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.,
Respondents.

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

BRIEF OF *AMICI CURIAE* NATIONAL ASSOCIATION OF MANUFACTURERS AND AMERICAN TORT REFORM ASSOCIATION IN SUPPORT OF PETITIONERS

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QUESTIONS PRESENTED

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

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

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INTEREST OF *AMICI CURIAE*[1]

Amici National Association of Manufacturers (NAM) and American Tort Reform Association (ATRA) members include companies named in triple-windfall pharmaceutical refund RICO actions, such as this action, and other manufacturers that could be subjected to no-injury RICO lawsuits in the Ninth Circuit and other circuits that allow such claims. Forum-shopping plaintiffs will take advantage of sharp splits in the circuits on the Questions Presented to burden our members with cases that would not be permitted in other circuits.

The pharmaceutical industry, and manufacturing in general, stand at the technological cutting-edge of the American economy. These companies should not be subjected to abusive litigation that hampers their ability to innovate and grow. A sound and fair legal system requires remedies to be focused on persons with direct, actual harms–particularly the RICO statute because of its powerful and potentially crippling treble damages remedy.

The NAM is the largest manufacturing association in the United States, representing manufacturers in every industrial sector and in all 50 states. Manufacturing employs more than 12 million people, contributes $2.25 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for more than three-quarters of all private-sector research and development in the

[1] No counsel for any party authored this brief in whole or in part, and no person or entity other than *amici*, their members, or their counsel made a monetary contribution intended to fund its preparation or submission. The parties received timely notice of our intent to file this brief and consent to the filing.

nation. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that allows manufacturers to innovate and compete in an increasingly-advanced global economy, creating jobs across the United States.

ATRA is a broad-based coalition of businesses, corporations, municipalities, associations, and professional firms that have pooled their resources to promote reform of the civil justice system with the goal of ensuring fairness, balance, and predictability in civil litigation. For more than three decades, ATRA has filed *amicus* briefs in cases involving important liability issues.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

The reasons for this Court to grant certiorari are straightforward and compelling: the Ninth Circuit's ruling highlights deep splits in the circuits with respect to two fundamental issues in civil RICO litigation: proximate cause and Article III standing.

Clarity is needed in the circuits as to whether the doctrine of proximate cause in RICO cases will continue to have a limiting effect and require a "direct relation" between the injury and injurious conduct alleged or will permit attenuated claims by remote but "foreseeable" plaintiffs. The Ninth Circuit took the latter approach, joining the First and Third Circuits, while acknowledging that Plaintiffs' claims would fail in the Second and Seventh Circuits.

The second split concerns the kind of damages required for Article III standing: can someone who buys and uses a product without incident – someone who received the "benefit of the bargain" – sue for a

full refund based on the nearly impossible-to-defend claim that, with 20/20 hindsight, the person would not have purchased the product had a risk or defect been disclosed? Or, must a plaintiff assert an actual, concrete harm?

Each of these questions has far-ranging effects. Under the Ninth Circuit's approach, pharmaceutical and other manufacturers will face abusive no-injury RICO lawsuits by forum-shopping plaintiffs.

No-injury theories are a focus of the plaintiffs' bar because the universe of potential plaintiffs covers almost anyone that purchased the product. The size of the "all purchaser" class will always dwarf the much smaller set of consumers who suffer an injury-in-fact. *See* Victor E. Schwartz, et al., *The Rise of "Empty Suit" Litigation: Where Should Tort Law Draw the Line?*, 80 Brook. L. Rev. 599, 601 (2015).

Of course, this Court has its own experience with forum-shopping tort plaintiffs in recent personal jurisdiction rulings. *See* Phil S. Goldberg, et al., *The U.S. Supreme Court's Personal Jurisdiction Paradigm Shift to End Litigation Tourism*, 14 Duke J. Const. L. & Pub. Pol'y 51 (2009); *see also* Mark A. Behrens & Christopher Appel, *The New Gold Rush: Study Reveals Pharmaceutical Plaintiffs Flocking to California*, 24 No. 10 Westlaw J. Health L. 2 (Feb. 7, 2017) (data illustrating forum-shopping by pharmaceutical product liability plaintiffs).

Further, so long as the subject areas of litigation risk remain ill-defined, and therefore uncertain, they may lead to *in terrorem* settlements in the undecided circuits.

ARGUMENT

I. THE DEEP CIRCUIT SPLIT AS TO WHETHER ATTENUATED CLAIMS MEET CIVIL RICO'S PROXIMATE CAUSE REQUIREMENT NEEDS TO BE RESOLVED.

Proximate cause serves as a liability limiting doctrine in RICO as in tort. *See Holmes v. Sec. Inv'r Prot. Corp.,* 503 U.S. 258, 268 (1992) (proximate cause is a judicial tool to "limit a person's responsibility for the consequences of that person's own acts."); *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 133 (2014) ("the proximate-cause requirement generally bars suits for alleged harm that is 'too remote' from the defendant's unlawful conduct.").

