Consumer Class also differs from the National TPP Class in that, for the latter class, Plaintiffs offer a compelling regression analysis to circumvent individualized evidence on the element of injury with respect to Plaintiffs' civil RICO claims. In contrast, Plaintiffs do not offer such a solution for their UCL, FAL, or CLRA claims. Plaintiffs instead rely on California law to provide them with a presumption of reliance, but, as discussed, the facts here are too dissimilar from those in *Tobacco II* to warrant a finding in Plaintiffs' favor.

Lastly, the Court is unpersuaded by Plaintiffs' perfunctory efforts regarding their damages model. Until a model is constructed, or an analysis is performed, Plaintiffs receive a grade of "incomplete" with respect to damages and the predominance inquiry under Rule 23(b)(3). That missing piece—in tandem with the milieu of individualized questions discussed above—tips the balance against certifying the California Consumer Class for all three of Plaintiffs' claims.

V. Disposition

For the foregoing reasons, the Court hereby **ORDERS** as follows:

1. Plaintiffs' Motion to Certify is **GRANTED in part** and **DENIED in part**:

a. The National TPP Class is **CERTIFIED**. Painters is preliminarily **APPOINTED** as class representative. R. Brent Wisner, Michael L. Baum, and Christopher L. Coffin are also preliminarily **APPOINTED** as Class Counsel.

b. The Court declines to certify the California Consumer Class.

2. The parties are **DIRECTED** to confer forthwith and to file no later than June 16, 2023, a Joint Status Report that provides the Court with their jointly proposed case schedule or, if the parties cannot agree, their respective competing proposed case schedules and the reasons for their disagreement.

3. A Scheduling Conference is **SET** for June 30, 2023, at 11:00 a.m. in Courtroom 9D of the Ronald Reagan Federal Building and U.S. Courthouse, 411 W. 4th Street, Santa Ana, California.

4. Class Counsel is **DIRECTED** to propose a comprehensive notice plan for the National TPP Class.

IT IS SO ORDERED.

Dated: May 24, 2023 [handwritten: signature]

John W. Holcomb
UNITED STATES DISTRICT JUDGE

Appendix D

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 18-55588

PAINTERS & ALLIED TRADES DISTRICT COUNCIL 82 HEALTH CARE FUND, third-party healthcare payor fund; et al.,

Plaintiffs-Appellants,

v.

TAKEDA PHARMACEUTICALS COMPANY LIMITED, a Japanese Corporation; et al.,

Defendants-Appellees.

Argued & Submitted: June 6, 2019
Filed: Dec. 3, 2019

Before: Carlos T. Bea, Jacqueline H. Nguyen, and Paul J. Watford*, Circuit Judges.

OPINION

BEA, Circuit Judge:

Today we confront an issue of first impression in our circuit, and one that has caused an apparent

---

* Judge Watford was drawn to replace Judge Rawlinson. Judge Watford has read the briefs, reviewed the record, and watched the recording of oral argument held on June 6, 2019.

circuit split among four of our sister circuits: In civil actions brought under the Racketeer Influenced and Corrupt Organizations Act ("RICO") against pharmaceutical companies, do patients and health insurance companies who reimbursed patients adequately allege the required element of proximate cause where they allege that, but for the defendant's omitted mention of a drug's known safety risk, they would not have paid for the drug?

I. Factual Background

This appeal arises from a putative class action against Takeda Pharmaceuticals USA, Inc., its parent company Takeda Pharmaceutical Company Ltd., and Eli Lilly & Co. (collectively, "Defendants"). Together, Defendants developed and marketed a drug named Actos. Actos was intended to lower blood sugar in type 2 diabetics. Defendants obtained Food and Drug Administration ("FDA") approval for Actos in 1999. The plaintiffs allege that despite learning through multiple studies over the next several years that Actos increased a patient's risk of developing bladder cancer, Defendants refused to change Actos's warning label or otherwise inform the public of such risk. Further, the plaintiffs allege that Defendants convinced the FDA that studies revealing that Actos increased the risk of bladder cancer were wrong. Defendants are alleged to have actively misled prescribing physicians, consumers, and third-party payors into believing that Actos did not increase a person's risk of developing bladder cancer. Defendants did all of this, the plaintiffs allege, simply to increase their profits from the sale of Actos.

On September 17, 2010, after further studies of Actos revealed an increased risk of bladder cancer, the FDA announced that it was conducting a safety review of Actos. On June 15, 2011, the FDA released an official warning to the public that Actos may be linked to bladder cancer in patients who use it over prolonged periods of time. Following the FDA's official warning, Defendants changed Actos's warning label to warn of a bladder cancer risk. The sales of Actos are alleged to have dropped shortly after the FDA issued its alert in 2010, and then again when the FDA issued its official warning in 2011, by a total of approximately 80%.

A group of patients who developed bladder cancer after ingesting Actos and their family members then brought personal injury and wrongful death claims against Defendants in the Western District of Louisiana. After a 37-day trial in 2014, the jury returned a verdict in favor of the plaintiffs, but the parties later agreed to a global settlement program for all eligible personal injury claimants who used Actos before December 1, 2011 and had been diagnosed with bladder cancer. *In re Actos (Pioglitazone) Prods. Liab. Litig.*, MDL No. 6:11-MD-2299, 274 F. Supp. 3d 485, 503 (W.D. La. 2017).[1]

The present action was also originally filed in the Western District of Louisiana. But in late 2017, the parties stipulated to transfer the case to the Central District of California. The plaintiffs in this case comprise five individual patients from different states (collectively, "Patients") and Painters and Allied

[1] No argument has yet been made in this action that the settlement encompassed the plaintiffs' RICO claims or mooted them.

Trades District Council 82 Health Care Fund ("Painters Fund") (together, "Plaintiffs").

Painters Fund is a third-party payor ("TPP") of health and welfare benefits to covered members and their families. As a TPP, Painters Fund reimburses its members' claims for drugs, including Actos, submitted by pharmacies and healthcare providers covered by its plan. Painters Fund "relies on each member to submit claims for prescription medications that are medically reasonable and necessary for treatment," with the expectation that patients and their prescribing physicians will "make informed decisions about which drugs will be prescribed and, in turn, submitted to [Painters Fund] for reimbursement." Painters Fund "has the authority to determine which drugs are covered under its plan, although, [it] entrusts the administration of claims and formulary determinations to Prime Therapeutics, LLC, based in Eagan, Minnesota."[2]

Patients are individuals with type 2 diabetes who were prescribed Actos by their physicians and who took Actos to help lower their blood sugar. Each patient paid an out-of-pocket sum for Actos. Patients each allege that neither they nor their physicians knew about Actos's risk of bladder cancer when they began taking the drug and that they immediately stopped taking Actos once they learned that it increased their risk of developing bladder cancer. Patients also allege that they never would have purchased Actos had they known that it increased

---

[2] Prime Therapeutics, LLC is not a party to this litigation and is not discussed elsewhere in the complaint.

their risk of developing bladder cancer, and thus, that they never would have submitted claims for reimbursement for purchases of Actos to their respective TPPs. Only one patient, Annie Snyder from California, alleges that prior to starting her prescription, she read and relied upon the Actos label. But Plaintiffs generally allege that Patients relied on Defendants' misrepresentations about Actos, by act or omission, in purchasing the drug, that physicians relied on such misrepresentations in prescribing Actos for their patients, and that TPPs relied on such misrepresentations in agreeing to pay for Actos prescriptions for their members.

Plaintiffs seek to represent a class of similarly situated patients and TPPs "who paid or incurred costs for the drug Actos, for purposes other than resale, between 1999, i.e., when the drug was approved, and the present," excluding "those consumers who are presently seeking a personal injury claim arising out of their use of Actos." Plaintiffs argue that Defendants conspired to commit mail and wire fraud under 18 U.S.C. §§ 1341, 1343 by intentionally misleading physicians, consumers, and TPPs to believe that Actos did not increase a person's risk of developing bladder cancer. Plaintiffs seek to recover economic damages under RICO for the payments they made to purchase Actos under the assumption that it was a safe drug, which they allege they would not have purchased had they known that Actos increases a person's risk of developing bladder cancer (this is called the "quantity effect theory" of

damages).[3] Plaintiffs do not, however, seek to recover economic or non-economic damages caused by any person's actual ingestion of Actos.

The district court dismissed with prejudice Plaintiffs' RICO claims under Federal Rule of Civil Procedure 12(b)(6) in a single paragraph, holding that Plaintiffs failed adequately to allege facts sufficient to establish that Defendants' acts and omissions were the proximate cause of their claimed damages. This appeal followed.[4]

II. Analysis

A. Standard of Review

We review *de novo* the district court's grant of a Rule 12(b)(6) motion to dismiss. *Bain v. Cal. Teachers Ass'n*, 891 F.3d 1206, 1211 (9th Cir. 2018). We take all of Plaintiffs' factual allegations as true, and we may affirm the dismissal "only if it appears beyond doubt that [Plaintiffs] can prove no set of facts in support of [their] claim[s] which would entitle [them] to relief." *Id.* (internal quotation marks omitted).

---

[3] Plaintiffs originally alleged a second damages theory—that they overpaid for Actos prescriptions because Defendants inflated the price of Actos under the guise that Actos did not increase a person's risk of developing bladder cancer—called the "excess price theory." But Plaintiffs have abandoned their excess price theory for damages on appeal.

[4] Plaintiffs also brought claims under state consumer protection laws of California, Florida, Massachusetts, Minnesota, Missouri, and New Jersey. In a separate order, the district court dismissed all of Plaintiffs' state law claims. With the exception of their Massachusetts claim, Plaintiffs also appeal the dismissal of their state law claims. We

B. Plaintiffs' RICO Claims

The crux of Plaintiffs' complaint rests on their civil RICO claims. Although the RICO statute was originally enacted to combat organized crime, "it has become a tool for everyday fraud cases brought against respected and legitimate enterprises." *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 499 (1985) (internal quotation marks omitted). Broadly speaking, there are two parts to a civil RICO claim. The civil RICO violation is defined under 18 U.S.C. § 1962,[5] while "RICO standing" is defined under 18 U.S.C. § 1964(c). The district court dismissed Plaintiffs' RICO claims only for lack of standing, and thus we address only that portion of Plaintiffs' RICO claims.

