No. 19-____

IN THE

Supreme Court of the United States

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS USA, INC., AND ELI LILLY AND COMPANY,

Petitioners,

v.

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

Respondents.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

This petition involves a putative nationwide class action under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), in which respondents seek treble-damages refunds of all payments they made for Actos, a prescription drug marketed by petitioners. Respondents are Actos patients and a third-party payor who allege that petitioners failed to disclose that Actos increases the risk of bladder cancer for a small, defined subset of patients. But respondents make no claim that Actos was ineffective or that they (or any patients they reimbursed) suffered a personal injury. Rather, respondents' sole theory is that they would not have paid for Actos had petitioners fully disclosed the risk.

The questions presented, each of which is the subject of an entrenched, broadly acknowledged, several-circuit split, are:

1. Whether the chain of causation between a manufacturer's allegedly false or misleading statements or omissions and end payments for prescription drugs is too attenuated to satisfy RICO's proximate cause requirement, given that every prescription-drug payment depends on numerous intervening factors, including a doctor's independent decision to prescribe.

2. Whether everyone who pays for a product with an alleged latent risk or defect necessarily suffers injury sufficient to confer Article III standing, even where the product is fully consumed, provides the bargained-for benefits, and causes no ill effects.

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

Petitioners are Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals USA, Inc., and Eli Lilly and Company, defendants-appellees below.

Takeda Pharmaceutical Company Limited is a publicly held entity traded on the Tokyo Stock Exchange. It has no parent company and no publicly held entity owns 10% or more of its stock.

Takeda Pharmaceuticals USA, Inc. is owned by Takeda Pharmaceutical Company Limited, which holds 75% of its stock, and Takeda Pharmaceuticals International AG, which holds the remaining 25% of its stock.

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

Respondents are Painters and Allied Trades District Council 82 Health Care Fund, Annie M. Snyder, Rickey D. Rose, John Cardarelli, Marlyon K. Buckner, and Sylvie Bigord, appellees below.

STATEMENT OF RELATED PROCEEDINGS

There are no other proceedings in state or federal trial or appellate courts directly related to this case within the meaning of this Court's Rule 14.1(b)(iii).

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PETITION FOR A WRIT OF CERTIORARI

Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals USA, Inc. ("Takeda"), and Eli Lilly and Company ("Lilly") respectfully petition this Court for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

OPINIONS BELOW

Petitioners seek review of two opinions of the Ninth Circuit issued the same day in the same case, one of which is reported at 943 F.3d 1243 and reproduced at page 1a of the Appendix to this petition ("App."), and the other of which is unreported and reproduced

at App. 39a. The pertinent opinions of the United States District Court for the Central District of California are unreported and reproduced at App. 46a and 56a.

JURISDICTION

The judgment of the Ninth Circuit was entered on December 3, 2019.[1] App. 2a. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

STATUTORY AND CONSTITUTIONAL PROVISIONS

The RICO statute states, in relevant part, that "[a]ny person injured in his business or property by reason of a violation of [18 U.S.C. § 1962] may sue therefor in any appropriate United States district court and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney's fee * * * ." 18 U.S.C. § 1964(c).

Article III, section 2 of the United States Constitution provides, in relevant part, that "[t]he judicial power" is limited to "cases" and "controversies."

INTRODUCTION

Respondents are patients and a third-party payor ("TPP"). Doctors prescribed the patients Actos, a diabetes drug, which the patients purchased and used safely, effectively, and without adverse side effects. The TPP paid for Actos prescribed to its insureds, who likewise used the drug safely, effectively, and without adverse side effects.

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[1] Because the Ninth Circuit resolved this single appeal in two opinions issued the same day, it is unclear whether the court issued one or two judgments. Regardless, petitioners seek review of both Ninth Circuit decisions. *See* S. Ct. Rule 12.4.

Nevertheless, respondents sued petitioners (Takeda, which manufactures Actos, and Lilly, which previously co-promoted it) under RICO, seeking three times their money back because petitioners allegedly failed to timely disclose a risk of a side effect the patients at issue undisputedly did not experience. That risk was made public in an FDA warning in 2011, and it is undisputed that in the ensuing nine years, doctors have continued to prescribe Actos, patients have continued to purchase it, and TPPs—including the TPP respondent ("Painters")—have continued to pay for it.

This petition presents an opportunity for the Court to resolve entrenched, acknowledged circuit splits on two issues of exceptional importance relating to RICO proximate cause and Article III standing. "[I]n the RICO context," unlike the standard tort context, the focus of the proximate cause inquiry "is on the ***directness*** of the relationship between the conduct and the harm," not "the concept of foreseeability." *Hemi Grp., LLC* v. *New York*, 559 U.S. 1, 12 (2010) (plurality op.) (emphasis added). Applying that standard in pharmaceutical refund cases like this one, the Second and the Seventh Circuits have held that the alleged harm (payment for the drug) is too remote from the alleged RICO violation because every patient's prescription-drug purchase (and thus every TPP's payment) results from, among other causes, a doctor's independent decision to prescribe and a pharmacy benefit manager's independent decision to recommend coverage. *See UFCW Local 1776* v. *Eli Lilly & Co.*, 620 F.3d 121, 126 (2d Cir. 2010); *Sidney Hillman Health Ctr. of Rochester* v. *Abbott Labs.*, 873 F.3d 574, 578 (7th Cir. 2017) (holding "that there are so many layers, and so many

independent decisions, between promotion and payment that the causal chain is too long to satisfy" the proximate cause requirement).[2]

The Ninth Circuit, acknowledging that this case is indistinguishable from those Second and Seventh Circuit cases, disagreed. It concluded that the intervening steps between alleged wrongdoing and alleged harm are irrelevant because, no matter the roles of independent actors in causing each plaintiff's claimed injury, it was "foreseeable" that the conduct alleged would increase drug sales overall. App. 32a. In so holding, the Ninth Circuit acknowledged a longstanding "dispute between the Second and Seventh Circuits and the First and Third Circuits," opted to join the First and the Third Circuits, and expressly rejected the "opposite" rule of "the Second and Seventh Circuits." App. 31a, 33a.

The Ninth Circuit's approach effectively replaces RICO's "directness" requirement with a "foreseeability" test this Court has already repudiated. That error deepens a circuit split that has existed for years and reflects widespread, longstanding confusion over the basic contours of the RICO proximate cause analysis. Moreover, the Ninth Circuit's approach vastly expands the original purpose behind the RICO statute and creates broad-based liability where it would not otherwise exist. The Court should grant certiorari to resolve the clear division among the circuits on this question and restore certainty to the law.

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[2] A pharmacy benefit manager is an entity that makes recommendations to TPPs about which drugs to cover as part of the TPPs' insurance plans. *See UFCW*, 620 F.3d at 126 (noting that TPPs can "modify the recommendations of their PBMs").

The second question presented—whether a plaintiff who paid for an effective medication that did not cause any ill effect has standing to seek a full refund—is closely related, equally important, and also the subject of an entrenched and acknowledged circuit split. The Third and Fifth Circuits have correctly held that a plaintiff who uses a product fully, safely, and effectively, and thus receives "the benefit of her bargain," lacks Article III standing to sue for a full refund based on nondisclosure of a defect that affected only others. *See In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices & Liab. Litig.*, 903 F.3d 278, 280-81 (3d Cir. 2018); *Rivera* v. *Wyeth-Ayerst Labs.*, 283 F.3d 315, 320 (5th Cir. 2002). The rule of those circuits would have resulted in dismissal here.