The Ninth Circuit's approach to proximate cause—holding that proximate cause is established whenever a particular injury might be foreseeable, no matter how attenuated the defendant's relationship to the plaintiff—will permit a range of RICO class actions to proceed in circumstances where plaintiffs cannot establish a direct relation between the injury and the alleged injurious conduct.

The ruling below exposes a split between various circuits on the question of whether RICO requires "directness" or "foreseeability" when establishing causation. In its decision below, the Ninth Circuit recognized a well-known split of authority between the Second and Seventh Circuits on one hand and the First and Third Circuits on the other. *Painters & Allied Trades District Council 82 Health Care Fund v. Takeda Pharmaceuticals Co., Ltd.,* 943 F.3d 1243, 1256-57 (9th Cir. 2019). It reasoned that whatever

"minor factual and procedural differences" might exist among those courts' precedents "do not help" to "resolve the central dispute," among them, which was "whether the decisions of prescribing physicians and pharmacy benefit managers constitute intervening causes that sever the chain of proximate cause between the drug manufacturer and the TPP." *Id.* at 1257. On that "central dispute," the Ninth Circuit sided with the First and Third Circuits, concluding that those two courts "have it right." *Id.*

While the Ninth Circuit spoke in terms of "prescribing physicians and pharmacy benefit managers," the logic underlying its decision—which treats "foreseeable" harms equivalent to a direct causal chain—will affect whether various product liability class actions proceed against manufacturers, as well as various companies' ability to innovate.

One vivid example of how this proximate cause requirement changes the outcome of manufacturing class actions is *In re Chrysler-Dodge-Jeep Ecodiesel Marketing, Sales Practices, & Prods. Liab. Litig.,* 295 F. Supp. 3d 927 (N.D. Cal. 2018). Plaintiffs asserted RICO claims alleging that manufacturers of diesel trucks misled regulators in order to pass vehicle emissions tests. Because of this alleged fraud, plaintiffs contended, the defendants were able to charge a higher price for their vehicles than otherwise.

The plaintiffs' proximate cause analysis ignored the realities of how many products are manufactured, distributed, and purchased. In particular, it revealed an ignorance of the automotive market, which is characterized by intense face-to-face negotiation over price. *See Robinson v. Texas Automobile Dealers Ass'n,* 387 F.3d 416, 423 (5th Cir. 2004) (rec-

ognizing the "realities of the haggling that ensues in the American market when one buys a vehicle").

Nonetheless, despite the fact that most courts have rejected these kinds of indirect allegations of "fraud on the market" or "fraud on the regulators" as insufficient to support proximate causation, the Northern District of California, following Ninth Circuit precedent, allowed plaintiffs' RICO theory to proceed. 295 F. Supp. 3d at 971-72. The logic the court used parallels the "foreseeability" analysis the Ninth Circuit employed in this case: while it held in conclusory fashion that the effects were direct, it also reasoned that "even where damages are based on *indirect* market effects … such a claim may lie in this circuit." *Id.* (emphasis added).

Had the *Ecodiesel* litigation been filed in the Second or Seventh Circuits, the attenuated theory of liability presented in that case would not have survived a motion to dismiss. An alleged fraud on a third-party, particularly one that lacks directly measurable effects on the price of a manufactured good, would not be considered sufficient grounds for tort liability. *Compare LaRoe v. FCA US LLC,* No. 17-2487-DDC-JPO, 2020 WL 1043564, *12-13 (D. Kan. Mar. 4, 2020) (dismissing RICO claim alleging "sham recall" communications to regulator as too attenuated to cause alleged harm to plaintiff).

The circuit split also has impacts cases in circuits that have yet to address the issues presented here. A defendant sued in an untested jurisdiction (like the Fourth or Eighth Circuit) would face strong pressure to settle, regardless of the merits, because of the risk of a trebled award involving a huge class—preserving any error begun in the First, Third, and

Ninth Circuits. Given the intense pressure that treble-damages RICO class actions put on defendants to settle even non-meritorious claims, this Court should take this opportunity to resolve the circuit split and clarify the law.

These pressures, of course, will mean more cases filed in the First, Third, and Ninth Circuits. Entrepreneurial plaintiffs rely on forum-shopping to keep RICO class actions of questionable merit viable.

The ill effects of maintaining RICO refund class actions—each of which offers the possibility of treble damages—reach beyond the payment of *in terrorem* settlements. They also threaten the smooth functioning of an economy that relies on private businesses to innovate. Like many manufacturers, pharmaceutical companies are often at the forefront of research and development. That innovation is vital to American well-being, economic and otherwise: it allows for the possibility of a cure for cancer, or a vaccine or treatment for a novel coronavirus.

Opening pharmaceutical or other manufacturers to liability for treble damages based solely on a vague and subjective notion of "foreseeability" will stifle that innovation. Coupled with Rule 23, the RICO statute has the power to transform run-of-the-mill failure-to-warn cases into large windfalls for third parties. Unshackling that power from the limits set by proximate cause would issue an invitation to file lawsuits no matter how tenuous their justification. A ruling that proximate cause requires more than just foreseeability would help preserve the freedom to innovate that has made the manufacturing sector such an important part of the economy.