To allege civil RICO standing under 18 U.S.C. § 1964(c), a "plaintiff must show: (1) that his alleged harm qualifies as injury to his business or property; and (2) that his harm was 'by reason of' the RICO violation." *Canyon County v. Syngenta Seeds, Inc.*, 519 F.3d 969, 972 (9th Cir. 2008). Defendants do not dispute that Plaintiffs have alleged an injury to their business or property. Rather, as the district court held, Defendants argue that Plaintiffs have failed to allege that their harm was "by reason of" the alleged RICO violation because they have failed to allege the claimed RICO violation was the proximate cause of their claimed losses.

---

[5] To recover for a civil RICO violation, "a plaintiff must prove that the defendant engaged in (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." *Chaset v. Fleer/Skybox Int'l, LP*, 300 F.3d 1083, 1086 (9th Cir. 2002) (citing 18 U.S.C. § 1962).

1. Supreme Court Precedent

The Supreme Court has interpreted the phrase "by reason of" in 18 U.S.C. § 1964(c) to require, as elements for a civil RICO recovery, both proximate and but-for causation.[6] *Holmes v. Sec. Inv'r Prot. Corp.*, 503 U.S. 258, 268 (1992). The requirement of proximate cause seeks to "limit a person's responsibility for the consequences of that person's own acts." *Id.* Put another way, "the proximate-cause requirement generally bars suits for alleged harm that is 'too remote' from the defendant's unlawful conduct." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 133 (2014). Thus, it "demand[s] . . . some direct relation between the injury asserted and the injurious conduct alleged." *Holmes*, 503 U.S. at 268.

This "direct relation" requirement is based upon three practical factors, stated in *Holmes*:

> First, the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent, factors. Second, quite apart from problems of proving factual causation, recognizing claims of the indirectly injured would force courts to adopt complicated rules apportioning damages among plaintiffs removed at different levels of injury from the violative acts, to obviate the risk of multiple recoveries. And, finally, the need to grapple with these problems is simply unjustified by the general

---

[6] Defendants do not argue in this appeal that Plaintiffs' allegations fail to allege but-for causation.

> interest in deterring injurious conduct, since directly injured victims can generally be counted on to vindicate the law as private attorneys general, without any of the problems attendant upon suits by plaintiffs injured more remotely.

Id. at 269-70 (internal citations omitted). The Supreme Court has applied the *Holmes* factors, along with its direct relation requirement, in each of its decisions addressing proximate cause for civil RICO claims.

In *Anza v. Ideal Steel Supply Corp.*, the plaintiff—a steel mill product retailer in New York City—alleged that one of its retail competitors caused it economic harm by failing to charge customers applicable New York state sales taxes, thereby defrauding the New York state tax authority. 547 U.S. 451, 457-58 (2006). This conduct, the plaintiff alleged, allowed the defendant to offer lower prices and attract more customers, which in turn caused the plaintiff to lose customers and profit. *Id.* The district court dismissed the plaintiff's complaint under Rule 12(b)(6) for failure to plead proximate cause, but the Second Circuit vacated the district court's judgment, holding that the plaintiff had adequately pleaded that the defendant proximately caused its damages. *Id.* at 455. The Supreme Court then reversed the Second Circuit's judgment and held that the plaintiff failed to satisfy the requirement to allege proximate cause under RICO because the "direct victim of this conduct was the State of New York, not [the plaintiff]." *Id.* at 458. Indeed, "[i]t was the State that was being defrauded and the State that lost tax revenue as a result." *Id.*

Although the plaintiff alleged that it suffered its own harms by losing customers and profits through the defendant's failure to tax its customers, the plaintiff's asserted harms were "entirely distinct from the alleged RICO violation (defrauding the state)," and thus the plaintiff's allegations failed the Supreme Court's direct relation requirement for the element of proximate cause. *Id.*

Likewise, in *Hemi Group, LLC v. City of New York*, the Supreme Court reversed the Second Circuit's holding that the plaintiffs had sufficiently alleged damages proximately caused by the defendants' actions under RICO to survive dismissal under Rule 12(b)(6). 559 U.S. 1, 4-5 (2010). There, the City of New York (the "City"), which imposed a $1.50-per-pack tax on each pack of cigarettes possessed within New York City for sale or use, sued a New Mexico retailer that sold cigarettes online to residents in New York City. *Id.* at 4-6. The City alleged that the New Mexico retailer failed to comply with a federal law requiring out-of-state vendors to submit customer information to the states into which it ships cigarettes. *Id.* at 4. That failure, the City argued, not only made it more difficult for the City to track down people who possessed cigarettes in New York City purchased elsewhere, but also constituted mail and wire fraud under RICO, which caused the City to lose millions of dollars in uncollected per-pack cigarette taxes. *Id.*

The Supreme Court disagreed. It held that the New Mexico retailer's failure to submit customer information to the State of New York was too attenuated from the City's loss of cigarette possession tax proceeds to satisfy the proximate cause allegation

requirement. *See id.* at 11. The Supreme Court explained that the conduct constituting the alleged fraud was the New Mexico retailer's failure to submit customer information to the State of New York, but "the conduct directly responsible for the City's harm was the customers' failure to pay their taxes." *Id.* Thus, "the conduct directly causing the harm was distinct from the conduct giving rise to the fraud," and therefore the City failed to satisfy the Supreme Court's direct relation requirement. *Id.*

In contrast, in *Bridge v. Phoenix Bond & Indemnity Co.*, the Supreme Court affirmed the Seventh Circuit's reversal of the district court's order dismissing the plaintiffs' complaint for failure sufficiently to allege the proximate cause element under RICO. 553 U.S. 639, 645, 661 (2008). The plaintiffs were bidders at a county tax lien auction. *Id.* at 643. To ensure fair distribution of tax liens during the auctions, the county enacted a "Single, Simultaneous Bidder Rule," requiring each "tax [lien] buying entity" to bid in its own name and not to use agents or employees to submit simultaneous bids on its behalf. *Id.* The plaintiffs alleged that the defendants violated that rule by using agents to submit simultaneous bids on the defendants' behalf and directing those agents to file false attestations that they had complied with the county's rules. *Id.* at 643-44. The plaintiffs alleged that this deceptive practice resulted in the defendants receiving a disproportionately higher share of tax liens at the county auction. *Id.* The plaintiffs further alleged that as a result of this deceptive practice, they were deprived of their ability to obtain their fair share of tax liens at the county auction. *Id.* at 644.

The defendants countered that the plaintiffs' alleged harm was too speculative to satisfy RICO's proximate cause requirement because the defendants misrepresented information to the *county*, not the *plaintiffs*. *Id.* at 648. But a unanimous Supreme Court rejected this argument, noting that proximate cause is "a flexible concept that does not lend itself to a black-letter rule that will dictate the result in every case." *Id.* at 654 (internal quotations omitted). Applying its direct relation requirement, the Supreme Court held that the plaintiffs' "alleged injury—the loss of valuable liens—is the direct result of [the defendants'] fraud. It was a foreseeable and natural consequence of [the defendants'] scheme to obtain more liens for themselves that other bidders would obtain fewer liens." *Id.* at 658. And unlike in *Anza* and *Hemi Group*, where other parties suffered more direct injuries than the plaintiffs, in *Bridge*, the county—which sold the tax liens at prices not dependent on who was the buyer—was not injured. *Id.* Rather, the plaintiffs were the immediate victims of the defendants' fraud and were best situated to sue the defendants. *Id.* Thus, the Supreme Court held that the plaintiffs had sufficiently alleged proximate cause under RICO. *Id.* at 661.

Under the Supreme Court's *Bridge* precedent alone, we think Plaintiffs' allegations satisfy the Supreme Court's direct relation requirement. Here, the alleged violation is that Defendants actively concealed Actos's risk of causing bladder cancer to sell more Actos to unsuspecting persons, thereby increasing Actos's revenue. And Plaintiffs' alleged injury is that they purchased Actos prescriptions for which they would not have paid had they been warned about Actos's risk of bladder cancer. Because Plaintiffs

were immediate victims of Defendants' alleged fraudulent scheme to conceal Actos's risk of bladder cancer, the alleged RICO violation (conspiracy to commit mail and wire fraud violative of 18 U.S.C. §§ 1341, 1343) has a direct relation to Plaintiffs' alleged harm.

The *Holmes* factors also weigh in favor of permitting Plaintiffs' RICO claims to proceed. The first *Holmes* factor tasks us with determining whether it would be too difficult to ascertain what damages are attributable to Defendants' alleged RICO violation, as opposed to factors other than, and independent of, Defendants' alleged misrepresentations. 503 U.S. at 269. While "it is often easier to ascertain the damages that flow from actual, affirmative conduct, than to speculate what damages arose from a party's failure to act," *Oregon Laborers-Employers Health & Welfare Trust Fund v. Philip Morris Inc.*, 185 F.3d 957, 965 (9th Cir. 1999) (internal quotation marks omitted), we are not persuaded that it is so difficult here that Plaintiffs should be denied the opportunity to prove their damages.[7] We leave it to the district court on

[7] We note that Defendants' argument that had Plaintiffs not taken Actos, they would have paid for an alternative drug to treat their type 2 diabetes, has not fallen on deaf ears. It seems quite logical that Plaintiffs would have paid for a different drug to treat patients' diabetes had they known that Actos increases a person's risk of developing bladder cancer. But at this stage in the proceedings, we take Plaintiffs' allegations that they would not have bought or paid for Actos as true. *Bain*, 891 F.3d at 1211. Plaintiffs do not allege that they would have paid for an alternative diabetes drug had they known Actos carries an increased risk of causing bladder cancer. Further, if what Defendants argue proves true, Plaintiffs may still be entitled to damages if the alternative drugs they would have paid for cost

remand to assess Plaintiffs' damages, if the litigation proceeds to that phase.