Yet the Ninth Circuit, following its own established circuit precedent, held that ***anyone*** who pays for a product has standing to sue for a full refund merely by alleging that the payment would not have been made if a risk or defect had been disclosed, even if the product was consumed completely, safely, and effectively. App. 40a-41a n.1. That holding also deepens an existing, acknowledged division among the circuits on a recurring and important question of federal law. *See In re Zurn Pex Plumbing Prods. Liability Litig.*, 644 F.3d 604, 623-24 (8th Cir. 2011) (Gruender, J., dissenting) (criticizing majority for not following *Rivera*); *Johnson & Johnson*, 903 F.3d at 295 & n.12 (Fuentes, J., dissenting) (noting split with Ninth Circuit). And it transforms product liability law—developed to provide a remedy for those truly injured by defective products—into a mechanism for providing triple-refund windfalls to massive classes of purchasers of products that are

fully consumed and beneficial and caused them no harm whatsoever.

This case presents an ideal opportunity to resolve both circuit splits. The district court and court of appeals emphasized the clear disagreement on the proximate cause question, identified conflicting cases from other circuits as directly on point, and made clear that resolution of the split in petitioners' favor would be outcome-determinative on the RICO claims. App. 30a-31a, 57a-58a. The standing question was also addressed by the court of appeals and, if this Court rules in petitioners' favor, would be dispositive of this entire case. And since the case comes to the Court on a straightforward motion to dismiss, there is no likelihood that a factual issue could interfere with the proper resolution of either question. The Court should therefore grant certiorari.

STATEMENT OF THE CASE

A. Proceedings In The District Court.

In 1999, the FDA approved Actos, whose active ingredient is pioglitazone, for the treatment of type 2 diabetes. In 2011, the FDA issued a warning stating that its review of a still-ongoing study suggested that "although there was ***no overall increased risk of bladder cancer*** with pioglitazone use, an increased risk of bladder cancer was noted among patients with the longest exposure to pioglitazone and in those exposed to the highest cumulative dose of pioglitazone." Ninth Circuit Excerpts of Record ("E.R.") at 46-47 (emphasis added). The FDA did not remove Actos from the market, and, although the FDA continues to update its warning as additional studies are released, Actos remains on the market now.

In 2014, respondents filed this putative class action in federal district court under RICO and various state laws. The patient respondents do not allege they ever suffered from bladder cancer or any other personal injury or even that they were in the limited risk category the FDA noted. App. 8a. The TPP respondent does not allege that the petitioners made direct misrepresentations to it about the safety of Actos. Nor does it seek recovery for any payment associated with any patient who suffered a personal injury. App. 7a-9a.[3] Respondents also do not rely on any assertion that the price of Actos was wrongfully inflated due to the alleged nondisclosure. App. 9a n.3 (noting that respondents expressly abandoned any such contention on appeal).

Instead, respondents seek to recover treble damages based on "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." App. 9a. They also seek to represent all patients and TPPs "who paid or incurred costs for" Actos from the drug's approval through the date of the complaint, E.R. 69, even though it is undisputed that notwithstanding the FDA's warning, doctors continue to prescribe Actos, millions of patients (including many in respondents' proposed class) continue to purchase and consume it, and Painters continues to pay for it. *See*, *e.g.*, Appellants' Ninth Cir. Reply Br. 14 n.3 (noting that "Painters continues to pay for" Actos prescriptions). Accordingly, despite their broad

[3] As the court of appeals noted, Takeda has established a "global settlement program" for "all eligible personal injury claimants." App. 7a.

claims and class-action allegations, respondents do not contend that a doctor aware of the bladder-cancer risk would necessarily refuse to prescribe Actos, or that a patient thus aware would necessarily refuse to pay for or take it. *See id.* (arguing that "only * * * a percentage" of Actos prescriptions were based on alleged omissions).

Noting the conflicting First and Third Circuit cases, the district court deemed "persuasive Judge Easterbrook's reasoning in his opinion for the Seventh Circuit in a highly similar case," "adopt[ed] the reasoning of Judge[] * * * Easterbrook" on "the RICO proximate causation issue," and, "accordingly," dismissed the RICO claims with prejudice. App. 57a-58a & n.3 (citing, *inter alia*, *Sidney Hillman*, 873 F.3d at 578 (Easterbrook, J.); *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 804 F.3d 633 (3d Cir. 2015); *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21 (1st Cir. 2013)). The court also dismissed respondents' state law claims on various related grounds. App. 47a-55a.

B. Proceedings In The Court Of Appeals.

Respondents appealed, arguing that the complaint satisfies RICO's proximate cause requirement because it alleges petitioners acted with "inten[t] to increase the volume of Actos prescriptions" and with knowledge that patients and TPPs would pay for them. Appellants' Ninth Cir. Br. 39-61. Respondents noted the district court's "recogni[tion] that [the] *Neurontin* and *Avandia* cases contradicted its holding," *id.* at 51, and criticized the court for instead following the Seventh Circuit's decision in *Sidney Hillman*, which they derided as "poorly decided," "incorrect," and entitled to "little deference." *Id.* at 59.

In response, petitioners defended the district court's decision on proximate cause. Takeda Ninth Cir. Br. 8-45.[4] Petitioners also argued that dismissal was proper on the alternative ground that respondents lacked Article III standing because, as the Third and Fifth Circuits have ruled, plaintiffs who "got what they paid for * * * have suffered no concrete injury." Takeda Ninth Cir. Br. 45-51.

The Ninth Circuit reversed, noting that it had not yet had occasion to address "whether patients and TPPs suing pharmaceutical companies for concealing an allegedly known safety risk about a drug can satisfy RICO's proximate cause requirement," but that "several of our sister circuits have addressed th[at] question in similar factual scenarios and have reached different results, creating an apparent inter-circuit split." App. 21a-23a. Specifically, the court said, the Second and Seventh Circuits have deemed plaintiffs' payments for prescription drugs an indirect result of alleged wrongdoing in drug marketing, because "an individual patient's diagnosis, past and current medications being taken by the patient, the physician's own experience with prescribing [the drug], and the physician's knowledge regarding * * * side effects," among other factors, are necessary, intervening factors with respect to any plaintiff's injury. App. 26a (quotation marks and alteration omitted). The Ninth Circuit recognized that the First and Third Circuits have held the "opposite," deeming the directness requirement (and, accordingly, the proximate cause requirement) satisfied as to every plaintiff who

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[4] Lilly joined in all of Takeda's arguments. *See* Lilly Ninth Cir. Br. 1.

claims that a generalized increase in drug purchases was a foreseeable result of the conduct they allege. App. 27a-30a.

In sum, the court explained, "the central dispute between the Second and Seventh Circuits and the First and Third Circuits" is on the purely legal question of "whether the decisions of prescribing physicians and pharmacy benefit managers * * * sever the chain of proximate cause." App. 31a. Moreover, the Ninth Circuit said, any "minor factual and procedural differences" that might exist among those courts' cases would "not help" to reconcile that "central dispute." *Id.*

In choosing between those dueling appellate decisions, the Ninth Circuit also sought guidance from this Court's decision in *Bridge* v. *Phoenix Bond & Indem. Co.*, 553 U.S. 639 (2008). *See*, *e.g.*, App. 15a-16a. In that case, a RICO defendant who allegedly defrauded an auctioneer to gain an advantage over competing bidders argued that the bidders were categorically barred from suing without allegations that ***they***, as opposed to the auctioneer, had relied on the defendant's fraudulent statements. 553 U.S. at 642-45. The Court granted certiorari solely "to resolve * * * whether first-party reliance is an element of a civil RICO claim predicated on mail fraud." *Id.* at 646, 661. In holding that it is not, the Court rejected an argument that first-party reliance was necessary to show directness. In a brief discussion far afield from the question presented, the Court noted that because the competing bidders' injury was a natural consequence of the alleged fraud, ***and*** because "there [we]re no independent factors that account[ed] for" it, the injury was direct. *Id.* at 658.

