No. 19-1069

In the Supreme Court of the United States

TAKEDA PHARMACEUTICAL COMPANY LIMITED ET AL.,
PETITIONERS,

v.

PAINTERS AND ALLIED TRADES DISTRICT COUNCIL 82
HEALTH CARE FUND, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

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QUESTIONS PRESENTED

1. Whether prescription drug end payors may recover treble damages under RICO for the consequences of fraud allegedly perpetrated on doctors and pharmacy benefit managers, as the First and Ninth Circuits have held, or whether the payors are simply too far removed from the alleged fraud to maintain a RICO claim, as the Second and Seventh Circuits have held.

2. Whether a plaintiff who paid for a prescription drug that treated a condition safely and effectively nonetheless has an Article III injury under RICO based solely on alleged fraudulent inducement to purchase the drug, as the Ninth Circuit held below, or whether Article III requires that the fraud result in an actual economic loss to the plaintiff, as the Third and Fifth Circuits have held.

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INTEREST OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's member companies research, develop, and manufacture medicines that allow patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $900 billion in the search for new treatments and cures, including an estimated $79.6 billion in 2018 alone—more R&D investment than any other industry in America. PhRMA's mission is to advocate public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA closely monitors legal issues that affect the pharmaceutical industry and frequently participates as an amicus curiae in cases before this Court.

This case presents two critically important and recurring questions concerning treble damages claims under the Racketeer Influenced and Corrupt Organizations Act (RICO). Health insurance companies and other third-party payors (TPPs), as well as patients, now regularly bring RICO lawsuits against *amicus*'s members on the theory that a pharmaceutical manufacturer's alleged wrongful statements and non-disclosures about its product caused the plaintiffs to buy too much of—or pay too much for—the product in comparison to available

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[1] No counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund the preparation of or submission of this brief. No one other than the *amicus curiae*, its members, or its counsel made a monetary contribution to the preparation or submission of this brief. The parties were given timely notice and consented to this filing.

alternatives. The decision below, in holding that the respondents pleaded injury and causation for a RICO claim, deepens two circuit conflicts, one on the application of this Court's RICO proximate-cause precedents to such claims, and another on the meaning of Article III's injury in fact requirement in the RICO context. These claims are proliferating, and the Ninth Circuit's decision encourages plaintiffs to bring still more.

More broadly, the Ninth Circuit's decision highlights uncertainty in the lower courts about the correct standard for proximate cause under RICO and the meaning of Article III injury in fact in the RICO context. The lure of treble damages, together with uncertain proximate-cause and Article III injury standards, invites increasingly tenuous claims that threaten to stretch civil RICO far beyond its original design. The flood of cases facing *amicus*'s members and the courts, and the uncertainty that the geographic divergence on these legal issues engenders, makes this Court's immediate review essential.

INTRODUCTION AND SUMMARY OF ARGUMENT

Congress enacted RICO to combat organized crime and to protect legitimate businesses from criminal elements and influence by imposing criminal and civil liability on persons and businesses operated in specified corrupt and illegal ways. The criminal RICO statute provides for significant prison sentences and fines, while the civil RICO statute, referred to as "the litigation equivalent of a thermonuclear device," *Miranda* v. *Ponce Fed. Bank*, 948 F.2d 41, 44 (1st Cir. 1991), permits private plaintiffs—individuals and businesses alike—to file lawsuits to recover threefold monetary damages for conduct that violates RICO.

In the words of Judge Gerard Lynch, RICO is supposed to address the crime of being a criminal. Gerard E. Lynch, *RICO: The Crime of Being A Criminal, Parts I & II*, 87 Colum. L. Rev. 661, 700-01 (1987). But decades after its enactment, RICO has drifted farther and farther afield. Civil RICO—as it is used today—is frequently invoked to address the "crime" of engaging in marketing and promotion of lawful, FDA-approved pharmaceutical products, at least where, as here, a plaintiff can stitch together enough facts to make out an allegation of some wrongful statement or non-disclosure by a product's manufacturer.[2]

So transformed, RICO threatens legitimate companies with potentially devastating triple-damages liability (plus attorneys' fees) for an alarming range of garden-variety torts that were once thought to be the province of state consumer-protection and anti-fraud statutes. RICO offers the lure of treble recovery to all who can shoehorn their claims into RICO's broad predicate acts, the most popular being allegations of unindicted (indeed, *unnoticed*) federal mail and wire fraud. All too often these claims of unindicted federal criminal fraud are brought against legitimate companies for nothing more than their harassment and settlement value.