Second, we consider the risk of multiple recoveries by plaintiffs at different levels of injury from the defendants' acts. *Holmes*, 503 U.S. at 269. Here, like in *Bridge*, and unlike in *Anza* and *Hemi Group*, there is no concern of "duplicative recoveries by plaintiffs removed at different levels of injury from the violation." *Bridge*, 553 U.S. at 658. It is each individual plaintiff who paid out money for Actos prescriptions who now seeks recovery of those payments. As we read Plaintiffs' complaint, the damages suffered by Patients and Painters Fund do not overlap, as it appears that Patients seek to recover only the dollars they paid for Actos out-of-pocket, for which they have not been reimbursed by a TPP.[8] Further, Plaintiffs' putative class expressly excludes individuals who are pursuing personal injury claims, so there is no risk that some plaintiffs will receive overlapping economic and personal injury damages.

Finally, under the third *Holmes* factor, we consider whether holding Defendants liable in this case justifies the general interest of deterring injurious conduct or whether there are more directly injured victims we can count on to hold Defendants

---

less than Actos. Plaintiffs have alleged there are at least three less expensive alternatives to Actos, and discovery may prove Plaintiffs were likely to have bought these alternatives. In any event, this is a damages question for another day.

[8] Of course, on remand, if discovery reveals that Patients' claimed damages overlap with damages claimed by Painters Fund or another TPP, Plaintiffs should not recover any overlapping damages.

liable. 503 U.S. at 269-70. Here, patients and TPPs who paid money for Actos are the most direct victims of those who suffered economic injury. Although people who ingested Actos and developed bladder cancer suffered an additional and greater harm than others who paid for Actos but did not develop bladder cancer, this does not change the fact that all patients and TPPs who paid for Actos on the premise that it did not cause an increased risk of bladder cancer were allegedly defrauded by Defendants and suffered the same direct economic injury: payments for a drug which would not have been purchased if suitably described. Additionally, others may have been affected by Defendants' alleged fraud. For instance, prescribing physicians who prescribed Actos for their patients may have watched their patients develop bladder cancer. But as far as we can tell from Plaintiffs' complaint, prescribing physicians did not suffer an economic injury. Thus, holding Defendants liable for Plaintiffs' alleged injuries advances the interest in deterring injurious conduct, without including others who did not suffer direct out-of-pocket losses.

2. Circuit Court Precedent

While our court has recognized the Supreme Court's direct relation requirement and *Holmes* factors for RICO proximate cause in several cases, *see, e.g.*, *Harmoni International Spice, Inc. v. Hume*, 914 F.3d 648 (9th Cir. 2019); *Canyon County*, 519 F.3d at 972; *Oregon Laborers*, 185 F.3d at 963-66,[9] we have

[9] *Oregon Laborers*, the case most closely related to the present action in this circuit to date, is distinguishable. There, six employee health and welfare benefit plans sued tobacco

companies and public relations companies under federal RICO and other antitrust and state laws. 185 F.3d at 961. The plaintiffs alleged that the defendants conspired to persuade the public that scientific studies linking smoking to health risks were not accurate and that the connection between smoking and disease was merely an "open controversy." *Id.* The plaintiffs alleged that this wrongful conduct "resulted in more smoking, less quitting, and smoking of more hazardous cigarettes" among their plan participants, which then resulted in more disease among their plan participants who smoked. *Id.* at 962. In turn, the plaintiffs alleged, they suffered higher expenditures to cover their plan participants' medical bills. *Id.*

The district court held that the plaintiffs failed to state a RICO claim for relief under Rule 12(b)(6), and we affirmed. *Id.* at 961. We held that the plaintiffs' alleged injury was "indirect" and too remote to satisfy RICO's proximate cause requirement. *Id.* at 963. We explained that "all of [the] plaintiffs' claims rely on alleged injury to smokers—without any injury to smokers, [the] plaintiffs would not have incurred the additional expenses in paying for the medical expenses of those smokers." *Id.* (second emphasis added). Instead of the plaintiffs, we reasoned, the smokers were the direct victims of the defendant's alleged wrongful conduct. *Id.* at 964. Thus, under the Supreme Court's direct relation requirement, we held that the alleged RICO violation was distinct from the plaintiffs' alleged injury. *See id.* at 963-64. Therefore, the plaintiffs failed to allege that their damages were proximately caused by the defendants' actions. *See id.* at 966.

Plaintiffs' alleged injury in this case is distinct from the plaintiffs' alleged injury in *Oregon Laborers*. There, the chain of causation from the defendant's alleged misrepresentation to the plaintiffs' alleged injury depended upon an independent link that required the smokers to develop illnesses that necessitated medical treatment, for which the plaintiffs then paid. But here, Plaintiffs' alleged injury is directly related to Defendants' alleged misrepresentations, as they allege that they paid money out-of-pocket for Actos, which they otherwise would not have paid had Defendants not fraudulently omitted Actos's risk of causing bladder cancer. Whether Plaintiffs developed bladder cancer is

never applied it to the situation at issue here—whether patients and TPPs suing pharmaceutical companies for concealing an allegedly known safety risk about a drug can satisfy RICO's proximate cause requirement.[10] But several of our sister circuits have

---

irrelevant to their claims. Thus, *Oregon Laborers* is distinguishable and does not control here.

[10] The Seventh Circuit once commented that the Ninth Circuit "deem[s] this [issue] so straightforward that [it] ha[s] issued nonprecedential decisions" about it. *Sidney Hillman Health Ctr. v. Abbott Labs.*, 873 F.3d 574, 578 (7th Cir. 2017). Not quite. Rather, in *In re Actimmune Marketing Litigation*, we summarily affirmed the district court's dismissal without prejudice of the plaintiffs' RICO claims where the district court held in part that the plaintiffs' complaint failed sufficiently to plead proximate cause for their civil RICO claim for lack of specificity under Federal Rule of Civil Procedure 8(a). 464 F. App'x 651 (9th Cir. 2011) (citing *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037, 1050-51 (N.D. Cal. 2009)). When the plaintiffs filed their amended complaint, they abandoned their RICO claims. *See In re Actimmune Mktg. Litig.*, No. C 08-02376 MHP, 2009 WL 3740648, at *1 (N.D. Cal. Nov. 6, 2009). Our summary affirmance of the district court's decision to dismiss the plaintiffs' RICO claims without prejudice can hardly be considered a decision on the merits of the issue that we deemed "so straightforward" as to issue a non-binding decision.

In *United Food & Commercial Workers Central Pennsylvania & Regional Health & Welfare Fund v. Amgen, Inc.*, the plaintiffs sued Amgen, Inc. for concealing adverse test results about a drug's off-label uses. 400 F. App'x 255, 257 (9th Cir. 2010). We held that the plaintiffs' complaint failed to identify false statements or material omissions that Amgen made about the drug's safety. *Id.* Further, we held that the plaintiffs failed to plead a cognizable theory of proximate cause for their civil RICO claim because the complaint "proffered an attenuated causal chain that involved at least four independent links"—(1) the United States Pharmacopeia-Drug Information ("USP-DI")'s listing of the drug to be used for a certain off-label use;

addressed this question in similar factual scenarios and have reached different results, creating an apparent inter-circuit split. We look to their reasoning for guidance.

a. Seventh Circuit

In *Sidney Hillman Health Center v. Abbott Laboratories*, two TPPs who had paid to cover their patients' off-label[11] uses of a prescription drug named Depakote sued the drug manufacturer under RICO for concealing its role in promoting Depakote's off-label uses to intermediaries, such as prescribing physicians. 873 F.3d 574, 575 (7th Cir. 2017). In relevant part, the district court dismissed the TPPs' complaint for failure to allege that their damages were proximately caused by the drug manufacturer's concealed off-label promotion, and the Seventh Circuit affirmed. *Id.* at 575, 578.

The Seventh Circuit first noted that, in some cases, an injury to one person caused by wrongs against another can satisfy RICO's proximate cause

---

(2) Medicare's decision to cover the drug for that off-label use; (3) third-party payors' decision to cover the drug for the off-label use; and (4) doctors' decisions to prescribe the drug for the off-label use. *Id.* But we never independently addressed whether patients and TPPs can meet RICO's proximate cause requirement under the Supreme Court's direct relation requirement and *Holmes* factors to hold pharmaceutical companies liable for mail and wire fraud. Further, our present case does not require as many causal links. And of course, because unpublished dispositions from our circuit are not precedential, *see* Ninth Circuit Rule 36-3(a), we are free to decide this issue in the first instance.

