No. 19-1069

IN THE

Supreme Court of the United States

TAKEDA PHARMACEUTICAL COMPANY, LTD., TAKEDA PHARMACEUTICALS USA, INC., and ELI LILLY & 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 U.S. Court of Appeals for the Ninth Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

CORY L. ANDREWS
Counsel of Record
CORBIN K. BARTHOLD
WASHINGTON LEGAL FOUNDATION
2009 Mass. Ave., NW
Washington, DC 20036
(202) 588-0302
candrews@wlf.org

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QUESTIONS PRESENTED

1. Whether everyone who pays for a drug with an allegedly latent risk suffers an injury in fact under Article III, even if the consumer takes the drug as prescribed, receives the bargained-for benefit, and suffers no ill effects.

2. Whether the chain of causation between a manufacturer's alleged omissions about a prescription drug and the end payment for that drug is too attenuated to satisfy RICO's proximate-cause requirement.

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INTEREST OF *AMICUS CURIAE*[*]

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes and defends free enterprise, individual rights, limited government, and the rule of law. It often appears as *amicus curiae* to urge that the federal judiciary decide only true "Cases or Controversies" under Article III of the Constitution. *See, e.g.*, *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540 (2016); *Clapper v. Amnesty Int'l USA*, 568 U.S. 398 (2013). WLF also participates in key cases construing the scope of civil liability under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961 *et seq*. (RICO). *See, e.g.*, *RJR Nabisco Inc. v. European Cmty.*, 136 S. Ct. 2090 (2016); *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639 (2008).

"Article III standing requires a concrete injury even in the context of a statutory violation." *Spokeo*, 136 S. Ct. at 1549. Yet if the decision below stands, plaintiffs in the Ninth Circuit may walk into federal court with no more than a bare statutory claim divorced from any real-world harm. None of this Court's precedents blesses so diluted a view of Article III's injury-in-fact requirement. Allowing a plaintiff who has suffered no actual harm to recover treble

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[*] No party's counsel authored any part of this brief. No person or entity, other than Washington Legal Foundation and its counsel, helped pay for the brief's preparation or submission. At least ten days before the brief's filing deadline, WLF notified each party's counsel of record of WLF's intent to file. Each party's counsel of record has consented to the filing of WLF's brief.

damages under RICO would carry the federal courts far beyond their traditional and proper role of adjudicating disputes and remedying concrete injuries.

Even when alleging some real-world harm, a RICO plaintiff still must show that the defendant's conduct proximately caused that harm. RICO's proximate-cause element ensures that only *directly* injured victims may "vindicate the law as private attorneys general, without any of the problems attendant upon suits by plaintiffs injured more remotely." *Holmes v. Sec. Inv'r Prot. Corp.*, 503 U.S. 258, 269-70 (1992). By excusing the respondents' obligation to prove proximate cause, the decision below sidesteps RICO's requirement that a plaintiff show harm "by reason of" the defendant's violation. *See* 18 U.S.C. § 1964(c).

The Ninth Circuit's opinion deepens an existing circuit split on both these recurring and important issues of federal law; and it contravenes this Court's precedents by virtually eliminating the case-or-controversy and proximate-cause requirements as meaningful checks on spurious RICO claims. WLF urges the Court to grant review and bar the door to plaintiffs alleging highly contingent, inchoate harms under RICO—before they swarm the federal courts.

STATEMENT OF THE CASE

In 1999 the FDA approved Actos as safe and effective for controlling high blood sugar in patients with type-2 diabetes. In 2011, after reviewing a then-ongoing ten-year epidemiological study, the FDA issued a Safety Announcement. While the FDA found "no overall increased risk of bladder cancer" with Actos use, the data suggested an increased risk of that cancer "among patients with the longest exposure" and "in those exposed to the highest cumulative dose." ER 46-47. After Takeda updated Actos's label to disclose that risk, the FDA did not remove Actos from the market. Instead, in 2012, the FDA expanded patient access to the drug by approving generic versions of pioglitazone (Actos's active ingredient). To this day, both branded and generic forms of pioglitazone remain widely prescribed for patients with type-2 diabetes.