This case is just one of the latest in a deluge of RICO suits brought by third-party payers and patients against pharmaceutical manufacturers seeking extraordinary sums for the consequences of purportedly wrongful

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[2] Plaintiffs began pleading RICO claims in consumer class actions to obtain class certification under Rule 23. False advertising class actions under state consumer protection statutes required courts to apply the varying consumer protection laws of all 50 states and, therefore, plaintiffs could not establish the predominance of common legal questions required by Rule 23(b)(3), resulting in the denial of class certification. Plaintiffs' attorneys turned to RICO to obtain class certification under a single applicable law.

statements and non-disclosures allegedly made to *different* parties. In these cases, plaintiffs seek treble damages under 18 U.S.C. § 1964(c) for injuries supposedly resulting from a pharmaceutical company's statements or non-disclosures about a product not to TPPs or patients themselves, but to pharmacy benefit managers (PBMs), physicians, and consumers. As here, plaintiffs usually allege, through a long and convoluted causal chain, that the manufacturer's failure to convey certain information about the risks or benefits of its drug amounted to unindicted wire and mail fraud that caused PBMs to add the drug to their formularies or physicians to prescribe the drug more often (or both), resulting in payments for more prescriptions than otherwise would have been written.

These cases are extraordinary in several respects. The plaintiffs in these cases do not allege that they saw, heard, or otherwise received any alleged misinformation. And they do not plan to prove their claims by showing that any individual physicians were actually misled. Rather, they plan to use a complex and imprecise regression analysis to show that some percentage of physicians must have been misled based on aggregate prescribing patterns—even though physicians are learned intermediaries who exercise independent medical judgment in making prescribing decisions, and even though PBMs are sophisticated consumers of information about prescription drugs that do their own research, study, and analysis of medications and are unlikely to add medicines to their formularies on the basis of drug manufacturer statements. The plaintiffs further admit that patients who used the product for which they now seek a full refund not only suffered no ill effects but actually benefitted by taking the medicine. The plaintiffs here thus are seeking a massive recovery based on purported derivative injuries, through a multi-step chain of causation, without suffering any real underlying injury.

The question whether the derivative injury at the heart of these cases states a plausible RICO claim recurs frequently and implicates a deeply unsettled area of law. This Court has long recognized the threat that RICO poses to legitimate commerce if permitted to sweep too far, and it has invoked ordinary tort principles to curb RICO's excesses. See, *e.g.*, *Anza* v. *Ideal Steel Supply Corp.*, 547 U.S. 451, 471 (2006) (Thomas, J., concurring in part and dissenting in part). Among the most powerful of these defenses is the requirement of proximate causation. More than two decades ago, this Court held in *Holmes* v. *Securities Investor Protection Corporation*, 503 U.S. 258 (1992), that § 1964(c) requires RICO plaintiffs to plead and prove proximate cause. And in the decades since *Holmes*, the Court has insisted that RICO proximate cause should restrict liability to a short causal chain to ensure that RICO suits are limited to *direct* victims of RICO violations. See *Hemi Grp. LLC* v. *City of New York*, 559 U.S. 1, 9-10 (2010) (plurality opinion); *Bridge* v. *Phoenix Bond & Indem. Co.*, 553 U.S. 639, 654-55 (2008); *Anza*, 547 U.S. at 457-58.

But *Holmes* did not articulate a clear test for proximate cause. And the Court's three decisions on the issue since then—*Hemi*, *Bridge*, and *Anza*—have not provided the needed clarity. Instead, as this Court has grappled with the issue, its divided rulings have sent mixed messages to lower courts. Though it has remained paramount that RICO proximate cause requires a direct injury, lower courts have been left to their own devices in how to apply this "direct" injury principle.

The result is that some circuits have been lengthening the causal chain substantially. In the process, these courts have triggered a torrent of class action treble damages RICO suits and jeopardized a broad sector of the American economy. The RICO false advertising cases against pharmaceutical companies are only the tip of an

enormous iceberg. In the First and Ninth Circuits, no business that engages in promotion and marketing is safe from a RICO suit. The only defense is empty pockets. And because of RICO's nationwide reach, plaintiffs bring these lawsuits in circuits with favorable rules. Savvy plaintiffs know to sue in the First and Ninth Circuits. The threat of sweeping RICO lawsuits in these circuits harms competition and legitimate enterprise nationwide by chilling truthful commercial speech to consumers everywhere.

