No. 19-1069

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.

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

REPLY BRIEF FOR PETITIONERS

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I. CERTIORARI IS WARRANTED ON THE RICO PROXIMATE CAUSE QUESTION.

As the Ninth Circuit repeatedly acknowledged, the first question presented has divided five circuits and was dispositive below. *See* Pet. 33-34. Respondents themselves concede "there is a circuit split regarding proximate causation" in pharmaceutical RICO cases. Opp. 27. Although respondents attempt to distinguish the Second and Seventh Circuit cases the Ninth Circuit rejected, the court of appeals made clear that the "minor factual and procedural differences" on which respondents now rely do "not help" reconcile the

entrenched conflict. App. 31a. Only this Court can resolve that conflict, and this case presents an excellent vehicle to do so.

A. This Case Squarely Presents The Circuit Split Respondents Acknowledge.

While conceding a circuit split in pharmaceutical RICO cases, respondents wrongly argue that the split has no bearing on ***this*** pharmaceutical RICO case. *Cf.* Opp. 27-33. The distinction respondents hypothesize between fraudulent off-label promotion and fraud by omission is immaterial to the RICO proximate cause inquiry, which focuses on the directness of injury, not the nature of the alleged fraud. *See Hemi Grp., LLC* v. *City of New York*, 559 U.S. 1, 14-15 (2010) (plurality op.).

As respondents admit, the critical factor in *Sidney Hillman Health Center of Rochester* v. *Abbott Laboratories*, 873 F.3d 574 (7th Cir. 2017), was that every plaintiff's injury was indirect, because it depended on "a physician's decision" to prescribe, which could be "influence[d]" by "many things" other than the alleged fraud. Opp. 28. Precisely the same attenuated causal chain exists here. As the Ninth Circuit noted, prescribing physicians "play[ed] a causative role" in every plaintiff's alleged injury, because no patient can lawfully purchase Actos without a doctor's intervening decision to prescribe it. Opp. 17 (quoting App. 32a).[1]

The alleged fraud was not the sole basis for those intervening decisions. Indeed, it is undisputed that physicians continue to prescribe Actos ***to this day***,

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[1] S*ee also*, *e.g.*, App. 34a (noting role of "prescribing physicians' decisions whether to prescribe Actos"); Opp. 17 (alleging "[p]hysicians were duped" into "prescribing Actos").

patients continue to benefit from it, and TPPs continue to pay for it notwithstanding the FDA's warning. Pet. 7; Opp. 2-3. Thus, as in *Sidney Hillman*, 873 F.3d at 577, "[d]isentangling the effects of the" alleged fraud "from the many other influences on physicians' prescribing practices would be difficult—much more difficult than following the one-step causal link" in *Bridge* v. *Phoenix Bond & Indem. Co.*, 553 U.S. 639 (2009).

The Ninth Circuit reached its holding by ***rejecting*** *Sidney Hillman*'s legal rule—not by distinguishing it. App. 31a-32a, 34a-35a. It was respondents who encouraged that outcome. Under the heading "*Sidney [Hillman]* Is Not Persuasive," respondents argued at length below that *Sidney Hillman* was "incorrect," made "little sense," depended on "untrue" assertions, and was a "poorly decided case" entitled to "little deference." Appellants' Ninth Cir. Br. 51-59 (Sept. 10, 2018). When the Ninth Circuit held that the "minor factual and procedural differences" on which respondents now rely do "not help" avoid a circuit split, App. 31a, it endorsed respondents' own argument.

If anything, respondents' newly minted "on-label"/"off-label" distinction makes their case ***weaker*** than *Sidney Hillman* and the circuit split even more stark. Respondents argue that because the alleged fraud involved omissions, rather than direct marketing to doctors and TPPs, "***everyone*** * * * was exposed" to the fraud, so ***everyone*** can establish proximate cause. Opp. 4 (emphasis added); Opp. 25 (asserting that "on-label" fraud "permeates and [a]ffects all levels of the pharmaceutical marketplace," and is a misrepresentation "to ***everyone***"). But RICO's proximate cause requirement focuses solely on

whether ***injury*** is direct, *see Hemi Grp.*, 559 U.S. at 14, not on who was "exposed" to the alleged fraud.[2] Respondents' alleged injury (if it even exists) flows through the same attenuated chain of causation, regardless of whether it involves omissions. Their broad "exposure" theory, even more than the one the Seventh Circuit rejected, would eviscerate RICO's direct injury requirement.[3]

