No. 15-1078

IN THE

Supreme Court of the United States

IN RE: AVANDIA MARKETING, SALES PRACTICES & PRODUCTS LIABILITY LITIGATION
GLAXOSMITHKLINE LLC,
Petitioner,

v.

ALLIED SERVICES DIVISION WELFARE FUND ET AL.,
Respondents.

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

BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND NATIONAL ASSOCIATION OF MANUFACTURERS AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF *AMICI 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. In 2014 alone, they invested an estimated $51.2 billion to discover and develop new medicines.[2] 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.

The National Association of Manufacturers (NAM) is the nation's largest manufacturing association, representing small and large manufacturers in every industrial sector and in all 50 states, including pharmaceutical manufacturers. Manufacturing employs nearly 12 million men and women, contributes nearly $2.17 trillion to the U.S. economy annually, has the largest economic impact of any

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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 *amici curiae*, their members, or their counsel made a monetary contribution to the preparation or submission of this brief. Letters from the parties consenting to the filing of this brief have been filed with the Clerk of the Court.

[2] PhRMA, *2015 Profile: Biopharmaceutical Research Industry* 35 (2015), http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf

major sector, and accounts for three-quarters of private-sector research and development. The NAM is the powerful voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States. The NAM regularly files amicus briefs in cases of importance to the manufacturing community.

This case presents important questions concerning the limits on treble-damages claims under the Racketeering Influenced and Corrupt Organizations Act ("RICO"). Insurance companies and other third-party payors ("TPPs") regularly assert RICO claims against *amici*'s members on the theory that a manufacturer's alleged wrongful statements about its product caused the TPPs to overpay for the product in comparison to available alternatives. The decision below, in holding that the respondent TPPs pleaded injury and causation for a RICO claim, deepens a circuit conflict on the application of this Court's precedents on proximate cause under RICO to TPPs' overpricing claims. These claims by TPPs are proliferating, and the Third Circuit's decision encourages TPPs to bring even more.

More broadly, the Third Circuit's decision highlights uncertainty in this Court's case law about the proper standard for proximate cause under RICO. Combined with the enticement of treble damages, an uncertain proximate-cause standard invites increasingly tenuous claims that threaten to stretch civil RICO even farther beyond its original intent. The deluge of cases facing *amici*'s members and the courts, and the uncertainty that the geographic divergence on the legal issue engenders, thus make it vital for this Court to grant review.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case is one of the latest in a growing torrent of RICO suits brought by TPPs against pharmaceutical manufacturers. In the typical case, TPPs seek treble damages under 18 U.S.C. § 1964(c) for injuries allegedly resulting from a pharmaceutical company's alleged wrongful statements about its product. Section 1964(c) permits "[a]ny person injured in his business or property by reason of a violation of" RICO's substantive provisions to sue for treble damages. TPPs usually allege that the pharmaceutical manufacturer's failure to convey certain information about the risks or benefits of its drug increased the amount the TPPs paid to cover prescriptions written by health care providers exercising their independent medical judgment.

The recurring question whether this dubious theory states a plausible RICO claim implicates a deeply unsettled area of law. More than two decades ago, this Court held in *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258 (1992), that § 1964(c) requires RICO plaintiffs to plead and prove proximate cause. But *Holmes* did not articulate a clear test for proximate cause. Nor have the Court's three decisions on the issue since *Holmes* provided the needed clarity. Instead, as this Court has grappled with the issue, its divided rulings have gravitated between multiple competing theories of proximate cause and varied readings of its own precedents.

The uncertain state of the law has resulted in sharp divisions between the circuits on whether TPP claims like respondents' state a valid theory of causation under RICO. The Second, Ninth, and Eleventh

Circuits have held that the chain of causation between purported misrepresentations and the TPPs' alleged injury is too attenuated to support a RICO claim for treble damages; the causal chain involves several intervening events, including physicians' exercise of their independent medical judgment in prescribing particular medications. But the First Circuit broke with that trend, and the Third Circuit in this case followed. *In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 804 F.3d 633 (3d Cir. 2015). Despite the absence of any allegation that patients suffered injuries or received inferior medical treatment, or that the alleged misstatements troubled prescribing physicians, the decision below incorrectly holds that respondents sufficiently alleged proximate cause to support a treble-damages RICO claim against petitioner GlaxoSmithKline LLC ("GSK"), for purported economic injuries based on GSK's alleged failure to disclose heart-related risks of Avandia.