Relying on the "*Bridge* precedent alone," App. 16a, the Ninth Circuit concluded that "the First and Third Circuits have it right." App. 31a-32a. Despite acknowledging that prescribing physicians "serve as intermediaries" between manufacturers and drug purchasers, the court reasoned that such physicians "do not constitute an intervening cause to cut off the chain of proximate cause," because "it was perfectly foreseeable that physicians who prescribed Actos would play a causative role in" increasing revenues therefrom. App. 32a (emphasis omitted). The court further noted that both the role of physicians as arbiters and the fact that patients and TPPs would ultimately pay for drugs would have been foreseeable to manufacturers engaged in the alleged wrongdoing. *Id.* Equating the directness requirement with a foreseeability test, the Ninth Circuit held that RICO's proximate cause requirement was satisfied. App. 16a-32a; *see* App. 33 (opining that if it were "to hold the opposite[,] 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").

The Ninth Circuit also briefly invoked two other points it thought supported that result. First, the court noted its conclusion that the three-factor inquiry for RICO proximate cause set forth in *Holmes* v. *Securities Investor Protection Corp.*, 503 U.S. 258, 269-70 (1992), weighed in favor of its holding. And second, pointing to this Court's observation that the proximate cause requirement "exists to 'limit a person's responsibility for the consequences of that person's own acts,'" App. 33a (citing

Holmes, 503 U.S. at 268), the court concluded that as long as respondents' injuries were but-for "consequences" of petitioners' "own acts and omissions," proximate cause was necessarily present. *Id.*

The Ninth Circuit addressed petitioners' Article III standing argument in a separate, unpublished memorandum reversing in part and affirming in part the dismissal of respondents' state law claims. There, the court of appeals noted that in a prior published decision "in the consumer fraud context," it had held that injury-in-fact necessarily exists "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.'" App. 40a-41a n.1 (quoting *Mazza* v. *Am. Honda Motor Co.*, 666 F.3d 581, 595 (9th Cir. 2012)). The court of appeals also noted that in this case, "Plaintiffs alleged that they purchased Actos, which they would not have done absent Defendants' fraudulent scheme to conceal Actos's risk of bladder cancer." *Id.* Based on that allegation alone, the court of appeals concluded that *Mazza* governed and, accordingly, that respondents "alleged an injury in fact sufficient to support Article III standing." *Id.*

REASONS FOR GRANTING THE PETITION

I. THERE IS A PERSISTENT AND WIDELY ACKNOWLEDGED CIRCUIT SPLIT ON THE FIRST QUESTION PRESENTED.

The Ninth Circuit acknowledged that its proximate cause ruling followed holdings of the First and Third Circuits but was the "opposite" of at least two other circuits' holdings in materially indistinguishable

cases. App. 33a.[5] That intractable conflict among the circuits calls out for this Court's resolution.

A. The Second And Seventh Circuits Would Not Have Permitted This Case To Proceed.

In *Sidney Hillman*, the Seventh Circuit addressed RICO claims brought by TPPs who had provided coverage for patients' purchases of a prescription drug. 873 F.3d at 575. The plaintiffs sought treble-damages refunds of their payments on the ground that the manufacturer had made fraudulent statements to doctors in promoting the drug. *Id.* The district court dismissed, concluding that "tracing loss through the steps between promotion and payment would be too complex." *Id.* at 576-77.

The Seventh Circuit affirmed, identifying three reasons why the plaintiffs suing for "wrongs committed while marketing pharmaceuticals" could not establish direct injury even if the harms they alleged were foreseeable. First, the court held, some of the prescriptions might have been "beneficial to patients," such that any damages calculation would require the court to determine whether the cost of any wrongfully written prescriptions was offset by the drugs' benefits. 873 F.3d at 577. Second, it reasoned, some prescriptions would have been written notwithstanding the alleged wrongdoing, such that "[t]o calculate damages it would be necessary to determine the volume of * * * prescriptions that would have occurred in the

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[5] *See also* James Bogan III, *Ninth Circuit Deepens Circuit Split In Pharmaceutical Industry-Specific RICO Proximate Cause Ruling* (Feb. 3, 2020) (https://tinyurl.com/t5t8ouh) (acknowledging circuit split).

absence of [the] unlawful activity," which might "not be an easy task." *Id.* And third, the court held, tracing injury would necessarily require a showing that each physician who wrote an allegedly wrongful prescription did so in reliance on the wrongful conduct alleged, such that "[d]isentangling the effects of the" wrongful conduct "from the many other influences on physicians' prescribing practices would be difficult—much more difficult than following the one-step causal link in *Bridge*." *Id.* For those reasons and others, the court held, *Bridge*'s brief directness discussion was inapplicable. *See id.* at 576.[6]

The court next rejected plaintiffs' effort to sidestep those issues of proximate causation "by using a regression analysis." 873 F.3d at 577. Among other problems, the court noted, a statistical showing that the alleged wrongdoing was a but-for cause of an increase in the number of prescriptions "would not address" some of the issues with proximate cause, including "what to do about patients whose * * * use of [the drug] made them healthier." *Id.* In sum, the court said, "[t]he causal chain" in a TPP suit against a drug manufacturer "is longer than" causal chains this Court has already "deemed too long." *Id.* at 578. In so concluding, the Seventh Circuit noted that "other courts of appeals have considered the extent to which [TPPs] can recover under RICO for wrongs

[6] Although *Sidney Hillman* involved only TPPs, *id.* at 575, essentially the same reasoning applies to patients. No harm to a particular patient can occur without, *inter alia*, a doctor's decision to prescribe the medication, a pharmacy benefit manager's decision to include it on a formulary and a TPP's decision to cover it, and external circumstances (such as the availability and a doctor's prescribing of safer, cheaper, equally effective alternatives) that would have made refusing the medication a viable option if a full disclosure had been made.

committed while marketing pharmaceuticals," and explained that two Second Circuit cases "hold[ing] that there are so many layers, and so many independent decisions, between promotion and payment that the causal chain is too long to satisfy the Supreme Court's requirements" are the cases that "ha[ve] this right." *Id.*

The Ninth Circuit's decision in this case also conflicts with those Second Circuit cases. The earlier one involved putative classes of patients and TPPs seeking, *inter alia*, treble-damages refunds of payments made for prescriptions that would allegedly not have been issued but for alleged misrepresentations by the manufacturer. *UFCW*, 620 F.3d at 123-24. In finding no proximate cause, the Second Circuit noted that any "theory of liability" that would tie a particular drug purchase to conduct in marketing necessarily "rests on the independent actions of third and even fourth parties." *Id.* at 134 (quoting *Hemi Grp.*, 559 U.S. at 15). Specifically, the court explained, "TPPs typically pay for a prescribed medication only if the drug is authorized under their formulary, a list of medications approved for payment" and "usually managed by a Pharmacy Benefit Manager ('PBM')." *Id.* at 126. TPPs "rarely modify the recommendations of their PBMs," and, "[o]n the rare occasions when" they do, they do so in consultation with the PBMs. *Id.* Moreover, the court noted, in the pharmaceutical context any "negotiations over price * * * do not intersect with the therapeutic choice of what drug a patient should take, which is a decision made by a physician with only minimal input by her patient or the TPP." *Id.* And "physicians generally do not take the price of a drug into account when deciding among treatment

options, and often do not even know the price of the drugs they prescribe." *Id.* at 126-27.