This Court's intervention is urgently needed to reaffirm the core principle that RICO liability may only extend one "step" in the causal chain from the alleged fraud predicate to the alleged injury. "As [the Court] reiterated in *Holmes*, '[t]he general tendency of the law, in regard to damages at least, is not to go beyond the first step[.]'" *Hemi*, 559 U.S. at 10 (plurality opinion). The Ninth Circuit's decision in this case extends RICO liability far beyond the "first step," instead permitting numerous steps between the alleged wrong and injury. The Court should grant certiorari to make clear that RICO does not provide a cause of action to third parties who suffer speculative injuries many steps removed from an alleged predicate act.

The petition provides a second path for resolving this case, on Article III grounds. The Court should take up that issue as well. This Court instructed the Ninth Circuit only four years ago that, to give rise to standing, an Article III injury must be "concrete" and not a mere violation of a "statutory right." *Spokeo, Inc.* v. *Robins*, 136 S. Ct. 1540, 1548-49 (2016). In this case, the Ninth Circuit held that an alleged misstatement that induces a commercial transaction—even if the party allegedly defrauded receives every benefit he had hoped for from the transaction—nonetheless qualifies as an Article III injury.

Fraudulent inducement, without a corresponding concrete injury, is not an injury in fact. "In determining whether an intangible harm constitutes injury in fact, both history and the judgment of Congress play important roles." *Spokeo*, 136 S. Ct. at 1549. History and the judgment of Congress both show that fraudulent inducement alone—without a further concrete harm—is not actionable under RICO. Common law fraud has always required a showing of actual "pecuniary loss" from fraud, not a bare allegation of having bought one product rather than another because of an alleged misstatement or nondisclosure, where the product provided the purchaser everything she sought. Restatement (Second) of Torts § 537 (1977). Congress reflected that understanding in RICO, limiting recovery to persons "injured" in their "business or property," 18 U.S.C. § 1964(c), which reveals no intent to depart from the common law's concrete injury rule.

RICO fraud suits lacking any actual injury are common, and numerous circuits have rejected them. Not only have the Third and Fifth Circuits adopted rules at odds with the decision below, see Pet. 24-26, but so have the Eleventh and Second Circuits. See *Ironworkers Local Union 68* v. *AstraZeneca Pharm., LP*, 634 F.3d 1352, 1363 (11th Cir. 2011) (explaining that a patient suffers no economic injury by being prescribed an otherwise safe and effective drug); *McLaughlin* v. *Am. Tobacco Co.*, 522 F.3d 215, 228-29 (2d Cir. 2008) (explaining that smokers who would have purchased full-flavored cigarettes instead of Lights had they known that Lights were not healthier suffer no injury), *abrogated on other grounds by Bridge*, 553 U.S. 639. For all the reasons that this Court should consider the scope of RICO proximate cause in this case, it should address the question of Article III standing as well.

This case warrants this Court's review to clarify these two important legal questions and to avoid the adverse

consequences of the Ninth Circuit's erroneous decision. The decision below comes dangerously close to transforming RICO—a law meant to take down *La Cosa Nostra*—into a federal fraud regime. Review is warranted.

ARGUMENT

The issues in this case are of enormous importance to the nation's pharmaceutical industry. The First and Ninth Circuits' rulings on proximate cause expose pharmaceutical companies to billions of dollars in potential RICO liability and millions of dollars in legal expenses on the basis of nothing more than an alleged failure to disclose an alleged drug risk soon enough. Whether TPPs and patients, many steps removed from the alleged failure to disclose, can seek damages for three times the amounts of every prescription they reimbursed—even when the medication worked as intended and the patient benefitted from the treatment—is a question of exceptional national importance.

Even if there were no circuit split, the decision below is of such staggering nationwide impact that it would warrant this Court's review. The Ninth Circuit includes California, the largest economy in the United States and by itself the fifth largest in the world. And RICO's nationwide jurisdictional reach means plaintiffs can find a forum within the Ninth Circuit as a matter of course no matter where the alleged wrongdoing occurred. Thus, the fact that the holding below is now the law in the Ninth Circuit effectively makes it the law for the entire country on an issue of tremendous economic importance. Moreover, the sheer breadth of the holding, inviting RICO lawsuits by any plaintiff that can plausibly claim a "foreseeable" injury for a speculative harm, offers an easy-to-follow roadmap and promises a new phase of even more aggressive RICO litigation. The importance of the holding for every pharmaceutical company in America warrants certiorari in its own right.