In 2014, the respondents, former Actos consumers and a third-party payor (TPP), filed this RICO action in federal court. They alleged that the petitioners, two affiliated Actos manufacturers and a former co-promoter of Actos, "engaged in a decade-long scheme" to sell Actos "while concealing the bladder cancer risks associated with Actos from consumers, prescribers, third-party payors, and the [FDA]." (Second Am. Compl. ¶ 1.) The respondents sought to certify a class of all "consumers and [TPPs] who were tricked into purchasing and/or reimbursing Actos prescriptions." (*Id.*)

The respondents do not allege that the petitioners affirmatively misled them about Actos. Nor do they claim that Actos failed to satisfactorily treat

their diabetes symptoms. The individual respondents disclaim any personal injury caused by ingesting Actos; and Painters Fund—the TPP respondent—disclaims any right to recover its reimbursements to personally injured members. Pet. App. 7a-9a. The respondents also have abandoned any "excess-price" theory of harm—*i.e.*, that the petitioners' alleged fraud caused the respondents to pay inflated prices for Actos. *Id.* at 9a.

The respondents' theory of harm is that the petitioners' failure to disclose Actos's bladder-cancer risk caused the respondents to pay for "more prescriptions for Actos than would have otherwise occurred." Pet. App. 43a. The respondents do not deny that doctors continue to prescribe, and that millions of patients—including many in the proposed class—continue to buy and consume, Actos. And Painters Fund continues to reimburse its members for Actos payments to this day. Even so, the respondents seek treble the amount of a full refund for "the payments they made to purchase [or reimburse payments for] Actos under the assumption that it was a safe drug," from the day of the FDA's approval until the FDA issued its 2011 Safety Announcement. *Id.* at 9a.

The district court dismissed the respondents' RICO claims for failure to adequately plead proximate causation. Noting a split in authority among the circuits, the district court found "persuasive" Judge Easterbrook's reasoning in "a highly similar case." Pet. App. 57a-58a (citing *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 873 F.3d 574, 578 (7th Cir. 2017)).

The Ninth Circuit reversed. Analyzing the existing circuit split over RICO's "direct relation" test for proximate cause, the panel rejected the Second and Seventh Circuits' view that the independent decisions of prescribing doctors and pharmacy benefit managers "sever the chain of proximate cause." Pet. App. 31a. Instead, the panel focused on "foreseeability," opining that "it was perfectly foreseeable that physicians who prescribed Actos would play a causative role in" more Actos sales. *Id.* at 32a. Any other conclusion, the appeals court said, would "insulate" prescription drug makers from liability for wrongdoing, by allowing them to "continuously hide behind prescribing physicians and pharmacy benefit managers." *Id.* at 33. So long as the respondents allege injuries that are the "consequences" of the petitioners' "own acts and omissions," the court held, RICO's proximate-cause requirement is satisfied. *Id.*

In a lone footnote in a separate, unpublished memorandum, the Ninth Circuit also rejected the petitioner's Article III standing challenge. Pet. App. 40a-41a n.1. Relying on circuit precedent, the panel reaffirmed that an injury in fact exists any time that plaintiffs—like the respondents here—allege they bought a product "'when they otherwise would not have done so, because Defendants made deceptive claims and failed to disclose known risks.'" *Id.* (quoting *Mazza v. Am. Honda Motor Co.*, 666 F.3d 581, 595 (9th Cir. 2012)). Applying that rule, the appeals court held that the respondents' core allegation—"that they purchased Actos, which they would not have done absent Defendants' fraudulent scheme to conceal Actos's risk of bladder cancer"—satisfies Article III's injury-in-fact requirement. *Id.*

SUMMARY OF ARGUMENT

The petition presents the Court with two independent and equally compelling reasons to grant review:

First, this Court has long scrutinized—and consistently rejected—any attempt to expand the bounds of what constitutes a "Case or Controversy" under Article III of the Constitution. As the petition convincingly shows, the decision below ignores that rigorous approach to Article III standing.

Not every injury in law is an injury in fact. To pass muster under Article III, a claimed injury to a statutorily conferred right "must actually exist"; it cannot be merely "abstract." *Spokeo*, 136 S. Ct. at 1548. A mere "self-contained" cause of action cannot establish standing. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 572 (1992). Instead, a plaintiff must show a "separate concrete interest" that is both impaired by the challenged conduct and redressable by the lawsuit. *Id.*

Yet apart from their desire for a treble-damages payday, the respondents here have no "personal stake in the outcome of the controversy." *Flast v. Cohen*, 392 U.S. 83, 99 (1968). The respondents admit to taking Actos as prescribed, receiving the bargained-for benefit, and suffering no ill effects. They disclaim any personal injury, as they must; and they have abandoned any excess-price theory of harm. The respondents may well have buyer's remorse; they doubtless would like treble their money back. But none of that is enough to establish a concrete, particularized injury under Article III.

