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, UFCW LOCAL 1776 AND PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, and UNITED BENEFIT FUND,
Respondents.

On Petition for a Writ of Certiorari to the U.S. Court of Appeals for the Third Circuit

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

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QUESTION PRESENTED

Amicus curiae addresses the following issues only:

Whether a third-party payor (TPP) plausibly alleges proximate causation in a civil claim filed under the Racketeer Influenced and Corrupt Organizations Act (RICO), where a TPP alleges that it paid more because a manufacturer's misrepresentations to doctors caused doctors to write more prescriptions for a medication approved by the Food and Drug Administration.

Whether a TPP, in order to adequately plead factual causation, must allege specific facts tying an alleged fraud to its own decision to cover a drug under its prescription plan.

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INTERESTS OF *AMICUS CURIAE*

Washington Legal Foundation (WLF) is a non-profit public interest law firm and policy center with supporters in all 50 states.[1] WLF devotes a substantial portion of its resources to defending free enterprise, individual rights, a limited and accountable government, and the rule of law.

To that end, WLF has appeared before this Court as well as other federal and state courts to argue against overly expansive theories of tort liability and excessive punitive damages. Of particular relevance to this case, WLF has appeared in this Court to argue against an overly expansive interpretation of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961 *et seq.* *See, e.g., RJR Nabisco Inc. v. The European Community,* No. 15-138, *cert. granted*, 136 S. Ct. 28 (2015); *Pfizer Inc. v. Kaiser Found. Health Plan, Inc., cert. denied*, 134 S. Ct. 786 (2013); *Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639 (2008); *Beck v. Prupis*, 529 U.S. 494 (2000).

WLF is concerned that the reflexive invocation of RICO by civil litigants engaged in otherwise garden-variety commercial disputes does violence to the original purpose of RICO and unnecessarily burdens our federal judicial system. While Congress adopted

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. More than 10 days prior to the due date, counsel for WLF provided counsel for Respondents with notice of its intent to file. All parties have consented to the filing; letters of consent have been lodged with the Court.

RICO as a tool to fight organized crime, civil RICO is now all too often invoked in "everyday fraud cases brought against respected and legitimate enterprises." *Sedima, S.P.R.L. v. Imrex Co.,* 473 U.S. 479, 499 (1985). While such use of RICO is at times a reflection of the statute's expansive language, much of the time RICO is invoked inappropriately by opportunistic plaintiffs seeking to force the settlement of doubtful claims by defendants unable to cope with the threat of treble damages and the unfavorable publicity that arises from being labeled a "racketeer."

WLF applauds the Court for its efforts to impose reasonable limits on civil RICO litigation by requiring plaintiffs to demonstrate that the defendants' conduct proximately caused their alleged injuries. WLF is concerned that the Third Circuit decision, if allowed to stand, would substantially undermine those efforts.

STATEMENT OF THE CASE

Avandia is the brand name for rosiglitazone, a widely prescribed pharmaceutical drug recognized as effective in treating Type 2 diabetes mellitus. After concluding that Avandia was safe and effective for its intended uses, the Food and Drug Administration (FDA) in 1999 approved the marketing of Avandia by Petitioner GlaxoSmithKline LLC (GSK). After the expiration of GSK's patent in 2012, rosiglitazone has also been marketed by generic drug manufacturers.

The safety and effectiveness of Avandia has been extensively studied in the years following its initial FDA approval. A focus of many of those studies has been whether use of Avandia increases the risk of heart

attacks and heart-related diseases. Those studies have reached widely varying conclusions. As new studies have emerged, FDA's assessment of Avandia's overall safety profile has varied over time; FDA has required several changes in the product labeling to reflect that varying assessment.

In response to one widely reported 2007 study, FDA requested GSK to add a "black box" warning to the label, to warn of cardiovascular risks associated with use of Avandia. Pet. App. 4a. Although GSK disputed the conclusions of the 2007 study, it complied with FDA's request in August 2007. In September 2010, FDA concluded that Avandia's risk-benefit profile warranted continued marketing approval, but it limited access to existing users and to new patients whose blood sugar could not be controlled with other medications. *Id.* at 5a.