Given the *in terrorem* effect of treble-damages suits and the potent incentive they provide for increased litigation, it is essential that courts enforce appropriate limits on private RICO claims. The Third Circuit's decision does just the opposite. By dropping the bar for TPPs to bring such claims, the decision below removes a crucial counterweight to the significant impetus to sue that treble damages under RICO provide. TPPs already have been bringing more and more RICO claims against pharmaceutical companies. And with proximate cause easier than ever to plead at least in the Third Circuit, lower courts will likely witness a surge of TPP suits, founded on attenuated causal theories and burdening the judicial system and the pharmaceutical industry for years to come.

This case accordingly warrants this Court's immediate review, not only to clarify an important legal question, but also to avoid the adverse consequences that will likely flow from the Third Circuit's erroneous decision.

ARGUMENT

I. THE THIRD CIRCUIT'S ERRONEOUS DECISION ON PROXIMATE CAUSE UNDER RICO SHOWS THE NEED FOR CLEAR GUIDANCE FROM THIS COURT

The Third Circuit incorrectly held that the TPPs' allegations regarding GSK's purported misrepresentations about the heart-related risks of Avandia plausibly stated RICO violations that proximately caused economic injury to the TPPs. That decision, rooted in confusion regarding this Court's prior decisions, vastly expands the reach of RICO's civil suit provisions. This case presents an ideal and much-needed opportunity for the Court to clarify its jurisprudence and to demarcate the proper boundaries of the proximate-cause inquiry for § 1964(c) claims.

A. This Court's Decisions Have Not Provided the Clarity Lower Courts Need

In four cases decided over the past two-and-a-half decades, this Court has wrestled with the question of proximate causation under RICO's civil suit provision. Those decisions have not provided lower courts with the guidance they need. For one, the decisions are hard to reconcile in important respects. Moreover, the Court's most recent pronouncement, *Hemi Group LLC v. City of New York*, 559 U.S. 1 (2010), produced no majority opinion and highlighted persistent

uncertainties about the content of the proximate-cause standard and its underlying theory.

1. In *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258 (1992), this Court recognized the proximate-cause requirement inherent in § 1964(c). But beyond stating that the plaintiff had not established proximate cause on the facts of that case, *Holmes* did not offer substantial guidance for evaluating the issue.

In *Holmes*, the Securities Investor Protection Corp. (SIPC) brought RICO claims based on the defendant's stock-manipulation scheme. SIPC claimed that the scheme rendered two securities broker-dealers unable to meet their obligations to customers, and that the broker-dealers' ensuing insolvency triggered SIPC's statutory duty to reimburse the broker-dealers' customers, which, SIPC argued, was a cognizable injury under RICO. *Id.* at 262–63. The question was whether § 1964(c)'s authorization of civil suits to recover treble damages for an injury to business or property "by reason of" a RICO violation required proof of proximate cause.

Holmes held that § 1964(c) requires proximate cause, *id.* at 268, but did not articulate a clear test. The Court rather "use[d] 'proximate cause' to label generically the judicial tools used to limit a person's responsibility for the consequences of that person's own acts. . . . [A]mong the many shapes this concept took at common law was a demand for some direct relation between the injury asserted and the injurious conduct alleged." *Id.* (citations omitted). Three policy reasons supported a "directness of relationship" requirement: indirect injuries (1) raise difficulties in ascertaining damages attributable to the violation as opposed to independent causes and (2) require

complicated apportionment; and (3) redressing indirect injuries does not further general deterrence because more directly injured victims can be counted on to bring suit. *Id.* at 269–70. The Court held that the link between the injury suffered by the non-purchasing customers of the insolvent broker-dealer and the alleged stock manipulation was "too remote," because the customers' injury depended entirely on the broker-dealers' insolvency, which might have had other causes. *Id.* at 271. The three general policy reasons for requiring a direct relationship all supported the Court's conclusion that SIPC's theory failed to satisfy the proximate-cause requirement. *Id.* at 272–74.