II. THE DEEP CIRCUIT SPLIT AS TO WHETHER AN UNREALIZED RISK OF HARM CONSTITUTES AN ARTICLE III INJURY NEEDS TO BE RESOLVED.

The Ninth Circuit also held that injury-in-fact for Article III purposes is satisfied when plaintiffs allege they would not have bought a product except that the defendant "failed to disclose known risks," even though the risk never materialized during the life of the product. App. 40a-41a n.1. At least two dissenting opinions in the Third and Eighth Circuit have noted that holding creates a split among federal appellate circuits. *See In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices & Liab. Litig.,* 903 F.3d 278, 295 & n.12 (3d Cir. 2018) (Fuentes, J. dissenting); *In re Zurn Pex Plumbing Prods. Liability Litig.,* 644 F.3d 604, 623-24 (8th Cir. 2011) (Greunder, J. dissenting).

Article III standing governs who may avail themselves of the federal courts. By requiring a "case or controversy" involving a "concrete and particularized" injury, *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1548 (2016), the doctrine ensures that "federal courts do not exceed their authority as it has been traditionally understood." *Id*. at 1547.

Numerous courts, including the Third and Fifth Circuits, have held that a plaintiff who uses a product safely over its lifetime receives "the benefit of her bargain" and thus lacks Article III standing to sue based on nondisclosure of a defect that affected only other consumers. *Johnson & Johnson,* 903 F.3d at 280-81; *Rivera v. Wyeth-Ayerst Labs.,* 283 F.3d 315, 320 (5th Cir. 2002); *see also Koronthaly* v. *L'Oreal USA, Inc.*, 374 F. App'x 257, 258-59 (3d Cir. 2010)

(no injury in fact without "allegation that [the plaintiff] received a product that failed to work for its intended purpose or was worth objectively less than what one could reasonably expect").

The Ninth Circuit, however, has held that everyone who pays for a product has standing to sue for a full refund merely by alleging that they would not have made that purchase if a given risk were disclosed, regardless of whether that risk actually materialized during their use of the product. App. 40a-41a & n.1.

This holding has implications beyond the realm of drugs and medical devices. Risks of adverse events do not only occur in the medical context. Any modern product is made of various components, each of which necessarily carries with it a non-zero probability that it might not work as intended. As a result, numerous manufacturers of consumer products have faced tort claims, including RICO claims, based on alleged non-disclosure of a risk of malfunction.

Take the example of *In re General Motors LLC Ignition Switch Litigation*, No. 14-MD-2543, 2016 WL 3920353 (S.D.N.Y. Jul. 15, 2016). Plaintiffs asserted RICO claims against General Motors, alleging that the company knowingly sold certain cars with defective ignition switches that could possibly malfunction, causing the car to lose power, power brakes, and airbags. Even though the plaintiffs had not experienced any malfunction, they claimed they would have paid less for their GM cars had they known of the potential safety defect.

The court granted GM's motion to dismiss the RICO claim, holding that, without an actual mani-

festation of the alleged defect, the alleged injury was too "speculative." *Id.* at *16 (noting courts "have found speculative, expectation-based, benefit-of-the-bargain damages to be incompatible with RICO"). This logic extends beyond the RICO statute, because most courts balk at the idea of awarding damages to a plaintiff who received full use over the lifetime of the product she bought. *See, e.g., In re FCA US LLC Monostable Electronic Gearshift Litig.,* 280 F. Supp. 3d 975, 1018 (E.D. Mich. 2017) (dismissing tort claims of plaintiff who leased vehicle, experienced no issue, and returned vehicle at end of lease); *In re Canon Camera Litig.,* 237 F.R.D. 357, 360 (S.D.N.Y. 2006) (Rakoff, J.) ("A plaintiff who purchases a digital camera that never malfunctions over its ordinary period of use cannot be said to have received less than what he bargained for when he made the purchase.").

Nonetheless, it is clear that a plaintiff bringing any of these cases in the Ninth Circuit would be allowed to assert these speculative damage claims *despite* the fact that she may never have experienced the risk manifesting itself in her product. This would open liability to any consumer who, learning information after the fact about a transaction, became disappointed in her initial purchase—even though she had received all of the benefit that she bargained for.

Allowing Article III standing under these circumstances would again invite class actions of questionable merit, stifling innovation. Innovation in any industry is an iterative process: progress comes only after many attempts, some of which include some failures out in the field. Companies conscientiously

work to minimize the risk of failures in the field, and compensate those whose products malfunction. But it is unreasonable to ask companies to compensate those whose products worked as intended merely because *others* had less-than-ideal experiences. As the Third Circuit has recognized, "buyer's remorse, without more, is not a cognizable injury under Article III." *Johnson & Johnson,* 903 F.3d at 281.

CONCLUSION

For these reasons, *amici* request that the Court grant the Petition for a Writ of Certiorari.

Respectfully submitted,

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