By relieving the respondents of their burden to plead an injury in fact caused by an alleged RICO violation, the Ninth Circuit's holding contradicts this Court's Article III precedents, widens an entrenched circuit split, and invites an avalanche of no-injury RICO suits. We write separately to elaborate on just how badly the Ninth Circuit botched its perfunctory standing analysis, and to explain why the panel's departure from settled law invites great mischief.

Second, this Court has insisted that even real-world injuries "have countless causes, and not all should give rise to legal liability." *CSX Transp., Inc. v. McBride*, 564 U.S. 685, 692-93 (2011) (citation omitted). "Life is too short," Justice Scalia observed, "to pursue every human act to its most remote consequence." *Holmes*, 503 U.S. at 287 (Scalia, J., concurring).

That is why RICO's proximate-cause requirement exists—to prevent plaintiffs from recovering downstream economic harms for injuries more directly incurred by others. Proximate cause requires "some direct relation between the injury asserted and the injurious conduct alleged." *Bridge*, 553 U.S. at 654. Its function is to stop "intricate, uncertain inquiries from overrunning RICO litigation." *Anza v. Ideal Steel Supply*, 547 U.S. 451, 460 (2006).

The panel below refused to apply this Court's directness test for proximate causation. It flatly rejected any suggestion that the independent decisions of prescribing doctors and pharmacy benefit managers could "sever the chain of proximate cause." Pet. App. 31a. Although many contingencies influence a doctor's decision to prescribe Actos—and a TPP's de-

cision to reimburse for that prescription—the Ninth Circuit insists that none of that matters.

Regardless what the panel says, the respondents cannot escape RICO's proximate-cause requirement "merely by alleging that the fraudulent scheme embraced all those indirectly harmed by the alleged conduct." *Hemi Grp., LLC v. City of New York*, 559 U.S. 1, 13 (2010) (plurality op.). The Ninth Circuit's holding not only parts company with the Second and Seventh Circuits, as the petition shows; it flouts this Court's own RICO precedents. If allowed to stand, the panel's decision would transform civil-RICO's proximate-cause element into "a mere pleading rule." *Id.* That would be a calamity.

The holding below undermines the interests of basic fairness, *stare decisis*, and the rule of law. This Court's intervention is sorely needed.

REASONS FOR GRANTING THE PETITION

I. REVIEW IS NEEDED TO ENSURE THAT THE DECISION BELOW DOES NOT CREATE A RICO EXCEPTION TO ARTICLE III'S INJURY-IN-FACT REQUIREMENT.

Article III of the Constitution allows the federal courts to decide only "Cases" and "Controversies." *See* U.S. Const., Art. III, § 2. A party may raise the lack of a case or controversy "at any time in the same civil action, even initially at the highest appellate instance." *Kontrick v. Ryan*, 540 U.S. 443, 455 (2004).

To establish a case or controversy, a "plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo*, 136 S. Ct. at 1547 (citing *Lujan*, 504 U.S. at 560-61). This jurisdictional threshold is "inflexible and without exception." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 693, 705 (2013).

To pass muster under Article III, a plaintiff's alleged injury must be "distinct and palpable," *Gladstone, Realtors v. Vill. of Bellwood*, 441 U.S. 91, 114 (1979); "real and immediate," *City of Los Angeles v. Lyons*, 461 U.S. 95, 101-02 (1983); and "actual or imminent," not "'conjectural' or 'hypothetical,'" *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990) (quoting *Lyons*, 461 U.S. at 101-02). A mere statutory violation, unaccompanied by any real-world harm, is not enough. *Spokeo*, 136 S. Ct. at 1549.

The respondents' RICO claim flunks this bedrock constitutional test:

1. The only "compensable injury" flowing from a RICO violation is "the harm caused by [the] predicate acts." *Hemi Grp.*, 559 U.S. at 13 (plurality op.). Yet the respondents here identify no such harm. They have abandoned any suggestion that the petitioners' alleged omission caused them to pay inflated prices for Actos. *See* Pet. App. at 9a. They must disclaim any personal injury, not only because RICO limits recovery to damages caused by injury to "business or property," 18 U.S.C. § 1964(c), but also given the petitioners' global settlement and release with 99.4% of all known, eligible Actos personal-

injury claimants. *See In re Actos Prod. Liab. Litig.*, No. 6:11-MD-2299, 2017 WL 3033134, at *1, *13 (W.D. La. July 17, 2017). Indeed, the very premise of the respondents' suit is that they comprise a discrete class of plaintiffs *not* injured by ingesting Actos (or by reimbursing those who were).