Justice Scalia concurred in the judgment, arguing that § 1964(c) claims require a showing of proximate cause, not because of RICO's text, but as part of a statutory standing inquiry. *Id.* at 287 (Scalia, J., concurring in the judgment). He noted that the standing analysis also requires a zone-of-interests test; courts must ask whether a plaintiff falls within the class of persons that the statute is designed to protect. *Id.* Justice O'Connor, joined by Justices White and Stevens, also wrote separately to address standing (which the majority did not reach), though she concurred in the majority's proximate-cause analysis. *Id.* at 276 (O'Connor, J., concurring in part and concurring in the judgment).

2. Nearly 15 years later, in *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451 (2006), the Court sought to shed light on the proper test for proximate cause under RICO. But the complexities of the issue and the Justices' divergent views undermined any prospect of clarity. Instead, in the opinion of the Court, one concurrence, and two partial concurrences and partial

dissents, members of the Court described three theories of proximate cause, all of which differed from the theory in *Holmes*.

In *Anza*, Ideal Steel Supply Corp. asserted RICO claims against Joseph and Vincent Anza, who owned a competing steel supply business. Ideal claimed the Anzas had engaged in a fraudulent tax scheme and used the proceeds to open a new facility that diminished Ideal's market share. *Id.* at 454–55.

The majority in *Anza* held that Ideal's claim failed to satisfy RICO's proximate-cause requirement. *Id.* at 461. But even as the Court cited and elaborated on the principles in *Holmes*, it recognized key structural distinctions between the two cases. "The cause of Ideal's asserted harms . . . is a set of actions (offering lower prices) entirely distinct from the alleged RICO violation (defrauding the State). The attenuation . . . arises from a different source in this case than in *Holmes*, where the alleged violations were linked to the harms only through the broker-dealers' inability to meet their financial obligations." *Id.* at 458. "Nevertheless," the Court held, "the absence of proximate causation is equally clear in both cases." *Id.* *Anza* found that "the directness requirement's underlying premises"—including the difficulty in attempting to ascertain damages caused by remote actions, and the fact that New York, the "immediate victim" of the Anzas' unlawful conduct, could be relied on to bring suit—supported the conclusion that Ideal had failed adequately to plead proximate cause. *Id.* at 458–60.

Justice Scalia concurred to note that Ideal's claim also failed the zone-of-interests test that he had discussed in *Holmes*. *Id.* at 462 (Scalia, J., concurring).

Partially concurring and dissenting, Justice Thomas pointed out analytical inconsistencies in the majority opinion. He suggested that, while purporting to rely on *Holmes,* the *Anza* majority in fact applied an approach to "directness" different from the test outlined in *Holmes*. Justice Thomas observed that, under the *Holmes* test, the Anzas' tax underpayment directly caused Ideal's injury because the Anzas' own conduct permitted them to divert business from Ideal. *Id.* at 465 (Thomas, J., concurring in part and dissenting in part). He argued that the actual basis for the majority's conclusion that the injury was too indirect was not proximate cause, as in *Holmes,* but rather the difficulty in determining which damages the Anzas' unlawful acts had caused. *Id.* at 465–66. Justice Thomas also criticized the Court for conflating the determination of the amount of damages on the one hand with the analysis of causation on the other. *Id.* at 466. In his view, the Court had erroneously "adopt[ed] the converse proposition that any injuries that are difficult to ascertain must be classified as indirect for purposes of determining proximate causation." *Id.* And he noted that the Court's approach ran counter to the common-law notion of foreseeability, "permit[ing] a defendant to evade liability for harms that are not only foreseeable, but the *intended* consequences of the defendant's unlawful behavior." *Id.* at 470.