The decision below is also clearly wrong, and this case is an ideal vehicle for resolving the questions presented. RICO's proximate cause requirement cuts off liability after the first step. All the important reasons for that rule coalesce here: the purported damages are difficult to ascertain; the suits raise a serious risk of double recovery; and in the already highly regulated pharmaceutical industry, RICO suits are more likely to over-deter and seriously damage the marketplace than promote the public interest. And the mere fact that a manufacturer's alleged wrongful statement or non-disclosure caused a buyer to purchase one product rather than another does not give rise to an Article III injury in fact. The Court should decide these questions now. Both questions are dispositive in this case and there are no barriers to this Court's review.

I. THE QUESTIONS PRESENTED ARE IMPORTANT

The lack of clarity from this Court on the two questions presented has caused an onslaught of RICO lawsuits against *amicus*'s members brought by TPPs and patients based on alleged wrongful prescription drug marketing. The Ninth Circuit's decision invites a new wave of RICO litigation that further threatens to burden lower courts for years to come and which, in turn, could chill the incentives to settle underlying product liability or False Claims Act cases. Without this Court's guidance, these cases will continue.

A. Courts Are Flooded With RICO Suits Accusing Pharmaceutical Companies of Racketeering

Consistent with its origins as a statute that targets criminal activity, to win a civil RICO suit, a plaintiff must prove that the defendant (or someone who conspired with the defendant) committed multiple crimes (so-called "predicate acts") over an extended period. See 18 U.S.C. § 1961(1). RICO's predicates cover specified federal

felony offenses, including mail and wire fraud, *id.* §§ 1341, 1343, as well as various violent offenses, *id.* § 1961(1). If there is no crime, there is no RICO violation.

Remarkably, given the serious wrongdoing a RICO predicate implies, over the last decade TPPs and patients have brought dozens of multibillion-dollar RICO suits against many of the nation's leading pharmaceutical companies. There are at least half a dozen such suits pending right now. Nearly all of them implicate the proximate cause and Article III injury questions presented in this case:

- *In re Testosterone Replacement Therapy Prod. Liab. Ligitation*, No. 14 C 1748, 2019 WL 652217, at *8–9 (N.D. Ill. Feb. 14, 2019), *aff'd sub nom. Med. Mut. of Ohio* v. *AbbVie Inc.*, 784 F. App'x 457 (7th Cir. 2019) (finding no RICO proximate cause under the controlling Seventh Circuit test);
- *In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-2804, 2020 WL 871539, at *8 (N.D. Ohio Feb. 21, 2020) (joining the First and Ninth Circuits in finding plaintiff adequately pleaded RICO proximate cause);
- *City of Rockford* v. *Mallinckrodt ARD, Inc.*, 360 F. Supp. 3d 730, 774–75 (N.D. Ill. 2019) (finding no RICO proximate cause); and
- *In re Xarelto (Rivaroxaban) Prod. Liab. Litig.*, No. 15-4790, 2017 WL 4517287 (E.D. La. Oct. 10, 2017) (claims by TPPs to recover for alleged fraud on doctors and PBMs).

Like respondents in this case, the plaintiffs in these similar lawsuits accuse manufacturers of engaging in an ongoing pattern of criminal racketeering, based solely on alleged wrongful marketing to other parties. Without this Court's intervention, more of these RICO suits will be launched against leading pharmaceutical companies

accusing them of engaging in felony mail and wire fraud in the coming years—not because it is likely they actually committed criminal acts, but because of the allure of treble damages.

These suits are commonplace because the factual allegations underpinning plaintiffs' RICO claims are ordinary. The FDA regularly issues warning letters to pharmaceutical companies challenging particular statements in the companies' labeling of their products or promotional materials. In the past three years, the FDA Office of Prescription Drug Promotion has issued 22 such letters.[3] FDA often concludes, after communications with the company, that the statements at issue do not warrant sanction, but its warning letters have nevertheless proven a potent stimulus to private lawsuits alleging misrepresentations or nondisclosures. The court of appeals decisions validating RICO claims and dangling the incentive of treble damages incentivize these types of lawsuits.