The respondents' theory of harm runs something like this: the petitioners sold Actos; the petitioners allegedly failed to report an increased risk of bladder cancer to the FDA; the FDA, in turn, failed for a time to require Takeda to warn doctors, through Actos's label, about that risk; the respondents bought and used Actos (or, for Painters Fund, reimbursed those who did); before the FDA required Takeda to revise the label, doctors prescribed more Actos than they otherwise would have; *other* patients—but *not* the respondents—were injured by Actos; the respondents would like treble their money back.

But no respondent has been personally affected by the petitioners' alleged omission. Again, respondents do not claim that Actos caused them any physical or emotional injury, failed to control their high blood sugar, or adversely affected them in any way. Indeed, even accepting all the respondents' allegations as true, the petitioners' alleged omission hasn't impacted the respondents in the slightest. An injury in fact "requires more than an injury to a cognizable interest. It requires that the party seeking review be himself among the injured." *Sierra Club v. Morton*, 405 U.S. 727, 734-35 (1972). The respondents clearly are not.

In the Ninth Circuit's view, however, *everyone* who pays for a drug with a latent, undisclosed risk suffers an injury under Article III—even if one takes the drug as prescribed, receives the bargained-for benefit, and suffers no ill effects. *See* Pet. App. 40a-41a. That holding jettisons Article III's rule that "the party bringing suit must show that the action injures him in a concrete and personal way," *Lujan*, 504 U.S. at 581, and replaces it with a rule by which a plaintiff need only plead a federal cause of action.

RICO changes nothing. A mere right to seek statutory damages cannot confer standing; it is no more than "a wager upon the outcome" of the suit, which is "unrelated to injury in fact." *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 772 (2000). The respondents' demand for treble damages is a "'byproduct' of the suit itself." *Id.* at 773. "Merely asking for money does not establish an injury in fact." *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 319 (5th Cir. 2002).

The respondents' RICO claim is neither needed, nor intended, to make them whole. They are no worse off than they would have been had Actos's label disclosed, on day one, an increased risk of bladder cancer. *See id.* at 320 ("Duract worked. Had Wyeth provided additional warning or made Duract safer, the plaintiffs would be in the same position they occupy now.") Put differently, "buyer's remorse, without more, is not a cognizable injury under Article III." *In re Johnson & Johnson Talcum Powder Prods. Mktg.*, 903 F.3d 278, 281 (3d Cir. 2018).

2. Private citizens lack "a judicially cognizable interest" in enforcing federal law. *Linda R.S. v.*

Richard D., 410 U.S. 614, 619 (1973). Even assuming a RICO violation here, the respondents cannot sue in federal court merely to vindicate a generalized interest in seeing federal law obeyed. *FEC v. Akins*, 524 U.S. 11, 24 (1998) (collecting cases).

This is no picayune formality. The Constitution's broad limits on federal-court jurisdiction are "founded in concern about the proper—and properly limited—role of courts in a democratic society." *Warth v. Seldin*, 422 U.S. 490, 498 (1975). Article III's case-or-controversy requirement "prevent[s] the judicial process from being used to usurp the powers of the political branches." *Clapper*, 568 U.S. at 408. By preventing unelected, life-tenured judges from exercising legislative or executive powers, the injury-in-fact requirement cabins the federal courts within their constitutional role—redressing "actual or imminently threatened injury to persons caused by private or official violation of law." *Summers v. Earth Island Inst.*, 555 U.S. 488, 492 (2009).

The decision below, if left to stand, would erode the Constitution's carefully calibrated separation of powers. Though the respondents admit they suffered no real injury and incurred no actual harm, the Ninth Circuit held that their RICO claim presents a case or controversy under Article III. This failure to police Article III's jurisdictional threshold will invariably lead to "an overjudicialization of the processes of self-governance." Antonin Scalia, *The Doctrine of Standing as an Essential Element of the Separation of Powers*, 17 Suffolk U. L. Rev. 881, 881 (1993).