Given this complexity, the court determined that a drug purchaser hoping to show proximate cause would have to demonstrate, among other things, the "degree[]" to which an "individual physician[] prescribing [the drug] * * * relied on" the alleged misstatement or omission and that a prescription written in such reliance "actually caused loss, given the likelihood of substitute prescriptions for other drugs." 620 F.3d at 136. The court held that no such proximate cause showing could be made. *Id.* at 134, 136. The Second Circuit followed that decision in the other case the Seventh Circuit referred to, *Sergeants Benevolent Association Health & Welfare Fund* v. *Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 74-75, 90-91 (2d Cir. 2015), where it held that a plaintiff's RICO claims involving allegedly fraudulent pharmaceutical marketing were foreclosed by *UFCW's* holding on proximate cause. *Cf. Ironworkers Local Union 68* v. *AstraZeneca Pharm., LP*, 634 F.3d 1352, 1370 (11th Cir. 2011) (Martin, J., concurring) ("As the Second Circuit explained in [*UFCW*], the independent decisions of the physicians and other intermediaries involved in [a drug's] allegedly increased usage and pricing eviscerates the chain of causation necessary to demonstrate a RICO violation.").[7]

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[7] The Eleventh Circuit has found proximate cause lacking in a similar factual context. *See Se. Laborers Health & Welfare Fund* v. *Bayer Corp.*, 444 F. App'x 401, 409-10 (11th Cir. 2011) (TPP could not show proximate cause without allegation that disclosure would have caused it to cease reimbursing for drug).

B. The First, Third, And Ninth Circuits Have Rejected *Sidney Hillman*'s and *UFCW*'s Common-Sense Rule.

As the Ninth Circuit repeatedly acknowledged, *see*, *e.g.*, App. 30a-31a, decisions of the First and Third Circuits, as well as the decision below, conflict with the Second and Seventh Circuit decisions discussed above.

In *Neurontin*, a jury awarded a TPP damages for payments it incurred for prescriptions induced by a drug manufacturer's fraud on physicians. 712 F.3d at 25-26. "Unlike the Second and Seventh Circuits," *see* App. 27a, the First Circuit held that the causal chain between the manufacturer's wrongdoing and the purchaser's injury was "anything but attenuated." 712 F.3d at 38. The court rejected as irrelevant to proximate cause the important role doctors play in deciding which medications their patients are prescribed, reasoning instead that the issue went only to the "total number of prescriptions that were attributable to" the fraudulent scheme and was therefore exclusively "a damages question." *Id.* at 39. Dismissing that concern, the court concluded that such causation was present solely because, in engaging in its fraudulent actions, the manufacturer "always kn[ew] that, because of the structure of the American health care system," any scheme to increase drug sales would result in increased end payments. *Id.* at 38-39.

The Third Circuit followed suit in *Avandia*, a putative RICO class action brought by TPPs alleging that a diabetes drug manufacturer misrepresented heart-related safety risks. *See* 804 F.3d at 634-36. Like the First Circuit, the Third Circuit rejected any 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. That is because, the court said, *Bridge* establishes that ***any*** plaintiff, no matter how far removed from a wrong, can establish directness sufficient to satisfy RICO merely by claiming that their injury was the "foreseeable[,] natural," and intended "consequence" of a wrongful scheme. *Id.* at 645. For that reason, the court concluded, "*Bridge* precludes" any proximate cause argument based on the need to prove reliance by third parties, no matter how many intervening third parties there are. *Id.*

In the decision below, the Ninth Circuit made clear that whatever "minor factual and procedural differences" might exist among the above-described cases "do not help" to "resolve the central dispute between the Second and Seventh Circuits' reasoning and the First and Third Circuits' reasoning." App. 31a. The "central dispute" among those courts, the Ninth Circuit explained, 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 the TPP." *Id.* And on that "central dispute," the Ninth Circuit unreservedly sided with the First and Third Circuits, concluding that those two courts "have it right." *Id.* at 31a-32a. Moreover, like the district court before it, *see* App. 57a-58a, the court of appeals acknowledged that its decision about which side of the split to endorse was central to its holding. *See*, *e.g.*, App. 33a (noting that adopting Second and Seventh Circuits' "opposite" rule would have been dispositive).

C. The Court Of Appeals Erred In Focusing On Foreseeability Rather Than Directness.

By substituting foreseeability for directness, the Ninth Circuit—like the First and Third Circuits before it—ignored this Court's instruction that directness, ***not*** foreseeability, is the critical consideration in assessing RICO proximate cause.

The directness requirement has been a central feature of this Court's RICO jurisprudence from the beginning. In the decision first recognizing RICO's proximate cause requirement, the Court held that RICO "demand[s] * * * some direct relation between the injury asserted and the injurious conduct alleged." *Holmes*, 503 U.S. at 268. Explaining the "relation" required to satisfy that test, the Court noted the "general tendency of the law * * * not to go beyond the first step." *Id.* at 271; *see also Hemi Grp.*, 559 U.S. at 10 (plurality op.). The Court confirmed the centrality of directness in *Anza* v. *Ideal Steel Supply Corp.*, 547 U.S. 451, 461 (2006), where it held that "[w]hen a court evaluates a RICO claim for proximate causation, the central question it must ask is whether the alleged violation led ***directly*** to the plaintiff's injuries." (emphasis added).

The Court has also made clear that the directness requirement cannot be satisfied merely by demonstrating that an alleged injury was foreseeable. In *Anza*, for example, the Court reversed a determination by a court of appeals that RICO proximate causation was adequately pleaded where the plaintiff charged that a business competitor systematically underpaid taxes (the alleged racketeering activity) with the specific aim of using the funds to lower prices and attract the plaintiff's customers. 547 U.S.

at 454-55, 460. The Court rejected the notion that a plaintiff adequately pleads proximate cause merely by alleging that the defendant's wrongful conduct "was intended to and did" cause the harm the plaintiff alleged. *Id.* at 454-55, 460 (a "RICO plaintiff cannot circumvent the proximate cause requirement simply by claiming that the defendant's aim" was to profit at the plaintiff's expense). Noting the "indirect route" the defendants had taken "to accomplish their goal," the Court held RICO's proximate cause requirement unsatisfied, notwithstanding the plaintiffs' allegation—virtually identical to the respondents' here—that the defendants had specifically intended to cause the injury alleged. *Id.* at 460-61.

Four Justices reaffirmed that approach in *Hemi Group*, the Court's most recent effort to bring clarity to the law of RICO proximate cause. There, an out-of-state seller of cigarettes to residents of New York City failed to report the sales to New York State, as required by statute, with the result that the City could not identify and tax the purchasers. 559 U.S. at 4-5. Even though the conduct of the seller was a but-for cause of the harm to the City, and the harm was foreseeable, *see*, *e.g.*, *id.* at 22-23 (Breyer, J., dissenting), the Court held that the seller's conduct was not the ***direct*** cause, and the RICO claim should thus have been dismissed. *Id.* at 12-13 (plurality op.). The dissent criticized the plurality for permitting a RICO defendant to invoke proximate cause principles to escape liability for a "foreseeable," "intended" harm, *see* 559 U.S. at 12 (plurality op.) (quoting *id.* at 24 (Breyer, J., dissenting)), but the plurality responded that "precisely the [same] argument [was] lodged against the majority opinion

in *Anza*," where "the dissent criticized the majority's view for 'permitting a defendant to evade liability for harms that are not only foreseeable, but the ***intended*** consequences of the defendant's unlawful behavior.'" *Id.* (quoting *Anza*, 547 U.S. at 470 (Thomas, J., concurring in part and dissenting in part)) (alterations omitted). The *Hemi Group* plurality thus criticized the dissent for endorsing a "line of reasoning" that "would have RICO's proximate cause requirement turn on foreseeability, rather than on the existence of a sufficiently 'direct relationship' between the fraud and the harm." *Id.* Adopting such an approach, the plurality said, would be tantamount "to revisit[ing]" *Anza*. *Id.*