B. The First And Ninth Circuits' Decisions Eliminate An Essential Safeguard Against Abusive RICO Suits

This Court recognized in *Holmes* that proximate cause is an essential safeguard against vexatious RICO litigation. See 503 U.S. at 268-70. "Allowing [RICO] suits by those injured only indirectly would open the door to massive and complex damages litigation, which would not only burden the courts, but would also undermine the effectiveness of treble damages suits." *Id.* at 274 (internal citations and quotations omitted). As the Court explained, the proximate cause requirement protects defendants by

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[3] See U.S. FDA Office of Prescription Drug Promotion, *Warning Letters and Notice of Violation Letters to Pharmaceutical Companies*, https://www.fda.gov/drugs/enforcement-activities-fda/warning-letters-and-notice-violation-letters-pharmaceutical-companies.

ensuring that (1) a plaintiff's damages are reasonably ascertainable so that defendants are not subjected to wildly uncertain liability; (2) defendants are not required to pay numerous plaintiffs to compensate for the same injury; and (3) defendants are not chilled from engaging in socially valuable conduct by overdeterrence. See *ibid.*

The Ninth Circuit's decision below, like the First Circuit's decision on the same side of the split, cast aside the directness inquiry by concluding that RICO lawsuits are governed by this Court's decision in *Bridge*, 553 U.S. 639.[4] Because the Court found proximate cause there, they concluded there must be proximate cause in these cases as well.

But this Court's more recent decision in *Hemi* reiterated that RICO proximate cause is about more than easy analogies or one-size-fits-all rules. As *Hemi* made clear, the *purpose* of RICO's proximate cause requirement is to draw a tight circle around the RICO predicates to ensure that RICO liability does not extend too far. *Hemi*, 559 U.S. at 17-18 (plurality opinion) (explaining that "[t]his Court has interpreted RICO broadly * * * but we have also held that its reach is limited"). The plurality in *Hemi* eschewed a view of proximate cause that would automatically extend liability whenever a RICO plaintiff's injury was the "*intended* consequences of the defendant's unlawful behavior." *Id.* at 12. And the *Hemi* plurality

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[4] The court below asserted that the Third Circuit's decision in *In re Avandia Marketing, Sales Practices & Product Liability Litigation*, 804 F.3d 633 (3d Cir. 2015), was on its side of the circuit split. See *Painters & Allied Trades Dist. Council 82 Health Care Fund* v. *Takeda Pharm. Co. Ltd.*, 943 F.3d 1243, 1256-57 (9th Cir. 2019). But the Seventh Circuit has concluded that the Third Circuit is instead on *its* side of the split. See *Sidney Hillman Health Ctr. of Rochester* v. *Abbott Labs.*, 873 F.3d 574, 578 (7th Cir. 2017). This only underscores the confusion calling out for this Court's resolution.

distinguished *Bridge* by stating that unlike in *Bridge*—which involved only one step between the fraud and the harm—the theory of liability in *Hemi* involved "[m]ultiple steps." *Id.* at 15.

Time and again, outside the context of proximate cause, this Court has interpreted other aspects of RICO relatively broadly. See *Boyle* v. *United States*, 556 U.S. 938, 946-47 (2009) (holding that a RICO enterprise need not have a formal structure); *H.J. Inc.* v. *Nw. Bell Tel. Co.*, 492 U.S. 229, 244 (1989) (declining to read "an organized crime limitation into RICO's pattern concept"); *Sedima, S.P.R.L.* v. *Imrex Co.*, 473 U.S. 479, 499 (1985) (declining to narrow RICO notwithstanding the "distress at the 'extraordinary, if not outrageous,' uses to which civil RICO has been put"). In light of these precedents, courts have long recognized the "relative ease with which a plaintiff may mold a RICO pattern from allegations" of "mail or wire fraud." *W. Assocs. Ltd. P'ship* v. *Mkt. Square Assocs.*, 235 F.3d 629, 636-37 (D.C. Cir. 2001) (quoting *Efron* v. *Embassy Suites (Puerto Rico), Inc.*, 223 F.3d 12, 20 (1st Cir. 2000); see also *U.S. Textiles, Inc.* v. *Anheuser-Busch Companies, Inc.*, 911 F.2d 1261, 1268 (7th Cir. 1990) ("Virtually every garden-variety fraud is accomplished through a series of wire or mail fraud acts[.]"); *Al-Abood ex rel. Al-Abood* v. *El-Shamari*, 217 F.3d 225, 238 (4th Cir. 2000) ("[I]t will be the unusual fraud that does not enlist the mails and wires in its service at least twice."); *Tabas* v. *Tabas*, 47 F.3d 1280, 1290 (3d Cir. 1995) (en banc) ("[T]hese types of fraud, more prevalent in the commercial world than in the world of racketeers, has caused concern that RICO sweeps too broad a swathe.").