3. The Court's standing jurisprudence "is grounded in historical practice." *Spokeo*, 136 S. Ct. at 1549. In crafting Article III, the Framers drew on "what were to them the familiar operations of the English judicial system and its manifestations on this side of the ocean before the Union." *Sprint Commc'ns Co. v. APCC Servs., Inc.*, 554 U.S. 269, 274-75 (2008) (internal citation and quotation omitted). In evaluating Article III standing, then, courts must look to whether an alleged statutory injury "has a close relationship to a harm that has traditionally been regarded as providing a basis for a lawsuit in English or American courts." *Spokeo*, 136 S. Ct. at 1549.

A tort claim premised on the respondents' theory of harm would have been unrecognizable to the Framers. In the English legal tradition from which the Framers drew, the category of wrongs justifying the exercise of judicial authority required some tangible, real-world harm. Blackstone famously enumerated the "several injuries cognizable by the courts of common law" and the "respective remedies applicable to each particular injury." 3 William Blackstone, *Commentaries on the Laws of England* 115 (1768). The kinds of legal wrongs Blackstone identified involved "real injury" to a person or his property. *Id.* at 167. The decision below thus flouts the common law's understanding that "tort recovery requires not only wrongful act plus causation reaching to the plaintiff, but proof of harm for which damages can reasonably be assessed." *Doe v. Chao*, 540 U.S. 614, 621 (2004).

True, some wrongs—like defamation and trespass—were redressable at common law with

general damages. *See Spokeo*, 136 S. Ct. at 1551 (Thomas, J., concurring). But such damages were available only if the plaintiff could prove some "special harm"—"harm of a material and generally of a pecuniary nature." 3 Restatement of Torts § 575 cmts. a & b (1938). The respondents here disclaim any of that.

Rather than try to connect the respondents' alleged injury to the kinds of harms redressable at common law, the Ninth Circuit decided—both below and in *Mazza*, on which it relied—to ignore the relevant common-law history. The panel simply announced that any plaintiff who bought something that she now supposes, in hindsight, that she would not have bought alleges a cognizable injury under Article III. Pet. App. 40a-41a n.1 (quoting *Mazza*, 666 F.3d at 595). But "there is a difference between allegations that stand on well-pleaded facts and allegations that stand on nothing more than supposition." *Finkelman v. Nat'l Football League*, 810 F.3d 187, 201 (3d Cir. 2016). The respondents' "speculation is not enough to sustain Article III standing." *Id*. at 200.

Even if the respondents relied on Actos's label—only one respondent claims even to have read that label, Pet. App. 8a—a "compensable loss exists only if the plaintiff incurred some actual loss in reliance on the misrepresentation, mainly out-of-pocket losses based on any difference between the purchase price and fair market value of the good." Jill Wieber Lens, *Honest Confusion: The Purpose of Compensatory Damages in Tort and Fraudulent Misrepresentation*, 59 U. Kan. L. Rev. 231, 268 (2011). The respondents disavow any such loss. Pet. App. 9a n.3

("Plaintiffs have abandoned their excess-price theory for damages on appeal.").

Left to stand, the decision below would render this Court's repeated directive to compare a plaintiff's alleged harm to the "historical practice" of the common law all but meaningless in RICO cases.

II. ONLY THIS COURT CAN PREVENT THE LOWER COURTS FROM EVADING CIVIL RICO'S CRUCIAL PROXIMATE-CAUSE REQUIREMENT.

RICO's civil damages provision affords a private cause of action to a person injured "by reason of" a violation of the RICO statute. 18 U.S.C. § 1964(c). The phrase "by reason of" precludes recovery on a mere showing that the defendant's RICO violation was a "but for" cause of the plaintiff's injury. *Holmes*, 503 U.S. at 265-68. Instead, a plaintiff must show that the defendant's conduct was the "proximate cause" of the plaintiff's injury. *Id.* Proximate cause ensures "some direct relationship between the injury asserted and the injurious conduct alleged." *Id.* at 268. The respondents' RICO claim fails that test.

1. The "general tendency of the law, in regard to damages at least, is not to go beyond the first step." *Associated Gen. Contractors of Cal., Inc. v. Carpenters*, 459 U.S. 519, 534 (1983) (quoting *S. Pac. Co. v. Darnell-Taenzer Lumber Co.*, 245 U.S. 531, 533 (1918)). This "general tendency" applies "with full force to proximate cause inquiries under RICO." *Hemi Grp.,* 559 U.S. at 10 (plurality op.); *Holmes*, 503 U.S. at 271-72. Because their theory of harm requires the courts to go well beyond the first step, the

respondents cannot satisfy RICO's proximate-cause requirement.