More recent studies have led FDA to conclude that GSK's challenges to the 2007 study's conclusions were well founded. FDA removed restrictions on Avandia prescriptions in November 2013 after concluding that new studies showed that Avandia does not pose "an increased risk of heart attack compared to the standard type 2 diabetes medicines metformin and sulfonylurea." In December 2015, FDA concluded, based on its continuing review of safety data, that special regulatory oversight of Avandia was no longer necessary. Labeling for Avandia no longer contains a black-box warning about the risk of heart attacks.

Proceedings Below. Respondents are union health and welfare funds that provide medical and prescription drug coverage to beneficiaries. As such,

they are often referred to as third-party payors. Respondents alleged that GSK fraudulently failed to disclose that Avandia poses a heart-attack risk, and that that fraud caused them to pay more for Avandia prescriptions for their beneficiaries than they would have paid in the absence of fraud. Specifically, Respondents alleged that they relied on GSK's representations when making formulary decisions, causing them to pay for Avandia when they otherwise would not have. They also alleged that doctors prescribed more Avandia than they would have because of GSK's representations, leading Respondents to cover a greater number of prescriptions.

Respondents filed putative class actions against GSK, alleging that GSK's allegedly fraudulent conduct violated, *inter alia*, the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961 *et seq.* In 2013, the district court denied GSK's Rule 12(b)(6) motion to dismiss the complaint for failure to state a cause of action. Pet. App. 30a-62a. In particular, the court concluded that Respondents had "alleged sufficient facts regarding the causal relationship between GSK's concealment of the drug's true safety profile and [Respondents'] injuries to satisfy the causation requirements at this stage of the litigation." *Id.* at 51a. The court nonetheless "note[d] the potential difficulty in proving causation in the next stage of the litigation," given that Respondents "did not act to remove Avandia from their formularies or even restrict their coverage of Avandia in light of research published and widely publicized in 2007." *Ibid.*

On interlocutory appeal, the Third Circuit affirmed the district court's denial of the motion to

dismiss. Pet. App. 1a-29a. GSK argued on appeal that "the presence of intermediaries, doctors and patients, destroys proximate causation because they were the ones who ultimately decided whether to rely on GSK's misrepresentations." *Id.* at 27a. The appeals court disagreed, concluding that the increase in Avandia prescriptions allegedly brought about by GSK's alleged fraud caused an injury to Respondents that "is sufficiently direct to satisfy the RICO proximate cause requirement." *Id.* at 28a.

The Third Circuit also held that Respondents had adequately pleaded causation under their "excess price" theory—that is, a claim that GSK's alleged misrepresentations permitted GSK to sell Avandia at a price higher than what the market would have borne had GSK not engaged in fraud. *Id.* at 24a-25a. In particular, Respondents allege that they (and the Pharmacy Benefits Managers on which they relied) would not have placed Avandia on their formularies had they not been misled. *Id.* at 24a. Although GSK argued that Respondents failed to allege sufficient facts to support a claim that GSK's conduct caused them to suffer any "excess price" injury, the appeals court held that that argument simply raised an "issue of proof " rather than demonstrating an absence of causation. *Id.* at 25a.[2]

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[2] The Third Circuit also rejected GSK's contention that Respondents inadequately alleged injury to business or property within the meaning of RICO. Pet. App. 12a-18a. That contention is the subject of the Petition's first question presented. WhileWLF supports GSK's efforts to obtain review on that issue as well, this brief does not separately address the issue.

To support its argument that the complaint did not adequately plead causation with respect to its "excess price" theory, GSK asserted that Respondents continued to cover Avandia in their formularies following release of the May 2007 study that raised questions about Avandia's safety. The Third Circuit dismissed that assertion, stating that "[a]t this stage ... we do not know this to be true." *Ibid.* In so ruling, the Third Circuit in essence imposed on GSK the burden of disproving causation rather than imposing on Respondents the burden of alleging facts to support its claim that it was injured by GSK's conduct.

SUMMARY OF ARGUMENT

This case raises issues of exceptional importance to the business community, and to the pharmaceutical industry in particular. As the Petition well documents, the lower federal courts are seeing a boom in RICO suits against pharmaceutical manufacturers for alleged inaccuracies in their marketing concerning the safety and efficacy of their prescription drugs. Given the ever-increasing annual expenditures for health care in general and especially for prescription drugs, it is unsurprising that health insurers are exploring all options for holding down costs. But if the Third Circuit's decision is upheld, one can reasonably expect that insurers will turn increasingly to the RICO option: attempting to brand pharmaceutical companies as "racketeers" in an effort to utilize RICO's treble-damages provision. The Third Circuit has interpreted RICO's causation requirements in a manner that conflicts with existing precedent and will make it much easier for future claimants of all stripes to bring gargantuan damage claims before juries.