[11] "Off-label" refers to using a drug to treat conditions other than those it was originally developed to treat.

requirement, as the Supreme Court held in *Bridge*, 553 U.S. at 661. 873 F.3d at 576. However, the Seventh Circuit held that the TPPs in *Sidney Hillman* were too far removed from the alleged RICO violation to satisfy the proximate cause requirement. *Id.* The Seventh Circuit opined that while TPPs "part with money . . . it is not at all clear that they are the initially injured parties, let alone the sole injured parties." *Id.* The Seventh Circuit explained that patients may be the most directly injured parties, as they incurred financial loss (if they paid a copayment to receive Depakote) and personal injury damages if they suffered harmful effects from using Depakote for an unsafe off-label use. *Id.* Moreover, the Seventh Circuit noted, the "patients' health and financial costs come first in line temporally; that pharmacies then send bills to [TPPs], which cover the remainder of the expense, does not make those [TPPs] the initial losers" from the drug manufacturer's unlawful promotion scheme. *Id.* The Seventh Circuit opined that prescribing physicians may also suffer loss, though indirectly, because "[i]f a physician prescribes an ineffective medicine and so does not provide [patients] help, patients may turn elsewhere." *Id.*

The Seventh Circuit next explained that physicians make independent decisions when prescribing patients medicine, and it would be difficult to disentangle which physicians' decisions, if any, were influenced by the drug manufacturer's unlawful promotions. *Id.* at 577-78. That, and other factors, such as the fact that some patients may have benefited from using Depakote for an off-label use, convinced the Seventh Circuit that it would be too difficult to calculate the plaintiffs' alleged damages. *Id.* Thus, the

Seventh Circuit held that the TPPs—"several levels removed in the causal sequence" from the drug manufacturer's actions—could not satisfy RICO's proximate cause requirement. *Id.* at 576-78.

b. Second Circuit

Similarly, in *UFCW Local 1776 v. Eli Lilly & Co.*, TPPs and individual patients brought a putative class action for civil RICO fraud against the manufacturer of the drug Zyprexa, alleging that the manufacturer misrepresented Zyprexa's side effects and effectiveness to physicians and promoted Zyprexa for off-label uses when there was no evidence that Zyprexa was effective for off-label uses. 620 F.3d 121, 123, 129 (2d Cir. 2010). The plaintiffs alleged two damages theories: (1) the "excess price theory"—that they overpaid for Zyprexa prescriptions because the manufacturer relied on its misrepresentations to charge higher prices; and (2) the "quantity effect theory"—that they paid for Zyprexa prescriptions "that would not have been issued but for the alleged misrepresentations." *Id.* The district court certified a class of TPPs based upon their excess price theory for damages, but the Second Circuit reversed. *Id.* at 123, 137.

As to the proximate cause requirement under RICO, the Second Circuit held that the plaintiffs' injuries under both of their damages theories were too attenuated, as they "rest[] on the independent actions of third and even fourth parties." *Id.* at 134 (quoting *Hemi Group*, 559 U.S. at 15). The Second Circuit was not persuaded by the plaintiffs' argument that "the ultimate source for the information on which doctors based their prescribing decisions was [the

manufacturer] and its consistent, pervasive marketing plan," because the manufacturer was "not . . . the *only* source of information on which doctors based prescribing decisions." *Id.* at 135 (emphasis in original). Rather, "[a]n individual patient's diagnosis, past and current medications being taken by the patient, the physician's own experience with prescribing Zyprexa, and the physician's knowledge regarding the side effects of Zyprexa are all considerations that would have been taken into account in addition to the alleged misrepresentations distributed by [the manufacturer]." *Id.* Accordingly, the Second Circuit held that the plaintiffs failed to allege that their damages were proximately caused by the drug manufacturer's wrongful conduct and reversed the district court's certification order.[12] *Id.* at 134, 136; *see also Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 90-91 (2d Cir. 2015) (holding that the plaintiff's RICO claims were foreclosed by *UFCW Local 1776*, 620 F.3d at 121).

c. First Circuit

To the contrary, in *In re Neurontin Marketing & Sales Practices Litigation*, a jury awarded Kaiser Foundation Health Plan ("Kaiser"), a TPP, damages

---

[12] The Second Circuit remanded, however, for the district court to consider individual claims based upon the plaintiffs' quantity effect damages theory. *UFCW Local 1776*, 620 F.3d at 136. The Second Circuit noted that "while that theory cannot support class certification, it is not clear that the theory is not viable with respect to individual claims by some TPPs or other [individual] purchasers." *Id.*

for the injury it suffered in paying for off-label Neurontin prescriptions that were induced by Pfizer's (the drug manufacturer) fraudulent scheme to misrepresent Neurontin's effectiveness for off-label conditions. 712 F.3d 21, 25-26 (1st Cir. 2013). The district court had found that Kaiser relied on Pfizer's fraudulent marketing campaign in deciding to include Neurontin in its formulary—a list of medications its treating physicians were authorized to prescribe. *Id.* at 28-29. The district court subsequently denied Pfizer's motion for a new trial, and Pfizer appealed. *Id.* at 27.

Pfizer argued that Kaiser could not satisfy RICO's proximate cause requirement as a matter of law. *Id.* at 34. But the First Circuit disagreed, holding that "Kaiser has met both the direct relationship and functional tests articulated in Holmes and its progeny." *Id.* at 38. Unlike the Second and Seventh Circuits, the First Circuit rejected the argument that there were "too many steps in the causal chain between [Pfizer's] misrepresentations and Kaiser's alleged injury" to meet the "direct relation" requirement. *Id.* Rather, the First Circuit held that "the causal chain in this case is anything but attenuated," because Pfizer "has always known that, because of the structure of the American health care system, physicians would not be the ones paying for the drugs they prescribed." *Id.* at 38-39. Pfizer's fraudulent marketing scheme, which was meant to increase its sales and profits, "only became successful once Pfizer received payments for the additional Neurontin prescriptions it induced." *Id.* at 39. Those payments came from TPPs, including Kaiser. *Id.*

The First Circuit also rejected Pfizer's argument that "because doctors exercise independent medical judgment in making decisions about prescriptions, the actions of these doctors are independent intervening causes" that cut off the chain of causation. *Id.* The First Circuit explained that "Pfizer's scheme relied on the expectation that physicians would base their prescribing decisions in part on Pfizer's fraudulent marketing." *Id.* "The fact that some physicians may have considered factors other than Pfizer's detailing materials in making their prescribing decisions does not add such attenuation to the causal chain as to eliminate proximate cause"; rather, "[t]his is a damages question" about the "total number of prescriptions that were attributable to Pfizer's actions." *Id.* Finally, the First Circuit noted that "[h]olding Pfizer liable will have an effect in deterring wrongful conduct," and thus it held that Kaiser had satisfied the proximate cause requirement under RICO. *Id.* at 39-40.

d. Third Circuit

Similarly, in *In re Avandia Marketing, Sales Practices & Product Liability Litigation*, the Third Circuit held that the TPP plaintiffs sufficiently alleged proximate cause for their civil RICO claims. 804 F.3d 633, 634 (3d Cir. 2015). There, TPPs filed a putative class action against the defendant alleging under RICO that the defendant misrepresented significant heart-related safety risks associated with the drug Avandia. *Id.* at 634-36. The plaintiffs alleged that they included Avandia in their formularies and covered it at favorable rates for their members in reliance on the defendant's misrepresentations about Avandia's

safety. *Id.* at 636. The plaintiffs also alleged that physicians relied on the defendant's misrepresentations in deciding to prescribe Avandia and that they would have prescribed it to fewer patients if the defendant had not concealed its safety risks. *Id.* The district court held that the plaintiffs adequately alleged that the defendant proximately caused their damages but certified its decision for interlocutory appeal. *Id.* at 637.

The Third Circuit affirmed. Applying the Supreme Court's direct relation requirement, the Third Circuit held that "[t]he conduct that allegedly caused [the] plaintiffs' injuries is the same conduct forming the basis of the RICO scheme alleged in the complaint—the misrepresentation of the heart-related risks of taking Avandia that caused TPPs . . . to place Avandia in the formulary." *Id.* at 644. Next, looking to the *Holmes* factors, the Third Circuit noted that it would not be too difficult to distinguish between the damages attributable to the defendant's alleged violation from other independent factors, and that at the pleadings stage, the question of damages was "a question for another day." *Id.* Further, the Third Circuit observed that the plaintiffs were best situated to sue, as the plaintiffs' alleged injury "is an economic injury independent of any physical injury suffered by Avandia users," and "prescribing physicians did not suffer RICO injury from [the defendant's] marketing of Avandia." *Id.*

The Third Circuit, like the First Circuit, rejected the defendant's argument that "the presence of intermediaries, doctors and patients, destroys proximate cause because they were the ones who

ultimately decided whether to rely on [the defendant's] misrepresentations." *Id.* at 645. The Third Circuit explained that "drug manufacturers are well aware that TPPs cover the cost of their drugs" and the defendant's "fraudulent scheme could have been successful only if [the] plaintiffs paid for Avandia, [which] is the very injury that [the] plaintiffs seek recovery for." *Id.* Thus, the plaintiffs' alleged injury had a direct relation to the alleged RICO violation. *Id.* Therefore, the Third Circuit affirmed the district court's holding that the plaintiffs adequately alleged RICO proximate cause at the pleadings stage. *Id.* at 645-46.

e. Circuit Court Precedent Analysis

Although each of these four circuit court opinions arises under similar factual scenarios, factual and procedural distinctions exist between them. For example, the Third and Seventh Circuits' opinions confronted the issue whether the plaintiffs could satisfy the proximate cause requirement under RICO at the pleadings stage, whereas the Second Circuit considered the issue at the class certification stage, and the Third Circuit reviewed the issue post-trial. Further, while the Second, Third, and Seventh Circuit cases involved putative class actions, the First Circuit's opinion involved a single TPP. But these minor factual and procedural differences do not help us resolve the central dispute between the Second and Seventh Circuits' reasoning and the First and Third Circuits' reasoning.

Indeed, it seems the central dispute between the Second and Seventh Circuits and the First and Third

Circuits is whether the decisions of prescribing physicians and pharmacy benefit managers constitute intervening causes that sever the chain of proximate cause between the drug manufacturer and TPP.[13] We think the First and Third Circuits have it right because their reasoning is more consistent with the Supreme Court's direct relation requirement.