In this case, the Ninth Circuit—like the First and Third Circuits before it—adopted the reasoning of the *Hemi Group* dissent, which the *Hemi Group* plurality rejected as contrary to *Anza*. Relying on those two other circuits, the court of appeals held that no matter what "intermedia[te]" factors came between petitioners' alleged conduct and respondents' alleged injury, those factors could not constitute "an ***intervening*** cause," because the injury would have been a "perfectly foreseeable" result of the alleged conduct. App. 32a. The court of appeals thus vitiated the directness requirement this Court's precedents require by decreeing it satisfied any time a claimed injury is foreseeable. *See id.* And the First and Third Circuits have used nearly identical language in making the same mistake. *See Avandia*, 804 F.3d at 645 ("injury" was "sufficiently direct" because alleged wrongdoing "could have been successful only if plaintiffs paid for Avandia"); *Neurontin*, 712 F.3d at 38 & n.12 (deeming foreseeability and intent dispositive and purporting

to distinguish *Hemi Group* on the ground that the plaintiff there was not a "foreseen and intended victim").[8]

The court of appeals' error cannot be justified by its invocation of the single-paragraph discussion of directness in *Bridge*. *Cf.* App. 16a-17a. In that case, the Court rejected the defendant's argument that, absent first-party reliance, there can be no sufficiently direct injury to establish proximate cause under RICO. While the Court mentioned that the claimed injuries were a foreseeable and natural consequence of the alleged fraud, it expressly relied on the absence of "independent factors" in concluding that the plaintiff's injury was direct despite the absence of first-party reliance. *Bridge*, 553 U.S. at 658. *Bridge* thus provides no support for the court of appeals' apparent view, shared with the First and Third Circuits, that such "independent factors," *id.*, are irrelevant. On the contrary, and as a plurality of this Court has made clear, the absence of those factors was essential to *Bridge*'s holding. *See Hemi Grp.*, 559 U.S. at 14-15 (plurality op.) (holding that causation was absent because, "in contrast to *Bridge*," the plaintiffs' "theory of liability rest[ed] on

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[8] The defendants in *Avandia* and *Neurontin* filed petitions for certiorari, but did so before *Sidney Hillman* and the Ninth Circuit's decision here, when the circuit split the court of appeals acknowledged was far less developed than it is now. *Compare*, *e.g.*, *Sidney Hillman*, 873 F.3d at 575 (affirming dismissal granted because "plaintiffs could not hope to show proximate causation") *with* App. 33a (rejecting "opposite" rule of "the Second and Seventh circuits"). Both petitions focused on questions presented distinct from those here, and both were denied. *See GlaxoSmithKline LLC* v. *Allied Servs. Div. Welfare Fund*, 136 S. Ct. 2409, 2409 (2016); *Pfizer Inc.* v. *Kaiser Found. Health Plan, Inc.*, 571 U.S. 1094, 1094 (2013).

the independent actions of third and even fourth parties"). Nor did the Court in *Bridge* backtrack from *Holmes* and *Anza* in its brief discussion of directness, which was unnecessary to resolving the question presented in any event. Foreseeability may be necessary to allege directness where first-party reliance is lacking, but *Bridge* makes clear that it is not sufficient.

The court of appeals also committed a basic logical error in concluding that *Holmes* supported its holding because "[p]roximate cause exists to 'limit a person's responsibility for the consequences of that person's own acts,'" and the claimed injury is allegedly a "consequence[]" of petitioners' alleged acts. App. 33a (quoting *Holmes*, 503 U.S. at 268). The quoted statement undermines rather than supports the Ninth Circuit's proximate cause analysis, since it establishes that but-for causation is ***not*** sufficient to demonstrate proximate cause. *See Holmes*, 503 U.S. at 268-69. But the Ninth Circuit turned that principle on its head, misreading *Holmes* to establish that proximate causation is present ***wherever*** but-for causation can be found. In the process, the court collapsed the long-recognized distinction between those two fundamental concepts. *See, e.g.*, *Associated Gen. Contractors of Cal., Inc.* v. *Cal. State Council of Carpenters*, 459 U.S. 519, 533, 536 (1983) (noting the "well-accepted common-law rule" that "the judicial remedy cannot encompass every conceivable harm that can be traced to alleged wrongdoing"). The Court should resolve the longstanding circuit split and correct this fundamental error.

II. THERE IS AN ENTRENCHED, ACKNOWLEDGED CIRCUIT SPLIT ON THE SECOND QUESTION PRESENTED.

The Ninth Circuit also exacerbated a circuit split, acknowledged by dissenting judges on two separate courts of appeals, on the related and equally important question of whether purchasers of a product that is fully, effectively, and beneficially consumed, who thus get the benefit of the bargain they struck in purchasing it, can allege Article III injury merely by pointing to an allegedly undisclosed risk or defect that materialized only as to others. *See* App. 40a-41a n.1. The Court should grant certiorari and reverse on that question as well.

A. The Decision Below Cannot Be Reconciled With The "Benefit Of The Bargain" Rule The Third And Fifth Circuits Apply.

Relying on its prior, published decision in *Mazza*, the Ninth Circuit held that plaintiffs can allege Article III injury merely by asserting that they would not have purchased a product if they had known of a given risk or defect, even if the product was fully consumed and provided the bargained-for benefits without ill effect. *See supra* at 12. Dissenting judges on two courts of appeals have already acknowledged a circuit split on that question. *See Johnson & Johnson*, 903 F.3d at 295 & n.12 (Fuentes, J., dissenting) (noting Third Circuit's disagreement with the Ninth Circuit's decision in *Mazza*, 666 F.3d at 595); *Zurn Pex*, 644 F.3d at 623-24 (Greunder, J., dissenting).

The Ninth Circuit's decision squarely conflicts with decisions of the Third and Fifth Circuits. In *Johnson*

& Johnson, over a dissent decrying the majority's departure from Ninth Circuit cases, the Third Circuit affirmed the dismissal of a consumer class action alleging that a baby powder manufacturer's failure to disclose the risk of ovarian cancer allegedly associated with its product entitled consumers who did not develop ovarian cancer to refunds. The court held that a plaintiff could not plead Article III standing by alleging that, "had she been properly informed that using Baby Powder could lead to an increased risk of developing ovarian cancer, she would not have purchased the powder in the first place." *Johnson & Johnson*, 903 F.3d at 282, 290. The mere allegation that the product was "unsafe ***as to others***," the Third Circuit held, did not adequately plead that ***the plaintiff's*** "economic benefit * * * was anything less than the price she paid." *Id.* at 289-90. As the Third Circuit explained, "succinctly, buyer's remorse, without more, is not a cognizable injury under Article III." *Id.* at 281; *see also Koronthaly* v. *L'Oreal USA, Inc.*, 374 F. App'x 257, 258-59 (3d Cir. 2010) (no injury in fact without "allegation that [the plaintiff] received a product that failed to work for its intended purpose or was worth objectively less than what one could reasonably expect").

The Fifth Circuit reached the same conclusion in *Rivera*. *See* 283 F.3d at 320. The plaintiff in that case purchased and used a painkiller that was later discovered to cause liver failure in some patients. *Id.* at 316-17. After the manufacturer took the drug off the market, the plaintiff sued, seeking to represent a triple-refund class of "all patients who were prescribed, had purchased, and had ingested [the drug] but suffered no physical or emotional injury."

Id. at 317 (emphasis omitted). The court held that the plaintiff "paid for an effective pain killer, and she received just that—the benefit of her bargain." *Id.* at 320; *cf. In re Canon Cameras Litig.*, 237 F.R.D. 357, 360 (S.D.N.Y. 2006) (Rakoff, J.) ("A plaintiff who purchases a digital camera that never malfunctions over its ordinary period of use cannot be said to have received less than what he bargained for when he made the purchase."). The Fifth Circuit therefore held that the plaintiffs lacked standing, because no matter how serious the drug's side effects had been as to others, the drug "was not defective as to the [plaintiff]." *Rivera*, 283 F.3d at 320; *cf. Zurn Pex*, 644 F.3d at 623 (Greunder, J., dissenting) (criticizing majority for departing from *Rivera* by permitting plaintiffs to plead standing based on defect that had materialized only as to others).