Respondents also assert that a "regression analysis" they hope to present would address the concerns underlying *Sidney Hillman*'s holding. Opp. 29-31. That assertion fails. *Sidney Hillman* affirmed a Rule 12(b)(6) dismissal, and thus had nothing to do with the strength of the plaintiffs' proof. Rather, the court held that ***no*** amount of proof could establish RICO proximate causation, because the "causal chain" leading to injury involved too "many independent decisions." 873 F.3d at 577-78. Likewise here, respondents' hoped-for regression analysis might help show ***but-for*** causation at one step in the causal chain, but it would not shorten the chain itself. It thus offers no way to distinguish *Sidney Hillman* on the issue of proximate cause. Indeed, although respondents portray this as a simple case of

[2] Contrary to respondents' suggestion, the Ninth Circuit did not distinguish *Sidney Hillman* because it involved so-called "off-label" fraud. Rather, the court hypothesized only that the alleged omissions in this case might have been more ***material*** to some individual doctors than the misrepresentations in *Sidney Hillman*. App. 33a-34a. But that distinction is irrelevant to proximate cause, which focuses on whether the injury is direct, and the Ninth Circuit ultimately did not rely on it.

[3] Even under respondents' flawed theory, petitioners' alleged omissions were to ***the FDA***, *cf.* Opp. 7-10, which is less direct than "off-label" marketing directed specifically at prescribing doctors.

marketing fraud causing Painters to pay for Actos prescriptions it otherwise would not have, their concession that a regression analysis is required to prove injury underscores the intricacy and complexity of their proposed causal chain.

Thus, the decision below directly conflicts with *Sidney Hillman*. Here, as there, the thousands of individual prescribing decisions at issue were motivated by numerous independent factors. Moreover, compounding the impossibility of assigning liability based on an unknowable subset of prescriptions that would not have been written, Painters admits that any award would have to be "offset" by the value of an equally unknowable quantity of cheaper drugs that would purportedly have been prescribed instead. Opp. 30. That respondents' complaint alleges the ***existence*** of those alternative medications, *id.* at 29-30, is no response to *Sidney Hillman*'s observation that it is impossible to determine which medication would have been prescribed to each patient in a counterfactual world, much less the share of the medication's cost that each patient and TPP would have borne. *See* 873 F.3d at 577. The impossibility of such an inquiry is precisely why RICO liability extends only to direct injury.

B. The Decision Below Also Conflicts With The Second Circuit's Holdings.

The clear conflict with *Sidney Hillman* itself warrants certiorari. But respondents also do not refute the conflict with the Second Circuit. The Ninth Circuit openly acknowledged that conflict, *see* App. 31a, as did the Seventh Circuit, *Sidney Hillman*, 873 F.3d at 578 ("[T]he Second Circuit has this right.").

Respondents attempt to cabin *UFCW Local 1776* v. *Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010), and *Sergeants Benevolent Ass'n Health & Welfare Fund* v. *Sanofi-Aventis U.S. LLP*, 806 F.3d 71 (2d Cir. 2015), to those cases' class action context. Opp. 17. But the Second Circuit's holdings would foreclose any proximate cause finding in this case. In *UFCW*, which also involved alleged fraudulent omissions, 620 F.3d at 129, the court held that the plaintiffs' class-wide proximate-cause problem arose because any "theory of liability" seeking to tie a prescription drug purchase to conduct in marketing necessarily "rests on the independent actions of third and even fourth parties," *id.* at 134; *see also Sergeants*, 806 F.3d at 90-92 (liability depends on "a doctor's decision to prescribe," which is a complicated intervening cause that cannot be attributed to any single factor); *Ironworkers Local Union 68* v. *AstraZeneca Pharm., LP*, 634 F.3d 1352, 1370 (11th Cir. 2011) (Martin, J., concurring) (noting *UFCW*'s holding that independent decisions "eviscerate[] the chain of causation"). That problem is equally present for any individual claim in the prescription drug context, because all such claims depend on a doctor's intervening decision. *See*, *e.g.*, Pet. 22-23 (quoting *Hemi Grp.*, 559 U.S. at 14-15).

C. The Presence of Patient-Plaintiffs Makes Certiorari Even More Appropriate.

Noting that the Seventh and Second Circuit cases involved TPP plaintiffs, respondents argue the Court should deny certiorari because this case involves individual plaintiffs ***in addition*** to a TPP (Painters). Opp. 22-23. That contention is unjustified. As the petition explains—and respondents nowhere refute—essentially the same reasoning applies to patients as to TPPs, because essentially the same causal chain

that has been held to defeat TPPs' claims exists for patients' claims. Pet. 14 n.6.