Review is warranted to address that conflict. GSK's Petition discusses at length the conflict between the decision below and the decisions of other federal appeals courts and district courts regarding the proximate causation requirement in RICO cases.

WLF writes separately to focus on the conflict between the decisions below and this Court's decisions. The Court held in *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258 (1992), that 18 U.S.C. § 1964(c)'s "by reason of " language imposes a "proximate cause" requirement on civil RICO claimants. It is not enough for a claimant to demonstrate that the defendant's actions were simply a but-for cause of his injury; there must also be a sufficiently "direct relationship" between the claimant and the defendant. *Id.* at 268. The directness of the relationship is a "central element" of proximate causation because "the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff 's damages attributable to the violation, as distinct from other, independent factors." *Id.* at 269.

The Third Circuit appeared to recognize that the requisite direct relationship cannot be established based solely on evidence that injury to the claimant was a "foreseeable" result of the defendant's actions. Pet. App. at 27a. The court asserted, however, that a direct relationship existed here because the evidence showed not only foreseeability but also that the TPPs were a "primary and intended victim of [GSK's] scheme to defraud." *Ibid.* But that latter assertion was based on little more than the court's determination that injury to the TPPs was foreseeable. It was not based on allegations that GSK set out purposely to injure

Respondents or that the causal chain here was particularly direct.

The appeals court concluded that the complaint plausibly alleged that increased Avandia prescriptions among the TPPs' members attributable to GSK's alleged misrepresentations would increase the TPPs' costs (in comparison to other treatment options), and thus that Respondents' injuries were a "foreseeable and natural consequence of the scheme." *Ibid.* But while it is foreseeable that a TPP might incur increased costs when a drug company misrepresents to doctors and patients the safety risks of one of its prescription drugs, the TPP cannot plausibly be viewed as the "primary and intended victim" of such a scheme. Rather, if there is a "primary" victim, it is the patient who may be injured by being administered an inappropriate drug. Another set of potential victims: competitors whose drugs might have been purchased (and paid for by the TPPs) in the absence of the alleged misrepresentation.

The Court has determined that Congress, when it created a right of action under RICO, intended to limit the universe of potential plaintiffs in order to avoid the intractable factual issues regarding causation and damages that inevitably arise whenever claims are asserted by those not most directly affected by the alleged racketeering activity. *Holmes* and subsequent decisions have made clear that a RICO plaintiff must demonstrate not only factual causation but also proximate causation, which places "a particular emphasis on the demand for some direct relation between the injury asserted and the injurious conduct alleged." *Bridge v. Phoenix Bond & Indemnity Co.*, 553

U.S. 639, 654 (2008). The Third Circuit stretches the concept of proximate cause to the breaking point when it asserts a "direct" relationship between GSK's alleged misconduct and the TPPs' alleged injuries—despite the fact that any injury is highly dependent on the uncertain conduct of intermediaries. Review is warranted to resolve the conflict between the decision below and this Court's proximate-cause case law.

Review is also warranted for the third Question Presented, which addresses minimum pleading standards for a RICO claim. Given the relative ease with which potential RICO claimants can transform differing interpretations of scientific evidence into alleged racketeering activities—and the increased willingness of the plaintiffs' bar to make that leap—it is increasingly crucial for federal courts to ensure that complaints do not proceed past the pleadings stage on the basis of unsupported allegations.

Yet, the Third Circuit ruled that the TPPs adequately alleged direct reliance on GSK's alleged misrepresentations, despite their failure to allege *any* facts supporting their claimed reliance. In particular, the complaint asserts—without any supporting factual allegations—that those misrepresentations caused them to make formulary decisions regarding Avandia that they would not otherwise have made. However, GSK asserts without contradiction that the TPPs' conduct (*e.g.*, their decision to continue to cover the costs of Avandia after 2007) was inconsistent with their claim of reliance.