B. The Decision Below Is Incorrect.

This Court should grant certiorari to make clear what the Third Circuit deemed "obvious": "a plaintiff does not have Article III standing when she pleads economic injury from the purchase of a product, but fails to allege that the purchase provided her with an economic benefit worth less than the economic benefit for which she bargained." *Johnson & Johnson*, 903 F.3d at 290. Like the plaintiffs in *Johnson & Johnson* and *Rivera*, the plaintiffs here make no allegation that they paid an artificially inflated price for Actos due to the alleged omissions. *See* App. 9a n.3.[9] Accordingly, the simple question

[9] Respondents also have not alleged or relied on any theory that, had the alleged omissions not occurred, any patient would necessarily have been prescribed and purchased an alternative medication that was cheaper but equally effective. *See* App. 17a n.7. Their failure to pursue that theory is no surprise,

the Ninth Circuit decided was whether a purchaser of a drug that was fully and effectively consumed, and that caused no physical injury, can establish Article III injury simply by alleging that, in retrospect and with hindsight knowledge, she wishes she had not paid for the medication and "would like her money back." *Rivera*, 283 F.3d at 319. The Third and Fifth Circuits' rejection of such claims was correct as a matter of both law and common sense, and the Ninth Circuit erred by departing from their rule.

III. THIS CASE IS AN EXCELLENT VEHICLE FOR ADDRESSING TWO QUESTIONS OF EXCEPTIONAL IMPORTANCE.

This case provides an ideal vehicle for the Court to address two widely-acknowledged circuit splits that are in urgent need of resolution. Refund RICO class actions such as this one are increasingly prevalent, and both questions presented cut to the heart of recurring issues critical to their viability. Moreover, since the Court last attempted to clarify the law of RICO proximate cause ten years ago in *Hemi Group*—a case that failed to yield a majority opinion—decisions of the courts of appeals on that issue have reflected persistent confusion.

A. The Viability Of Refund RICO Suits Is A Matter Of Exceptional Importance.

As Chief Justice Rehnquist observed, "there is no such thing as prosecutorial discretion to limit the use of civil RICO by plaintiffs' attorneys." William H. Rehnquist, *Remarks of the Chief Justice*, 21 St.

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since it would be impossible to prove on a classwide basis and, separately, would further devastate their position on proximate cause. *See supra* at 14 n.6.

Mary's L.J. 5, 10 (1989). His remark was prescient: RICO claims seeking treble damages based on alleged fraud in drug marketing have become legion.[10] Class counsel frequently target a manufacturer, as they have here, with conjectural theories of injury even when the products at issue are effective and caused no physical harm to the plaintiffs.[11] And commentators have noted that the growing trend of such suits has contributed to a

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[10] *See supra* at 12-18; *see also*, *e.g.*, *UFCW*, 620 F.3d at 135-36; *United Food & Commercial Workers Cent. Pa. & Reg'l Health & Welfare Fund* v. *Amgen, Inc.*, 400 F. App'x 255, 257 (9th Cir. 2010); *Ironworkers Local Union No. 68*, 634 F.3d at 1355-57; *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 248 (3d Cir. 2012); *Se. Laborers Health & Welfare Fund*, 444 F. App'x at 410; *In re Bextra & Celebrex Mktg. Sales Practices and Prod. Liab. Litig.*, 2012 WL 3154957, at *5-7 (N.D. Cal. Aug. 2, 2012); *Health Care Serv. Corp.* v. *Pfizer, Inc.*, 2012 WL 2505555, at *3-4 (E.D. Tex. Apr. 23, 2012), *report and recommendation adopted*, 2012 WL 2504884 (E.D. Tex. June 28, 2012); *Dist. 1199P Health & Welfare Plan* v. *Janssen, L.P.*, 784 F. Supp. 2d 508, 523-25 (D.N.J. 2011); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, 2010 WL 3119499, at *6-8 (S.D. Ill. Aug. 5, 2010); *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037, 1049-53 (N.D. Cal. 2009), *aff'd*, 464 F. App'x 651 (9th Cir. 2011); *S. Ill. Laborers' & Emp'rs Health & Welfare Fund* v. *Pfizer Inc.*, 2009 WL 3151807, at *5-7 (S.D.N.Y. Sept. 30, 2009).

[11] *See supra* at 12-18; *see also*, *e.g.*, *Ironworkers Local Union No. 68*, 634 F.3d at 1355-57; *UFCW*, 620 F.3d at 134; *Schering Plough*, 678 F.3d at 238-39, 242; *Se. Laborers*, 444 F. App'x at 401; *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 65 F. Supp. 3d 283, 292-93 (D. Mass. 2014); *Ind./Ky./Ohio Reg'l Council of Carpenters Welfare Fund* v. *Cephalon, Inc.*, 2014 WL 2115498, at *5-7 (E.D. Pa. May 21, 2014); *Plumbers & Pipefitters Local 572 Health & Welfare Fund* v. *Merck & Co.*, 2013 WL 1819263, at *6-7 (D.N.J. Apr. 29, 2013); *In re Bextra*, 2012 WL 3154957, at *6-8; *Yasmin & Yaz*, 2010 WL 3119499, at *6-7.

sharp increase in the number of pharmaceutical product liability cases in federal courts. *See*, *e.g.*, Victor. E. Schwartz & Cary Silverman, *The Rise Of Empty Suit Litigation: Where Should Tort Law Draw the Line*, 80 Brook. L. Rev. 599, 630-33 & n.171 (2015) (noting that more than 20,000 pharmaceutical product liability cases were pending in federal MDLs as of 2015, and that it is routine for plaintiffs' counsel to "generally allege that a drug is simply not as safe or effective as patients (or their doctors) were led to believe, or that the patient would not have purchased the drug, * * * even where the medicine worked for that individual"). The First, Third, and Ninth Circuit's rulings are an open invitation to forum shopping that will likely result in the continued proliferation of such claims. *See* Thomas M. Greene, *A New Weapon in Pharma Cases*, 47 Trial 40, 41, 44 (Nov. 2011) (authored by plaintiffs' counsel in *Neurontin*) (predicting increased RICO litigation against pharmaceutical companies because "RICO's powerful remedies make it an attractive tool" for civil litigants in such cases).

Moreover, there is tremendous pressure to settle even groundless claims in the oft-recurring context this case presents. *See*, *e.g.*, *AT&T Mobility LLC* v. *Concepcion*, 563 U.S. 333, 350 (2011) (noting the "in terrorem" effect of class actions on the incentive to settle). A civil RICO allegation presents the specter of damages amounting to three times the revenue attributable to a given drug and, as if that were not enough, the opprobrium associated with being labeled a racketeer by a federal court. *See*, *e.g.*, *Nichols* v. *Mahoney*, 608 F. Supp. 2d 526, 536 (S.D.N.Y. 2009). As commentators have observed, the settlement leverage these cases exert results in

payments that amount to a tax on drug manufacturers—payable to uninjured plaintiffs and their counsel—that will inevitably lead to increases in consumer prices and decreases in the development, quality, and availability of prescription drugs. *In re Bridgestone/Firestone, Inc., Tires Prods. Liab. Litig.*, 288 F.3d 1012, 1017 (7th Cir. 2002); A. Mitchell Polinsky & Steven Shavell, *The Uneasy Case for Product Liability*, 123 Harv. L. Rev. 1437, 1475 (2010) (explaining that pharmaceutical products litigation creates minimal value to consumers while adding billions of dollars of litigation-related costs to drug prices).

The decision below will only exacerbate the surge of coercive no-injury lawsuits. By recognizing claims for economic injury under RICO's civil provisions even where the causal chain depends on the decision-making of multiple independent actors, the Ninth Circuit's decision creates an irresistible incentive for countless TPPs and other insurance providers, as well as other plaintiffs, to burden the courts with speculative and attenuated RICO claims against manufacturers of pharmaceuticals and a range of other products. The result would be to virtually guarantee a tag-along, treble-damages refund RICO case after the filing of every product liability lawsuit.