Without a meaningful proximate cause requirement as a backstop, legitimate enterprises are all but defenseless against RICO accusations until long after costly and burdensome discovery ends and a lawful enterprise has been branded a "racketeer." For many companies, the

inability to rely on proximate cause as a defense makes settlement the only option. In the RICO context, "[m]any a prudent defendant, facing ruinous exposure, will decide to settle even a case with no merit." *Sedima*, 473 U.S. at 506 (Marshall, J., dissenting).

C. Sprawling RICO Liability Chills Commercial Speech, Harms Competition, And Redirects Limited Resources From Lifesaving Research

Unless carefully circumscribed, RICO threatens to impose significant costs on legitimate commerce. The threat of huge civil liabilities and litigation costs inevitably has a serious chilling effect on legitimate business activities to the detriment of consumers nationwide. For cases that lie at the heart of RICO—those which involve actual organized crime—a chilling effect on the defendant's activities is no cause for concern. But when RICO litigation involves socially valuable activities, including the release of innovative new pharmaceutical products and competitive forms of marketing practiced by legitimate businesses, the chilling effects can have disastrous social costs.

The threat of RICO liability chills valuable commercial speech. This Court has repeatedly recognized the importance of commercial speech to consumers, especially in the medical context. See *Nat'l Inst. of Family & Life Advocates* v. *Becerra*, 138 S. Ct. 2361, 2374 (2018); *Thompson* v. *W. States Med. Ctr.*, 535 U.S. 357, 374-77 (2002); *Virginia State Bd. of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976). "A consumer's concern for the free flow of commercial speech often may be far keener than his concern for urgent political dialogue * * * . That reality has great relevance in the fields of medicine and public health, where information can save lives." *Sorrell* v. *IMS Health Inc.*, 564 U.S. 552, 566 (2011). RICO suits like the one here—in which leading pharmaceutical manufacturers are accused of

"racketeering" and face potentially massive treble damage awards—are likely to chill the dissemination of valuable medical information.

The prospect of RICO suits also harms legitimate competition. The antitrust law on which RICO is modeled encourages businesses to compete by offering lower prices, better products, better methods of production, and better systems of distribution. But without the proximate cause limitation, TPPs unhappy with their arrangements with pharmaceutical companies can seek to improve their position through RICO suits based on claimed misrepresentations or non-disclosures. The prospect of burdensome treble damages suit discourages firms from vigorous negotiation and beneficial advertising. The ultimate victims of incentives discouraging ordinary competition are not the pharmaceutical companies, but *consumers*, who lose access to valuable information and revolutionary new medicines.

RICO suits do not just chill valuable commercial speech and distort the competitive landscape. They also force pharmaceutical companies to redirect tens of millions of dollars away from the development of lifesaving therapies and into defending RICO litigation. The biopharmaceutical industry is the global leader in R&D and its research intensity is unparalleled in the U.S. economy. The industry invests more in R&D relative to sales than all but one other manufacturing industry—over 20%, more than six times the average for the manufacturing sector as a whole. U.S.-based biopharmaceutical companies invested $79.6 billion in R&D in 2018, with most of those investments made in the United States. In fact, according to the National Science Foundation, this sector accounts for the single largest share of all U.S. business R&D, representing 1 out of every 6 dollars (17%) spent on

domestic R&D by U.S. businesses.[5] RICO litigation forces these companies to redirect resources away from this groundbreaking research to defending accusations of criminal wire and mail fraud in bet-the-company RICO suits. These RICO lawsuits thus act as a severe drag on one of the most innovative sectors of the U.S. economy.

II. THE NINTH CIRCUIT'S DECISION HAS GRAVE CONSEQUENCES

Even apart from deepening a clear circuit split, the decision below has such enormous practical and legal consequences that it warrants this Court's review.

A. The Ninth Circuit's Decision Provides A Roadmap For Abusive RICO Suits

The decision below disregards this Court's attention to RICO's broader context and reduces proximate causation to an easily satisfied foreseeability test—a test this Court has twice specifically rejected. See *Hemi*, 559 U.S. at 12 (plurality opinion) (rejecting "foreseeability" test and noting *Anza* had likewise rejected foreseeability). Moreover, by permitting plaintiffs to plead RICO claims without a showing of concrete injury, the Ninth Circuit has mapped out a path for class action lawyers nationwide to bring RICO lawsuits against pharmaceutical manufacturers that amount to no more than garden-variety failure to warn claims. The decision's breadth invites abusive and burdensome litigation.