Justice Breyer also concurred in part and dissented in part. *Id.* at 479 (Breyer, J., concurring in part and dissenting in part). Like Justice Thomas, he disputed the majority's conclusion that its holding with respect to the facts in *Holmes* controlled the outcome in *Anza*. He agreed with Justice Thomas that Ideal's alleged harm "flow[ed] directly from the purported RICO

violations." *Id.* at 481. And he outlined an alternative test, under which proximate cause does not exist "if the causal chain from forbidden act to the injury caused a competitor proceeds through a legitimate business' ordinary competitive activity." *Id.* at 482; *see also id.* at 486.

3. In its next decision, this Court unanimously held that first-party reliance is not a required element of a RICO claim, either as a matter of statutory interpretation or as a component of proximate cause. *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639 (2008). That question, however, was separate from the uncertain proximate-cause standards discussed in *Anza*. And the Court's opinion in *Bridge* did not offer further clarity on that latter question. To the contrary, Justice Thomas's opinion for the Court incorporated into the analysis the foreseeability approach he had invoked in his partial dissent in *Anza*.

The parties in *Bridge* were participants in county tax lien auctions. The plaintiffs claimed that the defendants had engaged in a scheme of collusive bidding. The defendants had allegedly lied in attesting that they had complied with the county rule forbidding the use of agents, employees, or other entities to submit multiple bids. In fact, the defendants had colluded with others to successfully bid on a disproportionate share of liens. The plaintiffs asserted that the scheme deprived the plaintiffs and other bidders of a fair share of liens and their attendant economic benefits. *Id.* at 643–44.

The defendants argued that the plaintiffs' claims failed because the plaintiffs had not received, and hence had not relied on, the purported false statements. *Id.* at 648. The Court rejected the notion

that RICO required such reliance. *Id.* at 649. And the Court held that the plaintiffs had satisfied RICO's proximate-cause requirement. Writing for a unanimous Court, Justice Thomas repeated *Holmes*' general language on the need for a direct relationship between the alleged violation and harm. *Id.* at 653–55. And he wrote, echoing his discussion of the common-law concepts of foreseeability in his *Anza* partial dissent, *see Anza*, 547 U.S. at 469–70 (Thomas, J., concurring in part and dissenting in part), that the plaintiffs' injury was "a foreseeable and natural consequence of petitioners' scheme." *Bridge*, 553 U.S. at 658. The case was easily distinguishable from *Holmes* and *Anza*, he wrote, because "there are no independent factors that account for respondents' injury, there is no risk of duplicative recoveries . . . and no more immediate victim is better situated to sue." *Id.*

Bridge closed the door to arguments that RICO requires first-party reliance. But though its straightforward facts might have made the proximate-cause analysis uncontroversial, *Bridge* still left a number of questions unanswered. First, the Court invoked foreseeability as a relevant consideration—a concept absent from the majority opinions in *Holmes* or *Anza*. And *Bridge* expressly left open the possibility that a plaintiff alleging mail fraud "must establish at least third-party reliance in order to prove causation." *Id.* at 659.

4. Thus, in its first three decisions on proximate causation under RICO, the Court had addressed three different fact patterns and invoked at least two different tests. Concurrences and dissents in each, except *Bridge*, pointed out the analytical inconsistencies and potential pitfalls of the majority's

approach. In its next decision, the most recent, the Court's inability to issue a majority opinion on the applicable standard for proximate causation laid bare the lack of consensus. In *Hemi Group LLC v. City of New York*, 559 U.S. 1 (2010), New York City alleged that out-of-state cigarette vendors' failure to report New York City cigarette sales to New York State tobacco tax administrators violated RICO. The failure to file those reports prevented the City from obtaining information about the sales and seeking back taxes. The City thus claimed that the vendors' actions deprived the City of cigarette excise tax revenue. *Id.* at 4–6.