In this case, although prescribing physicians serve as *intermediaries* between Defendants' fraudulent omission of Actos's risk of causing bladder cancer and Plaintiffs' payments for Actos, prescribing physicians do not constitute an *intervening cause* to cut off the chain of proximate cause. An intervening cause is "a later cause of independent origin that was not foreseeable." *Mendez v. County of Los Angeles*, 897 F.3d 1067, 1081 (9th Cir. 2018) (quoting *Exxon Co. v. Sofec*, 517 U.S. 830, 837 (1996)). Here, since Actos was a *prescription* drug, it was *required* to be prescribed by physicians. Hence, it was perfectly foreseeable that physicians who *prescribed* Actos would play a

[13] We note that all four of our sister circuits' opinions may support the claims by individual patients who are plaintiffs in this case, not just the First and Third Circuits' opinions. In *Sidney Hillman*, in holding that *TPPs* are too far removed from the drug manufacturer's alleged wrongful conduct to satisfy the RICO proximate cause requirement, the Seventh Circuit implied that *individual patients* may be able to satisfy the proximate cause requirement, as they are the most directly injured party whose "health and financial costs come first in line temporally." 873 F.3d at 576. And in *UFCW Local 1776*, although the Second Circuit reversed the district court's class certification order because the plaintiffs could not satisfy RICO's proximate cause requirement as a class, it remanded to the district court to consider in the first instance individual plaintiffs' claims based upon the quantity effect damages theory. 620 F.3d at 136.

causative role in Defendants' alleged fraudulent scheme to increase Actos's revenues. Further, "because of the structure of the American health care system," Defendants have always known that "physicians would not be the ones paying for the drugs they prescribed." *Neurontin*, 712 F.3d at 38-39. Rather, they are well aware that TPPs and individual patients pay for the drugs. *See Avandia*, 804 F.3d at 645. Defendants' alleged fraudulent marketing scheme, which was intended to increase Actos's sales, "only became successful once [they] received payments for the additional [Actos] prescriptions [they] induced"—the very injury for which Plaintiffs seek recovery. *Neurontin*, 712 F.3d at 39. This is consistent with the Supreme Court's requirement that the proximate cause inquiry focus on the direct relation between the alleged violation and alleged injury. *Hemi Group*, 559 U.S. at 12.

If we were to hold the opposite—that prescribing physicians' and pharmacy benefit managers' decisions constitute an intervening cause to sever the chain of proximate cause—as the Second and Seventh Circuits have held, drug manufacturers would be insulated from liability for their fraudulent marketing schemes, as they could continuously hide behind prescribing physicians and pharmacy benefit managers. That is not the purpose the requirement of proximate cause is intended to serve. Proximate cause exists to "limit a person's responsibility for the consequences of that person's own acts." *Holmes*, 503 U.S. at 268. Here, Plaintiffs seek to hold Defendants liable for the consequences of their own acts and omissions toward Plaintiffs: the money spent by Plaintiffs to purchase Actos.

There is also a difference between fraudulent promotion of "off-label" uses for a prescription drug as in *Sidney Hillman*, 873 F.3d at 575 and *UFCW Local 1776*, 620 F.3d at 127, and fraudulent failure to warn of a drug's known risk of causing bladder cancer, as in this case.

It was recognized in both *Sidney Hillman* and *UFCW Local 1776* that the drug manufacturer's fraudulent promotion of a prescription drug for off-label uses was not the *only* basis upon which the prescribing physicians relied in prescribing the drug. In *Sidney Hillman*, the Seventh Circuit noted that it would be too difficult to disentangle which physicians' prescribing decisions, if any, were influenced by the defendants' unlawful promotion of the prescription drug for off-label uses. 873 F.3d at 577-78. Similarly, in *UFCW Local 1776*, the Second Circuit noted that the drug manufacturer's unlawful promotion of the prescription drug for off-label uses was not the only source of information upon which the prescribing physicians based their decisions to prescribe the drug. 620 F.3d at 135.

Echoing the first factor of *Holmes*, the failure to warn of the bladder cancer risk in this case makes Plaintiffs' damages more clearly "attributable to [Defendants'] violation." 503 U.S. at 269. The damages claimed from off-label uses in *Sidney Hillman* and *UFCW Local 1776* are less directly attributable to the alleged false promotions. It is much more likely that Actos's risk of causing a disease as serious as bladder cancer would materially influence prescribing physicians' decisions whether to prescribe Actos. Plaintiffs' allegations confirm this theory, as they

allege that a survey conducted by Defendants in 2003 showed that 75% of surveyed physicians' interest in a different oral anti-diabetic drug declined "greatly" once they learned that it carried a risk of causing bladder cancer. Further, Plaintiffs allege that those survey results are confirmed by their allegation that sales of Actos decreased approximately 80% once the FDA issued its official warning that Actos may be linked to bladder cancer in patients who use it over a prolonged period of time. Taking those allegations as true, as we must, the question whether prescribing physicians would not have been influenced by Defendants' alleged fraudulent omission is less concerning in this case than it was to the Second and Seventh Circuits.

Moreover, the Seventh Circuit's distinction that TPPs' injuries are too far removed from the drug manufacturer's fraudulent scheme to satisfy the RICO proximate cause requirement because they are not "the sole injured parties" and because individual patients' "health and financial costs come first in line temporally" misses the mark. *Sidney Hillman*, 873 F.3d at 576. The Supreme Court has never made a distinction about temporal proximity of the plaintiffs to the damages caused to others when evaluating whether a plaintiff has adequately alleged that the defendant proximately caused the plaintiff's damages under RICO. Additionally, the fact that individual patients and TPPs both suffered economic injuries from a drug manufacturer's fraudulent scheme does not mean that one group of plaintiffs should be favored to recover over the other, so long as they both suffered the same economic injuries from the drug manufacturer's same misconduct. Finally, the

Seventh Circuit's comment that prescribing physicians may suffer indirect loss does not attenuate the chain of causation so far as to break it. *See id.* Even if prescribing physicians suffer an indirect loss such as reputational harm for prescribing an ineffective or unsafe drug, they are not out of pocket for the price of the drug and thus do not suffer the same economic loss as do individual patients and TPPs. For these reasons, we agree with the First and Third Circuits that Plaintiffs' damages are not too far removed from Defendants' alleged omissions and misrepresentations to satisfy RICO's proximate cause requirement.

3. Reliance

As a threshold matter, any argument that Patients have not alleged that they relied on Defendants' misrepresentations and omissions lacks merit. Each patient alleged that had he "known that Actos increased the risk of causing bladder cancer, he would never have purchased and ingested the drug." Additionally, Patients alleged that they "relied on Defendants' . . . misrepresentations of Actos'[s] safety in purchasing the drug." These statements are sufficient to allege that Patients relied on Defendants' misrepresentations.

Next, the Supreme Court has explained that if there is a direct relationship between a defendant's wrongful conduct and a plaintiff's alleged injury, a RICO plaintiff who did not directly rely on the defendant's omission or misrepresentation can still satisfy the requirement of proximate causation of damages. Recall that in *Bridge* the defendants' misrepresentations that they complied with the county's "Single, Simultaneous Bidder Rule" were

made to the tax lien selling *county*, not to the plaintiff tax lien *buyers*. 553 U.S. at 648. But the Supreme Court held that it was sufficient to establish proximate cause between the defendants' alleged wrongful conduct and the plaintiffs' alleged injury that the county had relied on the defendants' false attestations. *See id.* at 658-59. What mattered most in the RICO proximate causation inquiry was whether there was a direct relationship between the alleged RICO violation and the plaintiffs' alleged injury. *See id.* And there was. The plaintiffs' "alleged injury—the loss of valuable [tax] liens—[was] the direct result of . . . [the defendants'] scheme to obtain more liens for themselves." *Id.* at 658.

In so holding, the Supreme Court expressly rejected the defendants' argument that "[direct] reliance is an element of a civil RICO claim predicated on mail fraud." 553 U.S. at 646-49. The Supreme Court explained that the civil RICO statute has no reliance requirement on its face, and a person may be injured "by reason of" another person's fraud even if the injured party did not rely on any misrepresentation. *Id.* at 648-49. Nonetheless, the Supreme Court noted that it "may well be that a RICO plaintiff alleging injury by reason of a pattern of mail fraud must establish at least [indirect] reliance in order to prove causation." 553 U.S. at 658-59. This is because, logically, a plaintiff cannot even establish but-for causation if *no one* relied on the defendant's alleged misrepresentation. *Id.*

Despite this precedent, Defendants argue that Painters Fund failed to allege reliance on Defendants' omissions of Actos's bladder cancer risk, since

Painters Fund expressly alleged that, as a TPP, it "relies on [its] members and their prescribers to make informed decisions about which drugs will be prescribed and, in turn, submitted to Plaintiff Painters Fund for reimbursement." This argument is also meritless. Like in *Bridge*, where it was sufficient to satisfy RICO's proximate cause requirement that the county (a third party) had relied on the defendants' false attestations, here, it is sufficient to satisfy RICO's proximate cause requirement that Painters Fund alleged that prescribing physicians (also third parties, but not intervening causes) relied on Defendants' misrepresentations and omissions.

Finally, Defendants argue that even if Painter's Fund has alleged indirect reliance, its general allegations of indirect reliance—i.e., that prescribing physicians relied on Defendants' misrepresentations and omissions in prescribing Actos for their patients, which Painters Fund then reimbursed—are insufficient, because Painters Fund should have alleged with specificity exactly which prescribing physicians were misled by Defendants' alleged misrepresentations. Remembering that this case is before us at the pleadings stage and without the benefit of discovery, we recognize that it would be difficult for Painters Fund to determine with specificity exactly which doctors relied on Defendants' alleged misrepresentations. All that is required of Painters Fund at this stage is to allege that *someone* in the chain of causation relied on Defendants' alleged misrepresentations and omissions, which it has done here. Thus, we hold that Plaintiffs have adequately alleged the reliance necessary to satisfy RICO's proximate cause requirement.

III. Conclusion

While we express no opinion on Plaintiffs' chances of success in this litigation as it proceeds, we hold that Plaintiffs have satisfactorily alleged that Defendants proximately caused their claimed damages at the pleadings stage. We reverse the district court's judgment dismissing Plaintiffs' RICO claims under Rule 12(b)(6) for lack of RICO standing, and we remand to the district court for further proceedings consistent with this disposition.