The Third Circuit's decision to permit the complaint to proceed on the basis of such bare-boned

allegations directly conflicts with this Court's case law. *See, e.g., Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (holding that Fed.R.Civ.P. 8 requires that a complaint, to survive a motion to dismiss, must include sufficient factual allegations to "raise a right to relief above the speculative level."). The complaint includes no factual allegations from which one could reasonably infer that Respondents actually changed their behavior as a result of GSK's alleged misrepresentations, and thus the TPPs have not adequately alleged that misrepresentations made to them by GSK actually caused them to suffer any injury. Review is warranted to resolve the conflict between the Third Circuit's decision and this Court's Rule 8 case law.

REASONS FOR GRANTING THE PETITION

I. THE DECISION BELOW CONFLICTS WITH THIS COURT'S DECISIONS REGARDING PROXIMATE CAUSE IN RICO CASES

The Third Circuit's conclusion that RICO's proximate cause requirements can be satisfied based on little more than the foreseeability of the plaintiff 's injury—despite the independent decisions of intervening doctors—squarely conflicts with a long line of decisions from this Court. Review is warranted to address that conflict, particularly given the increasing frequency with which proximate-cause issues arise in RICO cases brought against pharmaceutical companies.

A. *Holmes* and *Anza* Established that Proximate Cause Requires a RICO Plaintiff to Demonstrate a Direct Relation Between the Injurious Conduct and the Asserted Injury

The Court held a quarter century ago in *Holmes* that a civil litigant may not recover damages for a RICO violation in the absence of evidence that his injuries were proximately caused by the violation. The statute creating a private right of action for violations of RICO, 18 U.S.C. § 1964(c), provides:

> Any person injured in his business or property by reason of a violation of section 1962 of this chapter may sue therefor ... and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney's fee.

Holmes relied on § 1964(c)'s "by reason of" language in concluding that Congress intended to require proof of proximate cause. While conceding that the language could be read to mean that a plaintiff demonstrates injury, and therefore may recover damages, "simply on showing that the defendant violated § 1962, the plaintiff was injured, and the defendant's violation was a 'but for' cause of plaintiff's injuries," the Court rejected that "expansive" reading, based largely on "the very unlikelihood that Congress meant to allow all factually injured plaintiffs to recover." *Holmes*, 503 U.S. at 265-66.

The Court stated that "the infinite variety of

claims that may arise make it virtually impossible to announce a blackletter rule that will dictate the result in every case" regarding whether an injury was "proximately caused" by the defendant's actions. *Id.* at 272 n.20 (quoting *Associated General Contractors of Cal., Inc. v. Carpenters*, 459 U.S. 519, 536 (1983)). Nonetheless, the Court provided some general guidelines for use in making that determination:

> [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. ... Although such directness of relationship is not the sole requirement of Clayton Act causation, it has been one of its central elements, for a variety of reasons. First, the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent factors.

Id. at 269 (citations omitted).[3]

Relying on *Holmes*, the Court in *Anza v. Ideal*

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[3] *Holmes* went on to conclude that the plaintiff could not demonstrate that its injury was proximately caused by the defendant's alleged racketeering activity (stock manipulation) because the link between the stock manipulation and its injury was "too remote"—the harm only arose because the stock manipulation caused harm to third parties who were thereby rendered insolvent and thus unable to meet their obligations to individuals in whose shoes the plaintiff claimed to stand. *Id.* at 271.

Steel Supply Corp., 547 U.S. 451 (2006), determined that the plaintiff's RICO action under 18 U.S.C. § 1964(c) failed to adequately allege proximate cause. The plaintiff was an entrepreneur who contended that a business rival violated RICO by failing to properly pay New York sales taxes on some of its sales. The plaintiff alleged that it was injured by the RICO violation because by failing to charge sales tax, the competitor was able to undercut the plaintiff's prices and thereby induce customers to reduce their purchases from the plaintiff.

The Court explained that in evaluating a RICO claim for proximate causation, the "central question" a court must ask is whether the alleged violations led "directly" to the plaintiff 's injuries. 547 U.S. at 461. The Court did not contest the dissent's contention that the plaintiff's injuries were an entirely foreseeable result of the defendant's fraudulent scheme. It nonetheless concluded that no "direct" relationship existed between the fraudulent scheme and the plaintiff's injuries, and thus that proximate cause was lacking. *Ibid.* Among the reasons the Court cited for determining that the relationship was insufficiently direct: "Businesses lose and gain customers for many reasons, and it would require a complex assessment to establish what portion of [the plaintiff's] lost sales were the product of [the defendant's] decreased prices." *Id.* at 459.