The causal chain running from the FDA-approved labeling and marketing of Actos to the respondents' alleged injury is long and imponderable. Under the respondents' theory of harm:

- The petitioners failed, when submitting Actos for FDA approval, to disclose an alleged increased risk of bladder cancer for certain users.

- The FDA approved the labeling and marketing of Actos.

- Physicians reviewed Actos's label and relied on it.

- TPPs like Painters Fund either chose to cover Actos or delegated that decision to pharmacy benefit managers (PBMs).

- PBMs recommended that TPPs, including Painters Fund, include Actos on payor formularies.

- Physicians, exercising their professional judgment while considering each patient's unique medical history, chose to prescribe Actos rather than some other FDA-approved diabetes drug.

- The individual respondents filled their Actos prescriptions.

- The individual respondents took Actos as directed, suffering no adverse effects.

- The individual respondents paid out of pocket for Actos or submitted their costs to Painters Fund for reimbursement.

- Painters Fund reimbursed those prescriptions (and continues to do so).

Far from being the first step, then, the respondents' payments are several steps removed down the chain of proximate causation.

"Payors part with money, to be sure, but it is not at all clear that they are the initially injured parties, let alone the sole injured parties." *Sidney Hillman*, 873 F.3d at 576 (Easterbrook, J.). Indeed, those who "suffer adverse health effects" and so "incur financial loss[es]" are harmed more directly than the respondents. *Id.* The very existence of more directly injured persons—those who allege personal injuries—only magnifies the indirectness of the respondents' alleged harms and the lack of proximate causation.

"Physicians may also lose, though less directly." *Id.* People with high blood sugar and type-2 diabetes want medical help. If a physician prescribes an unduly risky medicine that does more harm than good, "patients may turn elsewhere." *Id.* If that happens, physicians stand to "lose business and revenue." *Id.*

In contrast, the injury for which the respondents seek recovery "is remote indeed, the chain of

causation long," and "the damages wickedly hard to calculate." *Int'l Bhd. of Teamsters v. Philip Morris Inc.*, 196 F.3d 818, 825 (7th Cir. 1999) (Easterbrook, J.). This is precisely why the proximate-cause requirement exists. *See UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 134 (2d Cir. 2010) ("Plaintiffs' theory of liability rests on the independent actions of third and even fourth parties, as physicians, PBMs [Pharmacy Benefit Managers], and PBM Pharmacy and Therapeutics Committees all play a role in the chain between [the drug maker] and TPPs.").

The causal chain for Painters Fund's alleged harm is more attenuated still. *See Emp'r Teamsters-Local Nos. 175/505 Health & Welfare Trust Fund v. Bristol Myers Squibb Co.*, 969 F. Supp. 2d 463, 475 (S.D. W.Va. 2013) ("Between Defendants' alleged misleading marketing and Plaintiffs' prescription reimbursements lies a vast array of intervening events."). And the fact that Painters Fund continues to reimburse its members for Actos prescriptions—despite the alleged increased risk of bladder cancer—undercuts its case even more.

In fact, it is far from clear that "but for" the petitioners' alleged omission, Painters Fund would have done anything differently. *See Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 87 (2d Cir. 2015) ("[I]f the person who was allegedly deceived by the misrepresentation (plaintiff or not) would have acted in the same way regardless of the misrepresentation, then the misrepresentation cannot be a but-for, much less proximate, cause of the plaintiff's injury.").

The respondents' theory of causation carries the courts well beyond the first step. It cannot possibly satisfy RICO's direct-relationship test.

2. The Ninth Circuit insists that "it was perfectly foreseeable that physicians who prescribed Actos would play a causative role in" more Actos sales. Pet. App. 32a. Maybe so. But mere foreseeability isn't the test for proximate causation. "When 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." *Holmes*, 503 U.S. at 271.