Appendix E

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 18-55588

PAINTERS & ALLIED TRADES DISTRICT COUNCIL 82 HEALTH CARE FUND, third-party healthcare payor fund; et al.,

Plaintiffs-Appellants,

v.

TAKEDA PHARMACEUTICALS COMPANY LIMITED, a Japanese Corporation; et al.,

Defendants-Appellees.

Argued & Submitted: June 6, 2019
Filed: Dec. 3, 2019

Before: Carlos T. Bea, Jacqueline H. Nguyen, and Paul J. Watford*, Circuit Judges.

MEMORANDUM

---

* Judge Watford was drawn to replace Judge Rawlinson. Judge Watford has read the briefs, reviewed the record, and watched the recording of oral argument held on June 6, 2019.

Plaintiffs, individual patients and third-party payor Painters and Allied Trades District Council 82 Health Care Fund, appeal the district court's orders dismissing their civil claims under the Racketeer Influenced and Corrupt Organizations Act ("RICO") for failure to allege sufficiently proximate cause and their state-law consumer protection claims for related reasons.

1. We address Plaintiffs' civil RICO proximate cause arguments in a separate opinion filed simultaneously with this memorandum disposition, and we reverse the district court's holding that Plaintiffs failed sufficiently to allege Defendants' actions and omissions were the proximate cause of their damages under RICO.[1]

2. California Claims: Plaintiff Snyder alleges that Defendants—Takeda Pharmaceuticals Co.,

---

[1] We reject Defendants' argument that Plaintiffs lack Article III standing for failure to allege an injury in fact. We have held in the consumer fraud context that where plaintiffs contend that they bought a product "when they otherwise would not have done so, because [Defendants] made deceptive claims and failed to disclose [known risks] . . . they have suffered an 'injury in fact'" sufficient to support Article III standing. *Mazza v. Am. Honda Motor Co.*, 666 F.3d 581, 595 (9th Cir. 2012). Here, Plaintiffs alleged that they purchased Actos, which they would not have done absent Defendants' fraudulent scheme to conceal Actos's risk of bladder cancer. Thus, Plaintiffs have alleged an injury in fact sufficient to support Article III standing.

The district court did not address Defendants' other alternative arguments applicable to Plaintiffs' RICO claims or the separate arguments that Defendant Eli Lilly raises in its answering brief regarding Plaintiffs' RICO and state law claims. We decline to address them in the first instance on appeal; the district court may address those issues on remand.

Takeda Pharmaceuticals USA, and Eli Lilly & Co.—violated the California Consumer Legal Remedies Act, California's Unfair Competition Law, and California's False Advertising Law. *See* Cal. Civ. Code § 1750; Cal. Bus. & Prof. Code §§ 17200, 17500. Each of these claims requires Snyder to plead economic injury, causation, and reliance. *Veera v. Banana Republic, LLC*, 211 Cal. Rptr. 3d 769, 776 (Ct. App. 2016). The district court held that Snyder failed to meet the pleading standard under Federal Rule of Civil Procedure 8 for reliance. But the district court ignored Snyder's specific allegations in the complaint: that (1) she was prescribed a 15 mg daily dose of Actos, (2) that prior to taking her prescription, she "read and relied upon the Actos label," (3) that information about Actos's risk of causing bladder cancer "is information that a reasonable consumer and prescriber would consider important in making a purchasing and prescribing decision," and (4) that had she known that Actos increased the risk of developing bladder cancer, "she would never have purchased and ingested the drug." These allegations, if true, plausibly state a claim that Snyder relied on Defendants' misrepresentation, which caused her to purchase a drug that she otherwise would not have bought. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Therefore, we reverse the district court's holding that Snyder failed to allege reliance properly.

3. New Jersey Claim: Plaintiff Cardarelli alleges that Defendants violated the New Jersey Consumer Fraud Act ("NJCFA").[2] *See* N.J. Stat. Ann.

---

[2] We reject Defendants' argument that Plaintiffs waived their New Jersey, Florida, Missouri, and Minnesota claims for failure

§ 56:8-1. The NJCFA has a similar proximate cause requirement to that required for civil RICO claims. *See Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 2d 508, 530-31 (D.N.J. 2011); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-CV-5774 (SRC), 2009 WL 2043604, at *31 (D.N.J. July 10, 2009). Because we conclude in the simultaneously filed opinion that Plaintiffs have adequately alleged their damages were proximately caused for their civil RICO claims, we likewise hold that Cardarelli has adequately alleged proximate cause for his New Jersey claim. Therefore, we reverse the district court's dismissal of Cardarelli's New Jersey claim for failure to allege proximate cause.

4. Florida Claim: The district court dismissed Plaintiff Buckner's claim under the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA") for failure to plead damages.[3] *See* Fla. Stat. § 501.201. But an allegation that the plaintiff "would not have bought" a product "if he had known the product was not safe for human consumption . . . satisfies the

---

to raise them in district court. Plaintiffs raised their state law claims in their complaint and responded to Defendants' arguments about their state law claims in their opposition to Defendants' motion to dismiss.

[3] In dismissing Buckner's Florida claim, the district court cited a Florida case that held that damages based on "price inflation" are "too speculative." *See Prohias v. Pfizer, Inc.*, 485 F. Supp. 2d 1329, 1336 (S.D. Fla. 2007). But Plaintiffs have abandoned their excess price damages theory that Florida has rejected on appeal. Instead, Plaintiffs pursue their quantity effect damages theory, that they "pa[id] for more prescriptions for Actos than would have otherwise occurred absent the RICO violations." As explained above, Florida law supports Plaintiffs' second theory of damages.

damages element of a FDUTPA claim." *Jovine v. Abbott Labs., Inc.*, 795 F. Supp. 2d 1331, 1344 (S.D. Fla. 2011). Here, Buckner alleges that Defendants fraudulently concealed Actos's risk of causing bladder cancer, and that Buckner would not have purchased Actos if she had known about Actos's risk of causing bladder cancer. Accordingly, we reverse the district court's holding that Buckner failed to plead damages in her FDUTPA claim.[4]

5. Missouri Claim: Plaintiff Rose alleges that Defendants violated the Missouri Merchandising Practices Act ("MMPA"). *See* Mo. Rev. Stat. § 407.010. Under the MMPA, plaintiffs must plead an "ascertainable loss" that "was the result of an unfair practice." *Thompson v. Allergan USA, Inc.*, 993 F. Supp. 2d 1007, 1011-12 (E.D. Mo. 2014). Missouri courts measure an "ascertainable loss" under the "benefit-of-the-bargain" rule, which "awards a prevailing party the difference between the value of the product as represented and the actual value of the product as received." *Id.* at 1012; *see also Plubell v. Merck & Co.*, 289 S.W.3d 707, 715 (Mo. Ct. App. 2009). This is similar to Plaintiffs' excess price damages theory, which they expressly abandoned on appeal.

---

[4] Defendants also argue that Buckner's FDUTPA claim fails under Florida's "safe harbor" provision, which provides that the FDUTPA "does not apply to . . . [a]n act or practice . . . specifically permitted by federal or state law." Fla. Stat. § 501.212(1). But Plaintiffs allege that Defendants' actions violated federal civil RICO and drug labeling laws. Because we must assume Plaintiffs' allegations are true, *Bain v. California Teachers Association*, 891 F.3d 1206, 1211 (9th Cir. 2018), Defendants are not covered by Florida's "safe harbor" provision.

Thus, we affirm the district court's dismissal of Plaintiff Rose's MMPA claim.

6. Minnesota Claim: Plaintiffs argue that Takeda violated Minnesota Statutes §§ 325F.69(1), 325D.13, which address consumer fraud. Plaintiffs may assert violations of these statutes only if they seek a "public benefit." Minn. Stat. § 8.31(1); *Ill. Farmers Ins. Co. v. Guthman*, No. CV 17-270(RHK/SER), 2017 WL 3971867, at *3 (D. Minn. Sept. 7, 2017).

Plaintiffs do not seek a public benefit, as they ask only for damages (rather than injunctive relief), and they seek to remedy a past harm (rather than an ongoing harm). *Buetow v. A.L.S. Enters. Inc.*, 888 F. Supp. 2d 956, 961 (D. Minn. 2012); *Select Comfort Corp. v. Sleep Better Store, LLC*, 796 F. Supp. 2d 981, 986 (D. Minn. 2011). We affirm the district court's dismissal of Plaintiffs' Minnesota claim.

In sum, we **REVERSE** the district court's dismissal of Plaintiffs' RICO claims for lack of proximate cause. And we **REVERSE** the district court's dismissal of Plaintiffs' California, New Jersey, and Florida claims. But we **AFFIRM** the district court's dismissal of Plaintiffs' Missouri and Minnesota claims. We remand to the district court for further proceedings consistent with this disposition. Each party shall bear its own costs on appeal.

Appendix F

UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA

No. 17-cv-07223

PAINTERS & ALLIED TRADES DISTRICT COUNCIL 82 HEALTH CARE FUND, third-party healthcare payor fund; et al.,

Plaintiffs,

v.

TAKEDA PHARMACEUTICAL COMPANY LIMITED, a Japanese Corporation; et al.,

Defendants.

Filed: Apr. 3, 2018

IN CHAMBERS ORDER GRANTING MOTION TO DISMISS

I. Introduction

The Court previously dismissed Plaintiffs' RICO claims with prejudice. Dkt. 140. The Court simultaneously issued an order to show cause regarding whether it maintained jurisdiction over the remaining claims. *Id.* Having considered the parties' briefs on this issue, the Court is satisfied that it retains jurisdiction over this matter pursuant to CAFA, and DISMISSES Plaintiffs' state law claims.

Accordingly, the Court need not consider Plaintiffs' motion to sever.