B. RICO's Jurisdictional Reach Effectively Makes The Decision Below A National Rule

Forum shopping will be the inevitable result of the Ninth Circuit's decision. This Court's recent personal jurisdiction decisions have emphasized the importance under the Due Process Clause of protecting corporations

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[5] PhRMA, *The Biopharmaceutical Industry: Fueling the Economy and Global Competitiveness* 1 (2019), http://bit.ly/2U7eLDb.

from suit outside of their "home" jurisdictions. See, *e.g.*, *Daimler AG* v. *Bauman*, 571 U.S. 117 (2014); *Goodyear Dunlop Tires Operations, S.A.* v. *Brown*, 564 U.S. 915 (2011). But RICO sidesteps many of those protections by authorizing "nationwide service." *Republic of Panama* v. *BCCI Holdings (Luxembourg) S.A.*, 119 F.3d 935, 942 (11th Cir. 1997). "When a federal statute provides for nationwide service of process, it becomes the statutory basis for personal jurisdiction." *Ibid.* Thus, as long as a plaintiff's RICO claim "is not wholly immaterial or insubstantial, a plaintiff is entitled to take advantage of [RICO's] * * * nationwide service of process provision" to establish personal jurisdiction in the court of plaintiff's choosing. *Ibid.* As long as the defendant is a U.S. corporation doing business in the United States, it is subject to personal jurisdiction anywhere in the United States under RICO. See *ibid.* RICO's venue provision also makes venue proper in every judicial district where a defendant "is found, has an agent, or transacts his affairs," which for most national pharmaceutical companies is every judicial district in the country. 18 U.S.C. § 1965(a).

RICO's nationwide service provision thus permits plaintiffs to bring all defendants together in a single forum and in front of a single judge without having to worry about complex issues that arise when bringing state law consumer fraud claims in federal courts. Thus, the result of the Ninth Circuit's decision is that RICO class actions against pharmaceutical companies can—and predictably will—be brought in the Ninth Circuit.

III. THE NINTH CIRCUIT'S DECISION IS WRONG

A. RICO Requires That Lawsuits Be Brought By Those Harmed At The "First Step"

The decision below failed to apply the controlling proximate cause test from *Holmes* and *Hemi*—that "[t]he general tendency of the law, in regard to damages at least,

is not to go beyond the first step." *Hemi*, 559 U.S. at 10 (plurality opinion); *Holmes*, 503 U.S. at 271–72. As this Court explained in *Holmes*, three policy reasons support this "one step" rule: more causally attenuated injuries (1) raise difficulties in ascertaining damages attributable to the violation as opposed to independent causes, and (2) require complicated apportionment; and (3) redressing more remote injuries does not further the government's interest in deterrence. *Holmes*, 503 U.S. at 269-70.

All three of *Holmes*'s rationales weigh against permitting TPPs and patients to recover for manufacturers' alleged wrongful statements or non-disclosures to doctors and PBMs. *First*, the damages owed to TPPs on the basis of the "too many prescriptions" theory are nearly impossible to ascertain accurately. *Second*, these suits seek the same damages that patients actually injured by the alleged misstatements may also seek, posing a serious threat of multiple recoveries. *Third*, the risk of federal criminal liability, FDA regulatory sanctions, and state law consumer class actions already powerfully deter the sort of wrongful conduct alleged in this case and others like it. In the context of the highly regulated pharmaceutical industry, the blunt force of the racketeering statute does far more harm than good.

No one could seriously dispute that these suits are nowhere close to having just a single step in the causal chain leading from the alleged wrongdoing to the alleged injury. Consider the steps between the alleged wrongdoing and the alleged "injuries" to TPPs—

1. The manufacturer makes an allegedly false or misleading statement or non-disclosure about its drug to the TPP's PBM—the large outside company that manages most TPPs' prescription drug plans—or the FDA or, at its broadest, the "medical community."