Similarly, doctors treating patients with Type 2 diabetes may choose from a variety of treatment options, including Avandia. It would be extremely difficult for a court to distinguish between doctors who prescribed Avandia in reliance on GSK's alleged

misrepresentations and doctors who prescribed Avandia because, quite apart from GSK's alleged misrepresentations, they concluded that Avandia best met their patients' treatment needs. Yet, TPPs could plausibly claim that GSK's alleged misconduct caused them injury under an excess-prescriptions theory only under the first of those two scenarios. *Holmes* and *Anza* concluded that Congress adopted RICO's proximate-cause requirement in significant part because it sought to avoid entangling courts in such difficult-to-resolve causation issues.

The Court again invoked proximate-causation principles to dismiss a civil RICO action in *Hemi Group, LLC v. City of New York,* 559 U.S. 1 (2010). The plaintiff, New York City, sought to recover RICO damages from out-of-state cigarette retailers who allegedly violated New York law by failing to file customer information with New York State. The plaintiff alleged that the failure to file caused it injury (in the form of lost tax revenue) because the failure deprived it of the opportunity to contact cigarette purchasers to demand that they pay city taxes on their purchases. In rejecting a claim that proximate cause was established by allegations that the city's loss of tax revenue was a highly foreseeable result of the defendant's misconduct, the plurality opinion explained that "in the RICO context, the focus [of the proximate cause inquiry] is on the directness of the relationship between the conduct and the harm," not simply on whether the plaintiff was a foreseeable victim of the defendant's misconduct. 559 U.S. at 12 (plurality opinion).

The Third Circuit sought to distinguish *Holmes*,

Anza, and *Hemi* by asserting that, unlike in this case, "the conduct causing plaintiffs' injuries was different than the conduct allegedly constituting a RICO violation." Pet. App. 23a. That alleged distinction is not factually accurate. In both *Holmes* and *Hemi*, the plaintiffs asserted that the defendants' conduct constituting RICO violations (stock manipulation in *Holmes*, failure to file customer information in *Hemi*) was the cause of their injury. In both cases, the Court held that even if the alleged conduct could be deemed a but-for cause of the alleged injuries, the plaintiffs had not adequately alleged proximate cause.

The presence of intermediaries in each case (the broker-dealers driven into insolvency in *Holmes*, the taxpayers whose tax evasion the defendants facilitated in *Hemi*) rendered the causal relationship insufficiently direct to satisfy RICO's requirements. Similarly here, even though Respondents have alleged that GSK's misrepresentations to doctors ultimately caused them to incur increased costs, the independent actions of the intermediaries in the causal chain (doctors and patients) prevents a finding that those allegedly misleading statements proximately caused their injuries.

B. *Bridge* Did Not Retreat from the Direct Relationship Requirement

In concluding that the TPPs had adequately alleged proximate cause, the Third Circuit relied to a large extent on the Court's 2008 *Bridge* decision. It asserted, "[W]e view the case before us as more akin to *Bridge* than to *Holmes*, *Anza*, and *Hemi*." Pet. App. 23a. The appeals court read far too much into *Bridge*,

in which a unanimous Court stood firmly behind *Holmes*'s holding that proximate cause cannot be established in a RICO action in the absence of a "direct relation between the injury asserted and the injurious conduct alleged." *Bridge*, 553 U.S. at 654.

The parties in *Bridge* were competing bidders at tax lien auctions conducted by Cook County, Illinois. The county established bidding rules designed to ensure that bidders could acquire a roughly equal number of liens. The RICO defendants allegedly made false statements to the county as part of a mail-fraud scheme that, by direct operation of the bidding rules, resulted in tax liens being awarded to the defendants that should have been awarded to the plaintiffs. Because the defendants' false statements were directed to the county and not to the plaintiffs, the injured RICO plaintiffs could not allege that they had relied on those statements. The Court nonetheless unanimously affirmed the appeals court's reinstatement of the plaintiffs' RICO claim, holding that "a plaintiff asserting a RICO claim predicated on mail fraud need not show, either as an element of its claim or as a prerequisite to establishing proximate causation, that it relied on the defendant's alleged misrepresentations." *Bridge*, 553 U.S. at 661.