The Ninth Circuit's standing holding alone has implications far beyond the pharmaceutical context. For example, consumers recently filed a putative class action against Boeing and Southwest Airlines, contending that because of those companies' alleged misrepresentations and omissions about the risks of the 737-MAX aircraft, ***every person who purchased a ticket*** for a flight on those planes—including all who flew and arrived at their

destinations safely—is owed a treble-damages refund for every ticket they ever purchased. In rejecting the plaintiffs' claim to standing based on buyer's remorse—the precise theory the Ninth Circuit endorsed here—the district court in that case observed that such a "theory of injury is the type of no-injury products liability claim that [the Fifth Circuit's decision in] *Rivera* definitively foreclosed." Memorandum Opinion & Order at 9, *Earl* v. *The Boeing Co.*, No. 4:19-cv-507 (E.D. Tex. Feb. 14, 2020), ECF No. 56 (citing *Rivera*, 283 F.3d 315). Yet in the Ninth Circuit, such a claim could proceed unabated.

The proliferation of such suits threatens to expose countless companies to ruinous litigation costs and potentially catastrophic damages in cases brought by purchasers who, unlike traditional products-liability plaintiffs, received the full benefits of their bargains and suffered no physical harm. *Cf. E. River S.S. Corp.* v. *Transam. Delaval, Inc.*, 476 U.S. 858, 866-67 (1986) (noting that "[p]roducts liability grew out of a public policy judgment" focused on bodily injury). It also creates a liability regime that potentially compensates those who safely and effectively use a product at significantly greater total amounts than those who used the product and suffered an actual physical injury. The result is to award windfall recoveries to uninjured purchasers and their lawyers while diverting resources from the legitimately harmed. The Court should reject these efforts to pervert the purposes of tort law.

B. The Law Of RICO Proximate Cause And Standing Are In Dire Need Of Clarification.

Granting certiorari would also enable the Court to provide long-overdue clarification of the law of RICO

proximate cause. The combination of this Court's brief discussion of directness in *Bridge* and the failure of any opinion to command a majority in *Hemi Group* has led to persistent uncertainty in that area of law. *Compare Hemi Grp.*, 559 U.S. at 12 (plurality op.) (basing RICO proximate causation "on the directness of the relationship between the conduct and the harm") *with id.* at 18-19 (Ginsburg, J., concurring in part and concurring in the judgment), *and id.* at 22-29 (Breyer, J., dissenting).

Many lower courts have properly applied the "direct relation" test set forth in *Holmes* and *Anza* and reaffirmed in *Bridge* and *Hemi Group*. *See*, *e.g.*, *Sidney Hillman*, 873 F.3d at 575 (citing *Hemi Group*, *Holmes*, and *Anza*). But others, including the Ninth Circuit in this case, misapprehend this Court's precedents and interpret the proximate cause requirement so loosely as to nullify it. Indeed, the Ninth Circuit's decision, like the First Circuit's in *Neurontin* and the Third Circuit's in *Avandia*, reflects uncertainty about matters as fundamental as which of this Court's cases states the governing test. App. 16a-19a, 32a-33a (finding proximate cause under the "*Bridge* precedent alone," but nevertheless applying a separate, three-part balancing test based on the so-called "*Holmes* factors," and engaging in a separate analysis of foreseeability); *see also Neurontin*, 712 F.3d at 38 (applying "***both*** the direct relationship and functional tests articulated in *Holmes* and its progeny") (emphasis added).

The predictable result has been widespread confusion among the circuit courts on a range of questions pertaining to RICO proximate cause. In the ten years since *Hemi Group*, the Court has received numerous petitions alleging intractable

confusion and division among the circuit courts on how to interpret and apply RICO's proximate cause requirement.[12] The Ninth Circuit's decision here, in which it acknowledged and delineated the clear circuit split on how the requirement applies to a fact pattern that arises frequently in pharmaceutical cases, is a stark call for clarification. And despite the Court's attempts to restrict Article III standing in cases where plaintiffs allege no actual injury, *see*, *e.g.*, *Spokeo, Inc.* v. *Robins*, 136 S. Ct. 1540, 1550 (2016); *Clapper* v. *Amnesty Int'l USA*, 568 U.S. 398, 422 (2013), the circuit split presented in this petition demonstrates that the lower courts still cannot agree on when putative economic injury suffices to confer standing where a product has been consumed fully, safely and effectively.

C. This Case Is An Excellent Vehicle.

This case is an excellent vehicle for resolving both questions presented. Both the district court and the court of appeals made clear that their judgments required choosing sides in the clear circuit split on

[12] Petition for Certiorari, *Devon Drive Lionville, LP* v. *Bank*, No. 19-901 (Jan. 16, 2020) (whether plaintiff who is not the direct recipient of mail or wire fraud can show RICO proximate cause); Petition for Certiorari, *D'Addario* v. *D'Addario*, No. 18-890 (Jan. 8, 2019) (whether estate beneficiary can establish direct injury where RICO violation harms estate as a whole); Petition for Certiorari, *S.G.E. Mgmt., LLC* v. *Torres*, No. 16-1309 (Apr. 28, 2017) (whether proximate cause can exist in a fraud-based RICO claim without proof of reliance by anyone); Petition for Certiorari, *Walters* v. *McMahen*, No. 12-667 (Nov. 28, 2012) (whether depressed wages can be the proximate result of business's employment of undocumented workers); Petition for Certiorari, *Heartwood 88, LLC* v. *BCS Servs., Inc.*, No. 11-124 (July 22, 2011) (petition from decision on remand in *Bridge* asking whether *Bridge* altered the law of RICO proximate cause to focus on foreseeability, rather than directness).

the proximate cause question. The same was plainly true of the standing question. Moreover, because the case arrives to this Court on a motion to dismiss, there is no potential for a factual dispute to obscure either issue. Each question is also dispositive of respondents' claims. If this Court reverses the Ninth Circuit and upholds the district court's dismissal of the RICO claims, that will dispose of all of respondents' federal law claims. And if the Court finds that respondents lack Article III standing, that would dispose of all of their claims, both state and federal. Nor is there any prospect that remand proceedings in the district court would affect this Court's consideration of the issues, as the district court recently stayed proceedings pending consideration and final resolution of this petition. *See* Order Granting Joint Stipulation for Stay, *Painters & Allied Trades Dist. Council 82 Health Care Fund* v. *Takeda Pharm. Co.*, No. 17-cv-07223 (C.D. Ca. Jan. 16, 2020), ECF No. 167.

CONCLUSION

For the foregoing reasons, this Court should grant the petition and reverse the judgment.

Respectfully submitted,

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February 2020

APPENDIX

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APPENDIX A
FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

PAINTERS AND ALLIED TRADES DISTRICT COUNCIL 82 HEALTH CARE FUND, third-party healthcare payor fund; ANNIE M. SNYDER, a California consumer; RICKEY D. ROSE, a Missouri consumer; JOHN CARDARELLI, a New Jersey consumer; MARLYON K. BUCKNER, a Florida consumer; SYLVIE BIGORD, a Massachusetts consumer, on behalf of themselves and all others similarly situated,

Plaintiffs-Appellants,

v.

TAKEDA PHARMACEUTICALS COMPANY LIMITED, a Japanese Corporation; TAKEDA PHARMACEUTICALS U.S.A., FKA Takeda Pharmaceuticals North America, Inc., an Illinois corporation; ELI LILLY AND

No. 18-55588

D.C. No. 2:17-cv-07223-SVW-AS

OPINION

COMPANY, an Indiana corporation,

Defendants-Appellees.

Appeal from the United States District Court
for the Central District of California
Stephen V. Wilson, District Judge, Presiding

Argued and Submitted June 6, 2019
Seattle, Washington

Filed December 3, 2019

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

SUMMARY**

Racketeer Influenced and Corrupt Organizations Act

The panel reversed the district court's judgment dismissing civil RICO claims under Fed. R. Civ. P.