Though the panel insisted that foreseeability is the key to proximate causation, this Court has heard it all before. The Ninth Circuit's foreseeability test is the same one urged by the dissent—and roundly rejected by the majority—in *Anza v. Ideal Steel Supply*. After *Anza*, a RICO plaintiff "cannot circumvent the proximate-cause requirement simply by claiming that the defendant's aim" was to harm the plaintiff. 547 U.S. at 460. Instead, RICO looks to "whether the alleged violation led directly to the plaintiff's injuries." *Id.* at 461. Because the "answer" to that question in *Anza* was "no," it didn't matter that the plaintiff's injuries were foreseeable—or even intentional. *Id.*

Hemi Group, too, categorically rejected any foreseeability "line of reasoning." 559 U.S. at 12 (plurality op.) ("*Anza* and *Holmes* never even mention the concept of foreseeability."). Allowing "RICO's proximate cause requirement [to] turn on foreseeability rather than on the existence of a sufficiently 'direct relationship' between the fraud and the

harm," Chief Justice Roberts explained, would require the Court to overturn *Anza*. *Id*. (plurality op.). Try as it might, the Ninth Circuit cannot do that.

Foreseeability is easy. "If one takes a broad enough view, *all* consequences of a negligent act, no matter how removed in time or space, may be foreseen." *Consol. Rail Corp. v. Gottshall*, 512 U.S. 532, 552-53 (1994). Proximate cause demands more. Above all, proximate cause is "a necessary limitation on liability." *Exxon Co., U.S.A. v. Sofec, Inc.*, 517 U.S. 830, 838 (1996). Indeed, "there are clear judicial days on which a court can foresee forever and thus determine liability[,] but none on which that foresight alone provides a socially and judicially acceptable limit on recovery." *Thing v. La Chusa*, 771 P.2d 814, 830 (Cal. 1989).

This Court should grant review to prevent "foreseeability" from becoming the touchstone for proximate cause under RICO.

3. According to the Ninth Circuit, if "prescribing physicians and pharmacy benefit managers' decisions constitute an intervening cause to sever the chain of proximate cause," then "drug manufacturers would be insulated from liability for their fraudulent marketing schemes, as they could continuously hide behind prescribing physicians and pharmacy benefit managers." Pet. App. 33a.

But that rationale turns a blind eye to the 11,000 Actos personal-injury claimants who sued—and recovered—for any personal or financial injury caused by Actos. According to the MDL Court, 99.4% of all known, eligible claimants participated in the

global settlement. *See In re Actos Prod. Liab. Litig.*, No. 6:11-MD-2299, 2017 WL 3033134, at *1, *13. That settlement included a payor lien-resolution program. *Id.* at *18.

Contrary to the Ninth Circuit's view, there are many ways to deter wrongdoing by drug makers other than by bringing a treble-damages RICO class action. Indeed, the MDL settlement itself arose from product-liability claims. And unlike private plaintiffs, the government may punish and enjoin unlawful conduct under RICO without the added hurdle of proving an injury caused "by reason of" the violation. *See* 18 U.S.C. § 1963.

No authority exists permitting the Ninth Circuit to transform RICO into a tool for settling scores with the pharmaceutical industry, or for redistributing resources without regard to causation.

III. REVIEW IS NEEDED TO STEM THE TIDE OF CIVIL RICO ABUSE INVITED BY THE DECISION BELOW.

If RICO is a blunt instrument, civil RICO is "the litigation equivalent of a thermonuclear device." *Miranda v. Ponce Fed. Bank*, 948 F.2d 41, 44 (1st Cir. 1991). Given the statute's remarkable breadth and generous remedies, and given how easily a motivated plaintiffs' attorney can bring everyday business activities under its ambit, civil RICO is an invitation for *in terrorem* suits.

Though Congress enacted RICO as a new tool for combating organized crime, civil RICO is rarely used for that purpose. Instead, the ever-increasing

number of civil RICO suits filed each year target activity that would not fit most people's definition of "racketeering."

Because courts have construed RICO's text so broadly, civil-RICO claims now arise in disputes that Congress never could have intended the statute to cover. "Through innovative lawyering, civil RICO claims have centered on a myriad of subjects, including sexual harassment, the 1986 air strike on Libya, mismanagement of hazardous waste sites, anti-abortion protest activities, a parishioner's grievances against her former church, a strict products liability suit involving defective infant formula, and a wrongful discharge action." Petra J. Rodrigues, *The Civil RICO Racket: Fighting Back with Federal Rule of Civil Procedure 11*, 64 St. John's L. Rev. 931, 936-37 (1990).