According to the Third Circuit, *Bridge* held that the RICO plaintiffs satisfied *Holmes*'s "direct relation" requirement (and thus established proximate cause) "because" the plaintiffs' injury was a "foreseeable and natural consequence" of the defendants' fraudulent scheme. Pet. App. 23a. That account misreads *Bridge*, which recognized that foreseeability of injury is but one relevant factor in determining whether a "direct

relation" exists.

Bridge held that a "direct" relationship existed between the defendants' mail fraud and the plaintiffs' injury, even though the defendants' fraud was directed at an intermediary—Cook County. Key to that holding was the Court's recognition that the county's intermediary role was entirely ministerial. It exercised no discretion in responding to the defendant's fraudulent statements but rather simply allocated tax liens to the defendants in accordance with pre-existing regulations.[4] Because a larger percentage of available tax liens were allocated to the defendants than they would have received in the absence of their fraudulent scheme, the inevitable result was that the plaintiffs received fewer tax liens. Under those circumstances, *Bridge* had no difficulty in concluding that the plaintiffs' "alleged injury—the loss of valuable liens—is the direct result of [the defendants'] fraud," and thus that the plaintiffs had established proximate cause. *Bridge*, 553 U.S. at 658.

Key to *Bridge*'s "direct relation" determination was the absence of any discretionary decision-making by Cook County in awarding tax liens in response to bids. It was not only foreseeable but also inevitable

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[4] To ensure equitable allocation of tax liens among bidders, county regulations required those seeking tax liens to submit a single bid in their own names and to certify that they were not submitting multiple bids under assumed names. 553 U.S. at 643. Despite those rules, the principal defendant was alleged to have submitted numerous duplicate bids in the names of entities he controlled. Believing that each of the bids had come from independent entities, the county assigned a full share of tax liens to each of the defendant's entities.

that the plaintiffs would suffer their claimed injury (a decrease in the number tax liens awarded to them) as a result of the defendants' fraudulent scheme. "Unlike in *Holmes* and *Anza*," there were "no independent factors that [could] account for the [plaintiffs'] injury," *ibid*, because the county's extremely limited role as an intermediary between the misconduct and injury had no possible effect on the scope of the plaintiffs' injury.

The facts here differ sharply from those in *Bridge*. Under their excess-prescriptions theory, the TPPs allege that they suffered injury when GSK's misrepresentations to doctors regarding Avandia's safety caused doctors to write more prescriptions for the TPPs' beneficiaries than they would have written in the absence of those misrepresentations. But unlike in *Bridge*, numerous "independent factors" could have led those doctors to write Avandia prescriptions—such as their determinations, based on their independent professional judgments, that Avandia best met their patients' medical needs.

Moreover, it is far from clear whether Respondents incur a net expense when a doctor prescribes Avandia to one of their beneficiaries suffering from Type 2 diabetes. To resolve that issue, courts would need to determine on a case-by-case basis whether, in lieu of an Avandia prescription, the prescribing doctor would have prescribed an even more expensive treatment. Sparing courts from having to address such difficult causation and damages questions is a principal virtue of the "direct relation" test. As *Holmes* explained in support of its recognition of a proximate-cause requirement in RICO cases, "the less direct an injury is, the more difficult it becomes to

ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent factors." *Holmes*, 503 U.S. at 269.

Bridge also deemed it relevant to the causation analysis that the plaintiff bidders were "the primary and intended victims of the scheme to defraud." 553 U.S. at 650. No one other than rival bidders could possibly have been injured by the defendants' fraudulent scheme. Certainly the county itself (which profited from every tax lien sale, without regard to whether the liens were equitably distributed) was not injured by the scheme. In sharp contrast, it is quite a stretch to characterize TPPs as the "primary" victims of a drug manufacturer's alleged scheme to misrepresent safety concerns about one of its drugs. The most likely victims of any such schemes are patients, who may suffer injury if their doctors prescribe a contraindicated drug as a result of fraudulent statements by the drug manufacturer. Alternatively, as in *Bridge*, business competitors may be injured by the drug manufacturer's fraud; they stand to lose sales if doctors are fraudulently induced to switch away from using their prescription products. Thus, contrary to the Third Circuit's contention, a finding that TPPs cannot establish proximate cause will not provide a free pass to drug manufacturers that misrepresent a drug's safety profile.