A plurality of the Court held that the City's causal theory was "far more attenuated than the one [the Court] rejected in *Holmes*." *Id.* at 9. As in *Anza*, "the conduct directly causing the harm [the customers' failure to pay taxes] was distinct from the conduct giving rise to the fraud [the failure to file the required sale reports]." *Id.* at 11. The plurality noted that "the City's theory of liability rests not just on separate *actions*, but separate actions carried out by separate *parties*." *Id.* And the plurality distinguished *Hemi* from *Bridge*: while in *Bridge* "there were no independent factors that accounted for the plaintiff's injury, here there certainly were: The City's theory of liability rests on the independent actions of third and even fourth parties." *Id.* at 15 (brackets and quotation marks omitted).

Justice Ginsburg concurred in part and in the judgment. She wrote that endorsing the City's causal theory would permit the City to evade the constitutional limits on its authority to collect city taxes from an out-of-state seller. Justice Ginsburg declined to "subscrib[e] to the broader range of the

Court's proximate cause analysis." *Id.* at 19 (Ginsburg, J., concurring in part and in the judgment).

Justice Breyer, joined by Justices Stevens and Kennedy, dissented. They would have framed the analysis in terms of foreseeability. *Id.* at 22 (Breyer, J., dissenting). And in their view, the City's asserted injury was foreseeable. Moreover, they claimed, the defendants had *intended* the injury to occur, and the injury fell within the set of risks Congress sought to prevent by requiring out-of-state sellers to file reports. *Id.* at 24. The dissent further criticized the plurality's use of the "directness" test, pointing out that courts generally use that concept to *expand* liability beyond foreseeable consequences, rather than to restrict the scope of the proximate-cause inquiry. *Id.* at 25. And complicating matters further, the dissent disagreed with the plurality's view that the facts of *Hemi* were more aligned with *Holmes* and *Anza* than with *Bridge*. *Id.* at 27–28.

The plurality and dissenting opinions in *Hemi* evince continuing debate on the proper reading of *Holmes*, *Anza*, and *Bridge*. The only certain takeaway from these four cases on proximate cause under RICO is that the governing standard, the meaning of "direct relationship," and even the underlying theory, all remain deeply unsettled.

B. The Third Circuit's Error Arises from Unresolved Questions in this Court's Case Law

The Third Circuit below held that the respondent TPPs had sufficiently pleaded that GSK's purported misrepresentations proximately caused economic injury. The court considered this case "more akin to *Bridge* than to *Holmes*, *Anza*, or *Hemi*." It reasoned

that each of the three latter cases "featured plaintiffs alleging harm that was derivative of harm suffered by a more immediate victim of the RICO activity." *In re Avandia*, 804 F.3d at 644.

But the Third Circuit's facile comparison belies the core of uncertainties in this Court's case law. As described above, doubt surrounds the proper application of the "directness" theory of *Holmes* to the facts of *Anza*. The two dissenting opinions in *Anza* questioned the Court's effort to reconcile the two cases; the *Anza* majority itself recognized significant structural differences between the facts before it and *Holmes*. And the plurality and dissenting opinions in *Hemi* make plain that agreement on the meaning of the whole line of RICO proximate-cause cases remains elusive.

In addition, in rejecting GSK's argument that the presence of intermediaries broke the chain of causation, the Third Circuit relied on the notion, articulated in *Bridge*, that the TPP plaintiffs' injuries were "a foreseeable and natural consequence" of GSK's alleged misrepresentations. *Id.* at 645. The court's invocation of that language from *Bridge* implicates the debate, unresolved after *Hemi*, about the relevance of a foreseeability analysis to the RICO proximate-cause inquiry.

In any event, the Third Circuit's supposed reliance on the result in *Bridge* is inconsistent with *Bridge* itself. In attempting to align the facts of this case with *Bridge*, the Third Circuit emphasized that, in *Holmes*, *Anza*, and *Hemi*, this Court "was concerned that the conduct causing plaintiffs' injuries was different than the conduct allegedly constituting a RICO violation," which the Third Circuit asserted was not the case here. *Id.* at 643–44. But in so characterizing the case

law, the Third Circuit overlooked the language in *Bridge* that emphasized the lack of independent intervening factors accounting for the alleged injury in that case. The absence of those intervening factors placed *Bridge* in stark contrast with *Holmes* and *Anza*. Here, in contrast, multiple intervening elements, including physicians' exercise of their independent medical judgment in prescribing Avandia to treat their patients, and the TPPs' own failure to renegotiate prices with GSK, constitute additional links in the chain of causation.