Judges and legal scholars have routinely criticized civil RICO's overly expansive reach for giving "many ordinary civil cases" an "entrée to federal court." Anne B. Poulin, *RICO: Something for Everyone*, 35 Vill. L. Rev. 853, 857 (1990); *see Anza*, 547 U.S. at 471-72 (Thomas, J., dissenting) ("Judicial sentiment that civil RICO's evolution is undesirable is widespread."); William H. Rehnquist, *Remarks of the Chief Justice*, 21 St. Mary's L.J. 5, 13 (1989) (inviting "amendments to civil RICO to limit its scope to the sort of wrongs that are connected to organized crime, or have some other reason for being in federal court").

Of course, the allure of RICO for private plaintiffs and their attorneys is not hard to grasp. RICO applies not only to individual actors, but also

to corporations, and it promises treble damages and full recovery of costs, including attorney fees, to prevailing plaintiffs. *See Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 504 (1985) (Marshall, J., dissenting) ("RICO is out of control not only because it is so easy to claim grounds for a suit, but because the appeal of treble damages plus legal fees has proved irresistible for plaintiffs and their lawyers."). And RICO's liberal venue provision, which permits suit in any district in which the defendant "resides, is found, has an agent, or transacts his affairs," 18 U.S.C. § 1965(a), allows a civil-RICO plaintiff to effectively shop for a forum of her choosing.

"Once a clever lawyer can characterize an opponent's actions as constituting one or two of the myriad of predicate acts, it takes little imagination to deem those actions RICO violations." Robert K. Rasmussen, *Introductory Remarks and a Comment on Civil RICO's Remedial Provisions*, 43 Vand. L. Rev. 623, 626 (1990). Civil-RICO plaintiffs (and their attorneys) can leverage the disastrous public-relations impact of RICO's title to force settlements from firms that, understandably, fear the loss of goodwill and reputation that would accompany news of their alleged "racketeering" activity. Simply put, the "danger of vexatiousness" is acute in civil-RICO suits. *Int'l Data Bank, Ltd. v. Zepkin*, 812 F.2d 149, 153 (4th Cir. 1987).

What's more, data suggests that private plaintiffs are filing more and more RICO lawsuits for alleged "racketeering" that federal prosecutors see no reason to pursue. Between 2001 and 2006, for example, plaintiffs brought "an average of 759 civil-RICO claims" each year. Nicholas L. Nybo, *A Three-Ring*

Circus: The Exploitation of Civil RICO, How Treble Damages Caused It, and Whether Rule 11 Can Remedy the Abuse, 18 Roger Williams U. L. Rev. 19, 24 (2013). Yet during that same stretch of time, "a paltry average of 212 criminal RICO cases were referred to the United States Attorney's Office." *Id*. Similarly, a 2002 study found that, of all RICO cases decided by federal appellate courts between 1999 and 2001, 78% were civil and only 22% were criminal. Pamela H. Busy, *Private Justice*, 76 S. CAL. L. REV. 1, 22 & n.111 (2002). Even when injury in fact and proximate cause are not in dispute, civil RICO is uniquely prone to abuse.

In the end, a civil-RICO action in which a plaintiff need not show actual harm or proximate cause is a powerful cudgel for securing lucrative settlements. Few companies are prepared to roll the dice on incurring a treble damages judgment, plus an award of attorney fees, along with the stigma that attaches to a "racketeering" jury verdict. While this hydraulic leverage to settle is calculated to extract windfalls from large companies like the petitioners, small businesses are even more susceptible to *in terrorem* settlements. But a world in which companies feel obliged to settle baseless civil-RICO claims would not only be bad for business, it would erode the American legal system. Justice is never served when the plaintiff's payday does not reflect the likelihood that the plaintiff was harmed or that the defendant caused that harm.

"This Court has interpreted RICO broadly, consistent with its terms," but it has "also held that its reach is limited by the 'requirement of a direct causal connection' between the predicate wrong and

the harm." *Hemi Grp.*, 559 U.S. at 17-18 (plurality op.). Unless the Court reverses the aberrant holding below, speculative RICO claims will proliferate even more. And while civil actions under RICO have always been a lightning rod for criticism, extending RICO to cover purely abstract, inchoate harms—as the Ninth Circuit did here—further exacerbates the problem. Given the unusual breadth of RICO, the untold mischief to follow from eliminating Article III's injury-in-fact requirement offers the Court an independent reason to grant review.

CONCLUSION

The petition should be granted.

Respectfully submitted,

CORY L. ANDREWS
Counsel of Record
CORBIN K. BARTHOLD
WASHINGTON LEGAL FOUNDATION
2009 Mass. Ave., NW
Washington, DC 20036
(202) 588-0302
candrews@wlf.org

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