The Court also declines to strike Defendants' supplementary briefing. Dkt. 141. However, the Court cautions Defendant against abusing supplementary briefing to expand it beyond the scope of what was intended.

II. Legal Standard

A motion to dismiss under Rule 12(b)(6) challenges the legal sufficiency of the claims stated in the complaint. *See* Fed. R. Civ. Proc. 12(b)(6). To survive a motion to dismiss, the plaintiffs complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Co1p. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. A complaint that offers mere "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." *Id.*; *see also Moss v. U.S. Secret Service*, 572 F.3d 962, 969 (9th Cir. 2009) (citing *Iqbal*, 556 U.S. at 678).

In reviewing a Rule 12(b)(6) motion, a court "must accept as true all factual allegations in the complaint and draw all reasonable inferences in favor of the nonmoving party." *Retail Prop. Trust v. United Bhd. Of Carpenters & Joiners of Am.*, 768 F.3d 938,945 (9th Cir. 2014). Thus, "[w]hile legal conclusions can provide the complaint's framework, they must be supported by factual allegations. When there are well-pleaded

factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Iqbal*, 556 U.S. at 679.

III. Discussion

In its previous order, the Court dismissed the RICO claims on proximate causation grounds. Plaintiffs additionally bring claims under the consumer protection laws of various states. As explained below, many of the same considerations applicable in the RICO context mean that Plaintiffs' state law claims fail as well. To briefly summarize, Plaintiffs' claims are entirely based on the theory that they paid more for Actos than they otherwise would have, had they known about the increased risk of bladder cancer. In other words, they allege that Defendants were able to inflate the price of Actos by concealing the cancer risk. All of Plaintiffs' state law claims fail because they have not alleged reliance (California), because this damages theory has been rejected by the relevant courts (Florida, New Jersey, Massachusetts, Missouri), or because the statutes at issue are meant to be enforced by the state, not private citizens (Minnesota).

1. California

Plaintiffs bring claims under the California Consumer Legal Remedies Act, the Unfair Competition Law, and False Advertising Law. All of these claims require Plaintiffs to plead economic injury, causation, and reliance. *Wilson v. Frito-Lay N. Am., Inc.*, 260 F. Supp. 3d 1202 (N.D. Cal. 2017) ("To prevail on their causes of action under the UCL, FAL, and the CLRA, Plaintiffs must demonstrate that they

actually relied on the challenged misrepresentations and suffered economic injury as a result of that reliance. To do so, they 'must show that the misrepresentation was an immediate cause of the injury-producing conduct.'").

With regard to reliance, Plaintiffs' complaint simply states "Plaintiff Snyder and the California Consumer Class reasonably relied upon Defendants' misrepresentations regarding Actos in deciding whether to purchase and use the drug." SAC ¶ 273. Such a conclusory allegation is insufficient. Plaintiff Snyder does not even specifically allege that she or her physician was actually exposed to Defendants' fraudulent promotion of Actos. As recognized by the *Actimmune* court (which dismissed RICO claims as well as California state law claims) without specific allegations of reliance on the part of Plaintiff or her doctor, the claim cannot survive. *In re Actimmune Mktg. Litig.*, No. C 08-02376 MHP, 2010 WL 3463491, at *10 (N.D. Cal. Sept. 1, 2010), *aff'd*, 464 F. App'x 651 (9th Cir. 2011). Accordingly, these claims are DISMISSED WITHOUT PREJUDICE.

2. Missouri

This Count is brought pursuant to the Missouri Merchandising Practices Act (MMPA), §§ 407.010, *et seq*. This act states that the "use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce . . . in or from the state of Missouri, is declared to be an unlawful practice . . . . Any act, use

or employment declared unlawful by this subsection violates this subsection whether committed before, during or after the sale, advertisement or solicitation."

The MMPA requires Plaintiffs to plead an "ascertainable loss" that "was the result of an unfair practice." *Thompson v. Allergan USA, Inc.*, 993 F. Supp. 2d 1007, 1011 (E.D. Mo. 2014). In determining what qualifies as an "ascertainable loss" courts apply the "benefit of the bargain" rule. *Id.* If a plaintiff fail[s] to allege that she did not receive the benefit of the medication for which she bargained" or where the drug performed as purported there is no ascertainable loss. *Id.*; *see also Carter v. Alcon Labs., Inc.*, No. 4:13CV00977 AGF, 2014 WL 989002, at *4 (E.D. Mo. Mar. 13, 2014). Because Plaintiffs here received the benefits of Actos and did not suffer from bladder cancer, they fail to state a claim under the MMPA.

Additionally, claims that drug prices were inflated due to misrepresentations by the drug manufacturers are not viable under the MMPA. Drug pricing is complex and under Missouri law "courts are not regulators of the fair market price of products." *Thompson*, 993 F. Supp. 2d at 1013. The Missouri claims are therefore DISMISSED WITH PREJUDICE.

3. New Jersey

Plaintiffs bring claims under the New Jersey Consumer Fraud Act ("NJCFA"), N.J.S.A. 56:8-1 et eq. NJ.S.A. 56:8-2 provides:

> The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing,

> concealment, suppression, or omission of any material fact . . . Whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice.

This statute has a proximate cause requirement that is similar to that required by RICO. *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-CV-5774(SRC), 2009 WL 2043604, at *31 (D.N.J. July 10, 2009). Thus, Plaintiffs' New Jersey state law claims fail for the same reasons their RICO claims failed. New Jersey courts have repeatedly rejected similar claims in the

pharmaceutical context under this law. *See, e.g.*, *Int'l Union of Operating Eng'rs Local No. 68 Welfare Fund v. Merck & Co.*, 929 A.2d 1076, 1088 (NJ. 2007) ("[T]o the extent that plaintiff seeks to prove only that the price charged for Vioxx was higher than it should have been as a result of defendant's fraudulent marketing campaign . . . the theory must fail."); *New Jersey Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174, 178 (NJ. Super. Ct. App. Div. 2003) (same). This claim is therefore DISMISSED WITH PREJUDICE.

4. Florida

Plaintiffs bring claims pursuant to the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.201, et seq. ("FDUTPA"). To adequately plead a claim under this act, "[a]ctual damages . . . must directly flow from the alleged deceptive act" and "causation must be direct, rather than remote or speculative." *Hennegan Co. v. Arriola*, 855 F. Supp. 2d 1354, 1361 (S.D. Fla. 2012).

As with the other claims, Plaintiffs allege that they paid more money for Actos than they otherwise would have because of the undisclosed risk of bladder cancer. However, Courts have squarely rejected this damages theory under Florida law. *Prohias v. Pfizer, Inc.*, 485 F. Supp. 2d 1329, 1336 (S.D. Fla. 2007) ("(T]hey allege 'price inflation' damages. But, in the context of a market for a pha1maceutical drug, such damages are too speculative to constitute an injury-in-fact under Article III.") Accordingly, these claims are DISMISSED WITH PRETIJDICE.

5. Minnesota

Plaintiffs bring claims under Minnesota Statutes, sections 325F.69, subd. 1 and 325D.13. Minnesota Statute § 325F.69, subd. 1 makes it unlawful for any person by use of "any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby[.]" Minnesota Statute § 325D.13 provides that, "[n]o person shall, in connection with the sale of merchandise, knowingly misrepresent, directly or indirectly, the true quality, ingredients or origin of such merchandise."

Generally, only the Attorney General has the authority to seek enforcement of these statutes, but a private plaintiff can enforce them as a "private attorney general." *Illinois Farmers Ins. Co. v. Guthman*, No. CV 17-270(RHK/SER), 2017 WL 3971867, at *3 (D. Minn. Sept. 7, 2017). In order to do so, however, plaintiffs must allege that enforcement of

the statute will result in a "public benefit." *Id.* Plaintiffs have not alleged anywhere in their complaint that the Minnesota claim will result in a public benefit. Indeed, they seek only damages, and a public benefit generally does not exist when plaintiffs seek only damages. "This is because individual damages, generally speaking, merely enrich (or reimburse) the plaintiff to the defendant's detriment; they do not advance the public interest." *Select Comfort Corp. v. Tempur Sealy Int'l, Inc.*, 11 F. Supp. 3d 933, 937-39 (D. Minn. 2014). These claims are DISMISSED WITHOUT PREJUDICE.

6. Massachusetts

Plaintiffs bring claims under Massachusetts's Consumer Protection Act, Mass. Gen. Laws ch. 93A, §§ 1, et seq. SAC ¶ 350. This Act generally forbids unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce. Unfair acts or practices include practices that are within at least the penumbra of some common-law, statutory, or other established concept of unfairness; immoral, unethical, oppressive, or unscrupulous acts; or acts that cause substantial injury. Deceptive acts or practices include those that would reasonably cause a person to act differently from the way he or she otherwise would have acted.

To adequately plead a claim under Ch. 93A, a Plaintiff must allege "economic injury in the traditional sense." *Rule v. Fort Dodge Animal Health, Inc.*, 607 F.3d 250, 255 (1st Cir. 2010) (discussing Massachusetts state law). However, Plaintiffs' damages theory does not qualify as "economic injury in the traditional sense." When the purchaser of a

drug alleges fraudulent non-disclosure of a risk, they suffer no economic injury when they use the drug and the undisclosed risk does not manifest itself. *Id.* at 253. This is true even if a Plaintiff alleges that he or she would have paid less for the drug if aware of the risk. *Id.* They can accordingly state no claim under Ch. 93A. Here it is undisputed that Plaintiffs did not contract bladder cancer as a result of using Actos. Plaintiffs who did suffer from cancer had their claims heard as part of the multi-district litigation. The instant Plaintiffs claim only that they overpaid for Actos. The claims under Ch. 93A are therefore DISMISSED WITH PREJDICE.

IV. Conclusion

Plaintiffs' state law claims are all DISMISSED. IT IS SO ORDERED.