This case presents an attenuated causal chain closely resembling the RICO claim in *Holmes*. The respondent TPPs claim that GSK allegedly made fraudulent misrepresentations about the risks of Avandia; pharmacy benefit managers then supposedly relied on those misrepresentations in placing Avandia in the TPPs' formularies; physicians relied on the alleged misrepresentations in prescribing Avandia; and the TPPs covered the cost of Avandia, which was higher than it would have been absent GSK's misrepresentations. *See In re Avandia*, 804 F.3d at 636. This "House that Jack Built" approach thus presents an ideal opportunity for this Court to revisit and clarify its jurisprudence, and to offer much-needed guidance to the lower courts on proximate cause under RICO.

II. CLARITY ON THE GOVERNING STANDARD FOR PROXIMATE CAUSE UNDER RICO IS OF PARTICULAR AND PRESSING IMPORTANCE TO AMICI'S MEMBERS

This case is just one example of the lower courts' struggle to extract from this Court's case law coherent guiding principles on proximate cause under RICO.

But it demonstrates the especially urgent need for clarity on the issue as it applies to claims against amici's members.

Amici's members face a rising tide of RICO claims brought by TPPs based on alleged fraudulent marketing. The lack of clarity on the issue has resulted in widely divergent results among the lower courts. The Third Circuit's decision only adds to the disarray. Worse, in applying a lenient proximate-cause standard, the Third Circuit's decision invites a new wave of RICO litigation that 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 immediate guidance, these cases will continue to produce conflicting and inconsistent results.

A. The Decision Below Reinforces Divisions Among Lower Courts on RICO Overpricing Claims

In holding that the respondent TPPs plausibly alleged proximate cause, the Third Circuit exacerbated a conflict on whether claims like those here satisfy RICO's proximate-cause requirement.

The Second, Ninth, and Eleventh Circuits have roundly rejected claims similar to those in this case for failure to satisfy RICO's proximate-cause requirement. In *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010), one of the TPPs' theories of injury was that Eli Lilly's alleged misleading marketing of Zyprexa resulted in the TPPs' overpaying for Zyprexa prescriptions. *Id.* at 131. In reversing the district court's denial of summary judgment on the overpricing claim, the Second Circuit reasoned, "After *Hemi Group*, it is clear that plaintiffs' overpricing theory is

too attenuated to meet RICO's requirement of a direct causal connection between the predicate offense and the alleged harm." *Id.* at 136 (internal quotation marks omitted). As the court explained, "Plaintiffs' 'theory of liability rests on the independent actions of third and even fourth parties,' as physicians, PBMs, and PBM Pharmacy and Therapeutics Committees all play a role in the chain between Lilly and TPPs." *Id.* at 134 (citing *Hemi Group*, 559 U.S. at 15).

The Ninth Circuit similarly affirmed the dismissal of a TPP complaint for failure to plead a cognizable theory of proximate cause under RICO. *United Food & Commercial Workers Central Pa. & Reg'l Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255, 257 (9th Cir. 2010). The TPP plaintiffs had alleged economic injury resulting from Amgen's allegedly unlawful marketing of Aranesp and Epogen. Citing *Hemi*, the Ninth Circuit determined that the TPPs' RICO claim against Amgen "involved at least four independent links," relying on a causal theory that was "too attenuated to satisfy the Supreme Court's proximate causation requirement in the RICO context." *Id.* at 257.