Regardless, the patients' presence poses no obstacle to this Court's review. No matter how the their claims are resolved, the proximate cause issue is properly presented and dispositive as to Painters' claims. Thus, if anything, the patients' presence makes this case an even better vehicle, because it would allow the Court to clarify the law as to both kinds of plaintiffs (and more broadly, *see* Pet. 31-33), thereby obviating the need to decide the issue in a separate case. Moreover, the standing issue unquestionably applies to the patients, who (like Painters) paid for drugs that were fully consumed, safe, and effective. Because the proximate cause issue is plainly cert-worthy as to Painters' claims, the joinder of another, separate group of plaintiffs cannot preclude the Court from resolving a circuit split on a recurring, important question that is squarely presented.

D. The Ninth Circuit Improperly Equated Foreseeability With Proximate Cause.

RICO's proximate cause requirement focuses on directness, ***not*** foreseeability. *See* Pet. 19-23. Yet despite denying that the Ninth Circuit substituted foreseeability for directness, respondents cannot even quote that court's opinion without conceding precisely the opposite. Respondents argue on one page of their opposition that "[n]ot once did the Ninth Circuit, in assessing directness mention foreseeability, let alone equate it." Opp. 16 n.2. But on the very next page, they note the contrary—that the Ninth Circuit based its entire directness finding on the premise that "it was perfectly foreseeable that physicians who prescribed Actos would play a causative role" in the alleged scheme. Opp. 17 (quoting App. 32a). This

Court has squarely rejected the conflation of foreseeability and directness, just as it has rejected respondents' assertion that civil RICO provides a remedy for every foreseeable victim of an alleged fraudulent scheme. *Hemi Grp.*, 559 U.S. at 12.

II. CERTIORARI IS WARRANTED ON THE STANDING QUESTION.

Certiorari is also independently warranted because there is an intractable circuit split on the purely legal question of whether plaintiffs in respondents' position have Article III standing. Respondents got the full benefit of their bargain when they paid for Actos: a drug that was completely, safely, and effectively consumed without adverse side effects. Moreover, as the Ninth Circuit made clear, respondents ***expressly abandoned*** any claim that Actos' price would have been lower absent petitioners' alleged misconduct. Thus, the Ninth Circuit found standing not based on any economic injury, but solely due to a *per se* rule that injury-in-fact exists ***whenever*** plaintiffs "contend that they bought a product 'when they otherwise would not have done so.'" App. 40a-41a n.1 (quoting *Mazza* v. *Am. Honda Motor Co.*, 666 F.3d 581, 595 (9th Cir. 2012)). Under that rule, standing was found merely because respondents "alleged that they purchased Actos, which they would not have done absent Defendants' fraudulent scheme * * * ." *Id.* The Ninth Circuit's rule squarely conflicts with the clear holdings of two other circuits, *see In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices & Liab. Litig.* ("*Estrada*"), 903 F.3d 278 (3d Cir. 2018); *Rivera* v. *Wyeth-Ayerst Labs.*, 283 F.3d 315 (5th Cir. 2002), and is plainly wrong.

The conflict is clear. Indeed, in the Ninth Circuit, respondents argued that the Third Circuit's *Estrada*

decision was a "mistake," and urged the court of appeals to adopt the reasoning of the *Estrada* dissent, which they said "comports with [Ninth Circuit] caselaw." Appellants' Ninth Cir. Reply Br. at 27-28 (Jan. 21, 2019) (citing *Estrada*, 903 F.3d at 298 (Fuentes, J., dissenting)). As that dissent recognized, the Ninth and Third Circuits directly conflict on whether an injured purchaser can concoct standing merely by alleging she would not have purchased a product had certain disclosures been made.

In *Estrada*, the Third Circuit held that "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." 903 F.3d at 290. The court did ***not***, as respondents argue, hold that an uninjured plaintiff has standing merely by alleging that a defendant would have sold less of a product had it disclosed certain information. *Cf.* Opp. 34. Respondents quote an observation in *Estrada*'s separate discussion of the plaintiff's restitution claim, but in that discussion the Third Circuit emphasized that the "same rationale" that barred Estrada's monetary damages claim also "holds true as to her restitution claims—Estrada cannot invoke the federal judicial power simply by asserting that Johnson & Johnson has earned unlawful profits." 903 F.3d at 291.[4]

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[4] Estrada's restitution allegation specifically included the "overpayment" allegation respondents have abandoned here. *See id.* (noting that with respect to restitution, Estrada alleged that the defendant had "been able to sell the product for more than [it] otherwise would have had [it] properly informed consumers about the safety risks").