Appendix G

RELEVANT CONSTITUTIONAL PROVISIONS AND FEDERAL RULE

U.S. Const. art. III, §§1-2

Section 1. The judicial Power of the United States, shall be vested in one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish. The Judges, both of the supreme and inferior Courts, shall hold their Offices during good Behaviour, and shall, at stated Times, receive for their Services, a Compensation, which shall not be diminished during their Continuance in Office.

Section 2. The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority;--to all Cases affecting Ambassadors, other public Ministers and Consuls;--to all Cases of admiralty and maritime Jurisdiction;--to Controversies to which the United States shall be a Party;--to Controversies between two or more States; --between a State and Citizens of another State;-- between Citizens of different States,--between Citizens of the same State claiming Lands under Grants of different States, and between a State, or the Citizens thereof, and foreign States, Citizens or Subjects.

Fed. R. of Civ. P. 23. Class Actions

(a) Prerequisites. One or more members of a class may sue or be sued as representative parties on behalf of all members only if:

(1) the class is so numerous that joinder of all members is impracticable;

(2) there are questions of law or fact common to the class;

(3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and

(4) the representative parties will fairly and adequately protect the interests of the class.

(b) Types of Class Actions. A class action may be maintained if Rule 23(a) is satisfied and if:

(1) prosecuting separate actions by or against individual class members would create a risk of:

(A) inconsistent or varying adjudications with respect to individual class members that would establish incompatible standards of conduct for the party opposing the class; or

(B) adjudications with respect to individual class members that, as a practical matter, would be dispositive of the interests of the other members not parties to the individual adjudications or would substantially impair or impede their ability to protect their interests;

(2) the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole; or

(3) the court finds 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. The matters pertinent to these findings include: !

(A) the class members' interests in individually controlling the prosecution or defense of separate actions;

(B) the extent and nature of any litigation concerning the controversy already begun by or against class members;

(C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and

(D) the likely difficulties in managing a class action.

(c) Certification Order; Notice to Class Members; Judgment; Issues Classes; Subclasses.

(1) ***Certification Order.***

(A) *Time to Issue*. At an early practicable time after a person sues or is sued as a class representative, the court must determine by order whether to certify the action as a class action.

(B) *Defining the Class; Appointing Class Counsel*. An order that certifies a class action must define the class and the class claims, issues, or defenses, and must appoint class counsel under Rule 23(g).

(C) *Altering or Amending the Order*. An order that grants or denies class certification may be altered or amended before final judgment.

(2) Notice.

(A) *For (b)(1) or (b)(2) Classes*. For any class certified under Rule 23(b)(1) or (b)(2), the court may direct appropriate notice to the class.

(B) *For (b)(3) Classes*. For any class certified under Rule 23(b)(3)--or upon ordering notice under Rule 23(e)(1) to a class proposed to be certified for purposes of settlement under Rule 23(b)(3)--the court must direct to class members the best notice that is practicable under the circumstances, including individual notice to all members who can be identified through reasonable effort. The notice may be by one or more of the following: United States mail, electronic means, or other appropriate means. The notice must clearly and concisely state in plain, easily understood language:

(i) the nature of the action;

(ii) the definition of the class certified;

(iii) the class claims, issues, or defenses;

(iv) that a class member may enter an appearance through an attorney if the member so desires;

(v) that the court will exclude from the class any member who requests exclusion;

(vi) the time and manner for requesting exclusion; and

(vii) the binding effect of a class judgment on members under Rule 23(c)(3).

(3) ***Judgment.*** Whether or not favorable to the class, the judgment in a class action must:

(A) for any class certified under Rule 23(b)(1) or (b)(2), include and describe those whom the court finds to be class members; and

(B) for any class certified under Rule 23(b)(3), include and specify or describe those to whom the Rule 23(c)(2) notice was directed, who have not requested exclusion, and whom the court finds to be class members.

(4) ***Particular Issues.*** When appropriate, an action may be brought or maintained as a class action with respect to particular issues.

(5) ***Subclasses.*** When appropriate, a class may be divided into subclasses that are each treated as a class under this rule.

(d) Conducting the Action.

(1) ***In General.*** In conducting an action under this rule, the court may issue orders that:

(A) determine the course of proceedings or prescribe measures to prevent undue repetition or complication in presenting evidence or argument;

(B) require--to protect class members and fairly conduct the action--giving appropriate notice to some or all class members of:

(i) any step in the action;

(ii) the proposed extent of the judgment; or

(iii) the members' opportunity to signify whether they consider the representation fair and adequate, to intervene and present claims or defenses, or to otherwise come into the action;

(C) impose conditions on the representative parties or on intervenors;

(D) require that the pleadings be amended to eliminate allegations about representation of absent persons and that the action proceed accordingly; or

(E) deal with similar procedural matters.

(2) Combining and Amending Orders. An order under Rule 23(d)(1) may be altered or amended from time to time and may be combined with an order under Rule 16.

(e) Settlement, Voluntary Dismissal, or Compromise. The claims, issues, or defenses of a certified class--or a class proposed to be certified for purposes of settlement--may be settled, voluntarily dismissed, or compromised only with the court's approval. The following procedures apply to a proposed settlement, voluntary dismissal, or compromise:

(1) ***Notice to the Class.***

(A) *Information That Parties Must Provide to the Court.* The parties must provide the court with information sufficient to enable it to

determine whether to give notice of the proposal to the class.

(B) *Grounds for a Decision to Give Notice.* The court must direct notice in a reasonable manner to all class members who would be bound by the proposal if giving notice is justified by the parties' showing that the court will likely be able to:

(i) approve the proposal under Rule 23(e)(2); and

(ii) certify the class for purposes of judgment on the proposal.

(2) ***Approval of the Proposal.*** If the proposal would bind class members, the court may approve it only after a hearing and only on finding that it is fair, reasonable, and adequate after considering whether:

(A) the class representatives and class counsel have adequately represented the class;

(B) the proposal was negotiated at arm's length;

(C) the relief provided for the class is adequate, taking into account:

(i) the costs, risks, and delay of trial and appeal;

(ii) the effectiveness of any proposed method of distributing relief to the class, including the method of processing class-member claims;

(iii) the terms of any proposed award of attorney's fees, including timing of payment; and

(iv) any agreement required to be identified under Rule 23(e)(3); and

(D) the proposal treats class members equitably relative to each other.

(3) ***Identifying Agreements.*** The parties seeking approval must file a statement identifying any agreement made in connection with the proposal.

(4) ***New Opportunity to be Excluded.*** If the class action was previously certified under Rule 23(b)(3), the court may refuse to approve a settlement unless it affords a new opportunity to request exclusion to individual class members who had an earlier opportunity to request exclusion but did not do so.

(5) ***Class-Member Objections.***

(A) *In General.* Any class member may object to the proposal if it requires court approval under this subdivision (e). The objection must state whether it applies only to the objector, to a specific subset of the class, or to the entire class, and also state with specificity the grounds for the objection.

(B) *Court Approval Required for Payment in Connection with an Objection.* Unless approved by the court after a hearing, no payment or other consideration may be provided in connection with:

(i) forgoing or withdrawing an objection, or

(ii) forgoing, dismissing, or abandoning an appeal from a judgment approving the proposal.

(C) *Procedure for Approval After an Appeal.* If approval under Rule 23(e)(5)(B) has not been obtained before an appeal is docketed in the court of appeals, the procedure of Rule 62.1 applies while the appeal remains pending.

(f) Appeals. A court of appeals may permit an appeal from an order granting or denying class-action certification under this rule, but not from an order under Rule 23(e)(1). A party must file a petition for permission to appeal with the circuit clerk within 14 days after the order is entered, or within 45 days after the order is entered if any party is the United States, a United States agency, or a United States officer or employee sued for an act or omission occurring in connection with duties performed on the United States' behalf. An appeal does not stay proceedings in the district court unless the district judge or the court of appeals so orders.

(g) Class Counsel.

(1) ***Appointing Class Counsel.*** Unless a statute provides otherwise, a court that certifies a class must appoint class counsel. In appointing class counsel, the court:

(A) must consider:

(i) the work counsel has done in identifying or investigating potential claims in the action;

(ii) counsel's experience in handling class actions, other complex litigation, and the types of claims asserted in the action;

(iii) counsel's knowledge of the applicable law; and

(iv) the resources that counsel will commit to representing the class;

(B) may consider any other matter pertinent to counsel's ability to fairly and adequately represent the interests of the class;

(C) may order potential class counsel to provide information on any subject pertinent to the appointment and to propose terms for attorney's fees and nontaxable costs;

(D) may include in the appointing order provisions about the award of attorney's fees or nontaxable costs under Rule 23(h); and

(E) may make further orders in connection with the appointment.

(2) ***Standard for Appointing Class Counsel.*** When one applicant seeks appointment as class counsel, the court may appoint that applicant only if the applicant is adequate under Rule 23(g)(1) and (4). If more than one adequate applicant seeks appointment, the court must appoint the applicant best able to represent the interests of the class.

(3) ***Interim Counsel.*** The court may designate interim counsel to act on behalf of a putative class before determining whether to certify the action as a class action.

(4) ***Duty of Class Counsel.*** Class counsel must fairly and adequately represent the interests of the class.

(h) Attorney's Fees and Nontaxable Costs. In a certified class action, the court may award reasonable attorney's fees and nontaxable costs that are authorized by law or by the parties' agreement. The following procedures apply:

(1) A claim for an award must be made by motion under Rule 54(d)(2), subject to the provisions of this subdivision (h), at a time the court sets. Notice of the motion must be served on all parties and, for motions by class counsel, directed to class members in a reasonable manner.

(2) A class member, or a party from whom payment is sought, may object to the motion.

(3) The court may hold a hearing and must find the facts and state its legal conclusions under Rule 52(a).

(4) The court may refer issues related to the amount of the award to a special master or a magistrate judge, as provided in Rule 54(d)(2)(D).