Consistent with the Second and Ninth Circuits, the Eleventh Circuit in *Southeast Laborers Health & Welfare Fund v. Bayer Corp.*, 444 F. App'x 401 (11th Cir. 2011), affirmed the district court's dismissal of a TPP's RICO claim for failure adequately to plead proximate cause. *Id.* at 410. The Eleventh Circuit concluded that "the first *Holmes* factor"—that is, the difficulty in ascertaining the amount of damages attributable to the RICO violation as opposed to other independent causes—"weighed heavily against a finding of proximate causation." *Id.*

The Eleventh Circuit further found that its holding in *Bayer Corp.* was consistent with its prior decision in *Ironworkers Local Union 68 v. AstraZeneca Pharmaceuticals, LP*, 634 F.3d 1352 (11th Cir. 2011). *Bayer Corp.*, 444 F. App'x at 410 n.5. In *Ironworkers*, TPPs alleged that fraudulent statements by AstraZeneca induced the TPPs to "unnecessarily pay more for [the more expensive] Seroquel off-label prescriptions," when less expensive prescription medications were available. 634 F.3d at 1356–57. There, the Eleventh Circuit affirmed the dismissal of the claims for failure to plead proximate cause. The court reasoned that the TPPs had not plausibly alleged any injury, because they failed to show that they had not priced the risk of fraudulent misrepresentations by drug manufacturers into the premiums they charged enrollees. *Id.* at 1359–60, 1364.

The First Circuit departed from the Second, Ninth, and Eleventh Circuits in *In re Neurontin Marketing & Sales Practices Litigation*, 712 F.3d 21 (1st Cir. 2013). There, TPPs claimed that the defendant's fraudulent promotion of Neurontin caused them to spend more in covering Neurontin than they would have in covering alternative medications. Relying primarily on the Supreme Court's decision in *Bridge*, the First Circuit held that the TPP had met "both the direct relationship and functional tests articulated in *Holmes* and its progeny." *Id.* at 38. In the court's view, the defendants' characterization of the causal chain as involving at least four steps misconstrued the Supreme Court's framing of the direct-relation test and denied redress to victims whose injuries were foreseeable and intended. *Id.*

The Third Circuit, in issuing the decision below, has joined the First Circuit in its misplaced reliance on

Bridge and invocation of foreseeability principles. The lower courts are now intractably divided on how to evaluate whether RICO claims brought by TPPs based on overpricing satisfy proximate cause. This Court should step in to remedy the confusion.

B. The Decision Below Incentivizes Abusive, Speculative, and Burdensome Litigation

The decision below opens the door to a wave of TPP claims under § 1964(c). RICO already encourages plaintiffs to sue by offering a treble damages remedy. "The object of civil RICO is . . . not merely to compensate victims but to turn them into prosecutors, 'private attorneys general,' dedicated to eliminating racketeering activity." *Rotella v. Wood*, 528 U.S. 549, 557 (2000). As this Court has recognized, the proximate-cause requirement is an important counterweight to this strong incentive to sue. *See Holmes*, 503 U.S. at 266–68 (reasoning that the "very unlikelihood that Congress meant to allow all factually injured plaintiffs to recover" under § 1964(c) favors a proximate-cause requirement). "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 (brackets and internal citation omitted).

By applying a relaxed proximate-cause standard to respondents' RICO claims, the Third Circuit has removed an important bulwark against burdensome litigation. The issues in this case are far from rare or unique. The FDA regularly issues warning letters to pharmaceutical companies challenging particular

statements in the companies' labeling of their products or promotional material. In the past three years alone, the FDA Office of Prescription Drug Promotion has issued 42 such letters. *See Warning Letters and Notice of Violation Letters to Pharmaceutical Companies*, U.S. Food and Drug Administration, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/default.htm. The companies are often able to persuade the FDA of the propriety of the statements at issue, but those warning letters have historically proven a potent, albeit inappropriate, stimulus to private lawsuits. The Third Circuit's decision validating TPPs' RICO allegations and dangling the incentive of treble damages increases the potency of that stimulus. The decision below may tempt TPPs to range farther into dubious theories of liability and to misread or mischaracterize FDA's administrative actions, potentially spawning additional burdensome litigation.