Nor can respondents satisfy the Third Circuit's rule. They argue that "[a]t no time have any of the Respondent-Plaintiffs alleged that they have received any benefit from Actos." Opp. 34. But it was ***their*** burden to allege (and then prove) standing. *See*, *e.g.*, *Summers* v. *Earth Island Inst.*, 555 U.S. 488, 493 (2009). Accordingly, respondents must, at a bare minimum, have alleged they did not receive the benefit of their bargains. They make no such claim. Neither the patient-respondents nor the patients reimbursed by Painters ever suffered the allegedly undisclosed side effect (indeed, anyone who alleges such injury is expressly excluded from the putative class), and they alleged no other injury.

Respondents disingenuously argue that they alleged that petitioners' alleged fraud caused an "overvaluation" of Actos. Opp. 35. Respondents expressly abandoned any such claim. In the Ninth Circuit, they stated that while they had previously alleged that Takeda "was able to charge higher prices than it other[wise] would have been able," that theory "***is not raised here on appeal***." Appellants' Ninth Cir. Br. 50 n.7 (emphasis added). The Ninth Circuit then decided the case based on that concession.[5] Its standing holding depended entirely on respondents' bare allegation, divorced from any allegation of economic harm, that they would not have purchased Actos ***at all*** had they known about the alleged risk to

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[5] App. 9a n.3 ("Plaintiffs have abandoned their excess price theory for damages on appeal."); *id*. at 43a n.3 ("Plaintiffs have abandoned their excess price damages theory"); *id*. at 44a (affirming dismissal of Missouri law claims because controlling precedent "is similar to Plaintiffs' excess price damages theory, which they expressly abandoned on appeal").

other people. App. 40a-41a n.1.[6] Respondents cannot strategically abandon a claim on appeal, obtain a broad ruling in their favor on that basis, and then rely on the abandoned claim to oppose certiorari in this Court.

Nor can respondents defend the decision below based on purported "injury tied to a less expensive alternative." *Cf.* Opp. 35 n.5. Their complaint alleged only that less expensive alternatives existed, *id.*, not that any patient-plaintiff—much less all patients Painters reimbursed—would have been prescribed a specific, cheaper, equally effective alternative drug. It is unsurprising respondents made no such allegation, given that such claims would have been impossible to prove even under the Ninth Circuit's flawed proximate-cause test, particularly on a class-wide basis.

Respondents also cannot distinguish the Fifth Circuit's decision in *Rivera*. *Cf.* Opp. 35-36. Respondents quote from the court's separate discussion of causation, *see* 283 F.3d at 321, but *Rivera*'s analysis of ***injury*** turned on the fact that the plaintiff "paid for an effective pain killer, and she received just that—the benefit of her bargain," *id.* at 320. So too here. Respondents paid for an effective diabetes drug. They do not allege they received anything less.

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[6] Respondents cite *Blue Cross Blue Shield Ass'n* v. *GlaxoSmithKline LLC*, 417 F. Supp. 3d 531 (E.D. Pa. 2019) (cited at Opp. 35), but that case found standing only because the plaintiffs, unlike respondents here, had alleged and produced evidence that their drugs were "worth less than what they paid." *Id.* at 554.

III. THE ISSUES ARE IMPORTANT.

As shown by the broad group of supporting amici, the questions presented have national importance. They do not simply reflect an "industry-specific circuit split," *cf.* Opp. 29, although their effects on the multi-trillion dollar healthcare sector would be reason enough to grant review. *See, e.g.*, *Merck Sharp & Dohme Corp.* v. *Albrecht*, 139 S. Ct. 1668 (2019). In the decade since the Court's fractured decision in *Hemi Group*, RICO proximate cause has bedeviled circuits in all manner of cases. Pet. 31-33. The standing issue likewise has broad import, since the Ninth Circuit's rule invites a treble-damages follow-on class action by uninjured consumers in almost every product defect case. *See* Pet. 30-31; *see also*, *e.g.*, *Flynn* v. *FCA US LLC*, 2020 WL 1492687, at *5 (S.D. Ill. Mar. 27, 2020), *appeal docketed*, No. 20-1698 (7th Cir. Apr. 28, 2020) (relying on *Rivera* to find no standing where alleged vehicle defect did not affect plaintiffs and plaintiffs "received what they bargained for").

Nor do petitioners seek "blanket immunity for drug companies to engage in marketing fraud." Opp. 1. Claimants alleging actual personal injuries are eligible for a global settlement program. App. 7a. Applying this Court's precedents would thus simply limit the blunt, *in terrorem* weapon of civil RICO to direct injuries as this Court has required.

The questions presented recur often and involve the viability of crippling, predatory, no-injury class actions nationwide. The Court should grant certiorari to restore uniformity to the law.

CONCLUSION

The Court should grant certiorari and reverse.

Respectfully submitted,

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