2. Based on those statements, the PBM recommends adding the drug to the TPP's formulary.
3. The TPP accepts the recommendation of its PBM to place the drug on the formulary, rendering use of the drug eligible for reimbursement.
4. The TPP sets the premiums that it collects from its members at a level that anticipates fewer prescriptions of the drug than actually end up being written (because otherwise the TPP actually profited notwithstanding the alleged misconduct).
5. Based on the same wrongful statement or non-disclosure, rather than complying with their ethical obligations to prescribe mediations based on their independent medical judgment, physicians in the TPP's network choose to prescribe the drug for the TPP's beneficiaries, instead of a different drug or (less commonly) no drug at all.
6. Those patients choose to fill their prescriptions.[6]
7. If the drug has generic equivalents, the pharmacist fills the prescription with the drug that is the subject of the lawsuit, rather than a generic version.
8. Those patients submit their prescription claims for payment or reimbursement by the TPP.
9. The TPP reimburses those prescriptions—and, because it did not set its premiums high enough, it suffers a net out-of-pocket loss.

Moreover, as explained in the petition, see Pet. 14 n.6, much of the same reasoning applies to claims brought by patients, who would not suffer the supposed injury they claim unless, *inter alia*, their insurers covered the subject

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[6] See Jane E. Brody, *The Cost of Not Taking Your Medicine*, N.Y. TIMES, Apr. 17, 2017, https://nyti.ms/2WckvOR (noting that 20–30% of prescriptions go unfilled).

drug, their doctors prescribed it, and their pharmacists chose it over an available generic.

Thus, even *if* the Ninth Circuit were correct that the "*intended* consequences of the defendant's unlawful behavior" was to obtain payments from the TPP or patient, the sheer number of intervening steps between the alleged misconduct and the alleged harm precludes recovery under RICO. *Hemi*, 559 U.S. at 12 (plurality opinion). "The causal chain * * * is longer than the one *Hemi Group* deemed too long." *Sidney Hillman Health Ctr. of Rochester* v. *Abbott Labs.*, 873 F.3d 574, 578 (7th Cir. 2017).

B. Article III Bars RICO Claims Predicated On Fraudulent Inducement Without An Accompanying Concrete Harm

Article III requires that a plaintiff's injury be "concrete." *Spokeo*, 136 S. Ct. at 1548. To be sure, "intangible injuries" can be "concrete." *Id.* at 1549. But "[i]n determining whether an intangible harm" is concrete and thus "constitutes injury in fact, both history and the judgment of Congress play important roles." *Ibid.* Key to the historical inquiry is "whether an alleged intangible harm has a close relationship to a harm that has traditionally been regarded as providing a basis for a lawsuit in English or American courts." *Ibid.*

Here, the answer to that inquiry is plainly no. "[T]he common law has long insisted that a plaintiff in" a fraud case "show not only that had he known the truth he would not have acted, *but also that he suffered actual economic loss*." *Dura Pharm., Inc.* v. *Broudo*, 544 U.S. 336, 343-44 (2005) (emphasis added). The Restatement (Second) of Torts, which this Court has called the "most widely accepted distillation of the common law of torts," *Field* v. *Mans*, 516 U.S. 59, 70 (1995), says the same thing: A fraud victim must show pecuniary loss from the fraud to make out a claim. See Restatement (Second) of Torts §§ 525,

537 (1977); see also *Vaughn* v. *Consumer Home Mortg. Co.*, 470 F. Supp. 2d 248, 270 (E.D.N.Y. 2007) ("Their claim of common-law fraud fails because the [plaintiffs] concede that they have suffered no direct pecuniary loss as a result of the underlying transaction."), *aff'd*, 297 F. App'x 23 (2d Cir. 2008).

The plaintiffs in this case do not allege that they suffered any pecuniary loss as a result of the defendants' alleged wrongful actions. Instead, they allege only that they paid for more prescriptions than would otherwise have occurred absent the alleged acts. The patients suffered no harm at all, since they used Actos safely and effectively and thus received the full benefit of their bargains. And plaintiffs have expressly abandoned any claim that they overpaid for Actos. Moreover, the TPP plaintiff would have to reimburse for *some* medication to treat its insureds, and as noted, it does not allege that it overpaid for petitioners' medicine. The only allegation is that it bought more Actos than it otherwise would have. Buying more of one product than another because of an alleged misstatement is not "pecuniary loss." It is not within the historical reach of fraud at common law. See *Dura*, 544 U.S. at 343-45. And it is not a "concrete" injury sufficient to give rise to an Article III injury in fact.

CONCLUSION

The Court should grant the petition for a writ of certiorari.

Respectfully submitted.

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