There are thousands of product-liability cases pending throughout the country in both state and federal courts involving challenges to the labeling or promotion of pharmaceutical products. *See, e.g.*, *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig. (No. II)*, No. 2:14-mn-02502 (D.S.C.) (2,835 pending actions); *In re Benicar (Olmesartan) Prods. Liab. Litig.*, No. 1:15-md-2606 (D.N.J.) (1,224 pending actions). Given the sheer number of such cases, lay juries sympathetic to patients who suffered serious but well-known side effects of a drug often mistakenly impose liability on pharmaceutical companies. Frequently, appellate courts correct those mistakes. But under the Third

Circuit's new ruling, and with the enticement of treble damages, product-liability cases could become a new breeding ground for TPP RICO claims. Delaying clarification of the proper RICO proximate-cause standard could thus result in enormous burdens on courts and *amici*'s members in the interim.

Numerous TPP RICO claims related to product-liability cases have already been percolating through courts across the country. The *In re Testosterone Replacement Therapy Products Liability Litigation* in the Northern District of Illinois, for example, comprises 4,863 pending actions. No. 1:14-cv-01748 (N.D. Ill.). Nearly all of the plaintiffs in that multidistrict litigation alleged personal injury resulting from their use of testosterone replacement therapies. But that litigation also includes claims by TPP plaintiffs (first brought in 2014), based on alleged fraudulent marketing of testosterone replacement therapy drugs. *See* Class Action Complaint of Medical Mutual of Ohio, *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, Nos. 1:14-cv-8857, 1:14-cv-1748 (N.D. Ill. Nov. 5, 2014). Just last month, the district court denied the defendants' motion to dismiss, holding that the TPPs had alleged sufficient facts to show proximate cause. *In re Testosterone Replacement Therapy Prods. Liab. Coordinated Pretrial Proceedings*, 2016 WL 427553, at *14 (N.D. Ill. Feb. 3, 2016).

TPP overpricing claims have arisen in similar mass litigation—both multidistrict litigations and class-action suits—in numerous other courts. *See, e.g.*, *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 65 F. Supp. 3d 283, 294 (D. Mass. 2014) (dismissing TPPs' RICO claims as time-barred); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab.*

Litig., 2010 WL 3119499, at *5–8 (S.D. Ill. Aug. 10, 2010) (dismissing TPPs' RICO claims for failure to plead proximate cause); *see also, e.g.*, Amended Complaint, *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm.*, No. 6:14-cv-02359 (W.D. La. Sept. 9, 2014) (alleging, inter alia, RICO overpricing claims). In 2009, Merck Co. agreed to pay $80 million to settle some 190 third-party payor claims that had been brought in federal RICO and state-law consumer protection suits. *See Merck to Pay $80 mln to Settle Some Vioxx Cases*, Reuters (Aug. 3, 2009), http://www.reuters.com/article/merck-vioxx-idUSN038666120090803; *see also In re Vioxx Prods. Liab. Litig.*, No. 2:05-md-1657 (E.D. La).

The decision below will only add to the surge of lawsuits. By recognizing claims for economic injury under § 1964(c) even where the logical connection depends on numerous other links in the causal chain, the Third Circuit's decision creates an irresistible incentive for countless insurance providers, who insure millions of Americans, to bring spurious and attenuated RICO claims against manufacturers of products, ranging well beyond pharmaceuticals, that will burden the courts for years to come. The specter of these suits is especially ominous because they present the possibility of duplicative recovery. At least in multidistrict litigation involving alleged injuries that result from undisclosed risks, individual plaintiffs—more "directly injured victims"—also may assert claims against the manufacturer. *See Holmes*, 503 U.S. at 269–70. Lien provisions entitle TPPs to a share of any damages that these injured beneficiaries may recover in suits against the manufacturers. But the approach the Third Circuit sanctioned would allow TPPs to state a claim for the same injury, in suits that

require far less particularized showings that any beneficiary has been injured. And the decision below could chill defendants from settling a product liability case or False Claims Act case involving marketing of pharmaceuticals for fear of a tag-along RICO case by TPPs following the settlement.

CONCLUSION

For the foregoing reasons, the Court should grant the petition for a writ of certiorari.

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