* 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.

** This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

12(b)(6) for lack of RICO standing and remanded for further proceedings.

Plaintiffs brought a putative class action against pharmaceutical companies, alleging that the companies refused to change the warning label of their drug Actos or otherwise inform the public after they learned that the drug increased a patient's risk of developing bladder cancer. Plaintiffs were five patients and a third-party payor ("TPP") of health and welfare benefits to covered members and their families. Plaintiffs sought to represent a class of similarly situated patients and TPPs who paid or incurred costs for Actos. They alleged that defendants conspired to commit mail and wire fraud by intentionally misleading physicians, consumers, and TPPs to believe that Actos did not increase a person's risk of developing bladder cancer. Plaintiffs sought to recover economic damages under RICO for the payments they made to purchase Actos, which they allege they would not have purchased had they known of the bladder cancer risk. The district court held that plaintiffs failed to allege that their harm was "by reason of" the alleged RICO violation, as required for RICO standing, because they failed to allege the claimed RICO violation was the proximate cause of their claimed losses.

Agreeing with the First and Third Circuits, and disagreeing with the Second and Seventh Circuits, the panel held that plaintiffs sufficiently alleged proximate cause. Supreme Court precedent requires a direct relationship between the injury asserted and the defendant's conduct. The Supreme Court applies the *Holmes* factors, considering (1) whether it would

be too difficult to ascertain what damages are attributable to defendants' alleged RICO violation, (2) the risk of multiple recoveries by plaintiffs at different levels of injury from defendants' acts, and (3) whether holding defendants liable justifies the general interest of deterring injurious conduct. The panel concluded that plaintiffs sufficiently alleged a direct relationship, and the *Holmes* factors weighed in favor of permitting their RICO claims to proceed. The panel thus held that patients and TPPs suing pharmaceutical companies for concealing an allegedly unknown safety risk about a drug can satisfy RICO's proximate cause requirement. The panel concluded that, although prescribing physicians served as intermediaries between defendants' fraudulent omission of Actos's risk of causing bladder cancer and plaintiffs' payments for Actos, prescribing physicians did not constitute an intervening cause to cut off the chain of proximate causation. In addition, plaintiffs adequately alleged reliance on defendants' alleged misrepresentations and omissions.

The panel addressed additional claims in a concurrently filed memorandum disposition.

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OPINION

BEA, Circuit Judge:

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

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

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 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

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

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

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[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.

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).

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

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[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 address those claims in a concurrently filed memorandum disposition.

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.

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

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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).

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 interest in deterring injurious conduct,

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

> 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

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[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

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,

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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 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.

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 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 never

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[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

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

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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 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; (2) Medicare's decision to cover the drug

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

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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.

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 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

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.*

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 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

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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.

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 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 B

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

PAINTERS AND 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.	No. 18-55588 D.C. No. 2:17-cv-07223-SVW-AS MEMORANDUM[†*]

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

Appeal from the United States District Court
for the Central District of California
Stephen V. Wilson, District Judge, Presiding

Argued and Submitted June 6, 2019
Seattle, Washington

Before: BEA, NGUYEN, and WATFORD**, Circuit Judges.

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]

** 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.

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

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

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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.

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. § 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

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

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 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

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[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.

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. 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,

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[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.

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 C

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES – GENERAL

Case No. 2:17-cv-07223-SVW-AS Date April 3, 2018

Title *Painters and Allied Trades District Council 82 Health Care Fund et al v. Takeda*

Present: The Honorable STEPHEN V. WILSON, U.S. DISTRICT JUDGE

Paul M. Cruz	N/A
Deputy Clerk	Court Reporter / Recorder
Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:
N/A	N/A

Proceedings: IN CHAMBERS ORDER GRANTING MOTION TO DISMISS [119]

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 plaintiff's 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 Corp. 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 seq. N.J.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 (N.J. 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 (N.J. 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 pharmaceutical drug, such damages are too speculative to constitute an injury-in-fact under Article III.") Accordingly, these claims are DISMISSED WITH PREJUDICE.

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 PREJUDICE.

IV. Conclusion

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

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APPENDIX D

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES – GENERAL

Case No.	2:17-cv-07223-SVW-AS	Date	February 1, 2018

Title Painters and Allied Trades District Council 82 Health Care Fund et al v. Takeda

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Present: The Honorable STEPHEN V. WILSON, U.S. DISTRICT JUDGE

Paul M. Cruz	N/A
Deputy Clerk	Court Reporter / Recorder
Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:
N/A	N/A

Proceedings: IN CHAMBERS ORDER PARTIALLY GRANTING MOTION TO DISMISS [119]

Pending before the Court is Defendant Takeda Pharmaceutical's ("Takeda") and Defendant Eli Lilly

& Co.'s ("Lilly") motion to dismiss. Dkt 119.[1] For the reasons explained below, Defendants' motion to dismiss is partially GRANTED.

The subject of this motion–namely the RICO proximate causation issue–has been discussed at length in numerous trial court and appellate court opinions in this Circuit[2] and others.[3] The facts before this Court do not differ materially from those cases. This Court finds persuasive Judge Easterbrook's

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[1] Also pending before the Court is Plaintiff Painters & Allied Trades District Council 82 Health Care Fund's ("Painters") motion for summary judgment. Dkt. 88. The Court has not yet ruled on this motion.

[2] See, e.g., *United Food & Commercial Workers Cent. Pennsylvania & Reg'l Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255, 257 (9th Cir. 2010); *In re Bextra and Celebrex Mktg. Sales Practices & Prods. Liab. Litig.*, MDL No. 1699, 2012 WL 3154957, at *2-6 (N.D. Cal. Aug. 2, 2012) (Breyer, J.); *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037, 1051 (N.D. Cal. 2009), aff'd, 464 F. App'x 651 (9th Cir. 2011).

[3] *See, e.g., Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 873 F.3d 574, 578 (7th Cir. 2017) (Easterbrook, J.); *In re Yasmin and Yaz (Drospirenone) Mktg. Sales Practices &Prods Liab. Litig.*, MDL No. 2100, 2010 WL 3119499, at *7 (S.D. Ill. Aug. 5, 2010); *contra In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 804 F.3d 633 (3d Cir. 2015); *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 60 (1st Cir. 2013) .

reasoning in his opinion for the Seventh Circuit in a highly similar case. *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 873 F.3d 574, 578 (7th Cir. 2017) (Easterbrook, J.).[4] Judge Breyer's opinion (again in a case virtually identical to this) also offers valuable guidance. *In re Bextra and Celebrex Mktg. Sales Practices & Prods. Liab. Litig.*, MDL No. 1699, 2012 WL 3154957, at *2-6 (N.D. Cal. Aug. 2, 2012) (Breyer, J.)[5] This Court adopts the reasoning of Judges Breyer and Easterbrook, and accordingly the RICO claims are DISMISSED WITH PREJUDICE.[6]

In light of this, the Court has some doubts regarding whether it maintains jurisdiction over this action. Accordingly, the parties are ORDERED TO SHOW CAUSE why this Court retains jurisdiction. The parties will file simultaneous briefs (not to exceed 10 pages) within 14 days.

IT IS SO ORDERED.

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[4] In his opinion, Judge Easterbrook cited several Unpublished Ninth Circuit opinions, which adds to the persuasive force of his reasoning.

[5] The Court acknowledges the contrary opinions from the First and Third Circuits, but does not find the reasoning in those opinions persuasive.

[6] A "district court's discretion to deny leave to amend is particularly broad where, as here, the plaintiff has previously filed an amended complaint." *United Food & Commercial Workers Cent. Pennsylvania & Reg'l Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255, 258 (9th Cir. 2010).

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