In sum, the Third Circuit's reliance on *Bridge* was wholly misplaced. Properly understood, that decision strongly reaffirms *Holmes*'s "direct relation" test and sharply conflicts with the decision below. Review is warranted to resolve that conflict.

II. THE DECISION BELOW CONFLICTS WITH THIS COURT'S DECISIONS REQUIRING PLAINTIFFS TO PLEAD FACTS SUFFICIENT TO RENDER PLAUSIBLE THEIR FRAUD CLAIMS

As the *amicus curiae* brief filed by the Pharmaceutical Research and Manufacturers of America amply demonstrates, the plaintiffs' bar has filed scores of RICO claims against drug companies on behalf of TPPs in recent years. The complaints follow a general pattern: the defendant is alleged to have made false safety or effectiveness claims regarding its product, and the TPPs allege that they suffered injury when they reimbursed beneficiaries for the cost of drug prescriptions generated by the false claims. As this case well illustrates, evidence regarding a drug's safety and effectiveness is subject to multiple interpretations. Indeed, FDA's views regarding safety and effectiveness can vary considerably over time, as new clinical studies are completed. Accordingly, it takes little imagination for TPPs attracted by RICO's treble-damages provision to plausibly allege that a manufacturer's safety and efficacy claims were fraudulent. Given the increasing frequency with which drug companies are being targeted by RICO claims, review is warranted to provide lower courts with much-needed guidance regarding minimum pleading requirements for such claims. Unless drug companies can win dismissal of implausible claims at the pleadings stage, they face massive litigation costs in defending against such claims through the discovery phase.

Yet, the Third Circuit's decision allows Respondents to move forward with their claims that

they directly relied on GSK's alleged misrepresentations, based on nothing more than bare-bones allegations of reliance. In particular, the complaint asserts—without any supporting factual allegations—that those misrepresentations caused them to make formulary decisions regarding Avandia that they would not otherwise have made. The Third Circuit's decision to permit the complaint to proceed on the basis of those unsupported causation/reliance allegations directly conflicts with this Court's case law.

Fed.R.Civ.P. 8(a)(2) requires a complaint to include "a short and plain statement of the claim showing that the pleader is entitled to relief." While that rule eliminated the requirement that a claimant "set out *in detail* the facts upon which he bases his claim," *Conley v. Gibson,* 355 U.S. 41, 47 (1957) (emphasis added), the rule:

> [S]till requires a "showing," rather than a blanket assertion, of entitlement to relief. Without some factual allegation in the complaint, it is hard to see how a claimant could satisfy the requirement of providing not only "fair notice" of the nature of the claim, but also "grounds" on which the claim rests. See 5 Wright & Miller § 1202, at 94, 95 (Rule 8(a) "contemplate[s] the statement of circumstances, occurrences, and events in support of the claim presented" and does not authorize a pleader's "bare averment that he wants relief and is entitled to it").

Twombly, 550 U.S. at 555 n.3.

Twombly held that Rule 8(a) requires a complaint to include sufficient "factual matter" to provide "plausible grounds" to infer that the allegations of the complaint are true. *Id.* at 556. It held that requiring plausibility "reflects the threshold requirement of Rule 8(a)(2) that the 'plain statement' possess enough heft to 'sho[w] that the pleader is entitled to relief.'" *Id.* at 557. The Court explained that a test requiring plausibility is not so strict as to require "probability" but nonetheless requires more than that the allegations are merely possible or conceivable. *Id.* at 557, 570.

In addition to alleging reliance by doctors, the complaint asserts that the TPPs relied on GSK's alleged misrepresentations in making formulary decisions. The TPPs allege that but for those misrepresentations, they would not have continued to include Avandia on their formularies and instead would have steered beneficiaries to lower-cost and safer medications for treating Type 2 diabetes. Yet, the complaint does not include any factual allegations to support that reliance claim. The complaint does not satisfy *Twombly*'s mandate that it include sufficient "factual matter" to provide "plausible grounds" to infer that the allegations of reliance are true. *Id.* at 556.

Indeed, the evidence submitted by GSK in connection with its motion to dismiss suggests precisely the opposite. Because the TPPs continued to include Avandia in their formularies even after the release of reports in 2007 and later years suggesting that use of Avandia posed a significant risk of heart attacks, the logical inference is that the TPPs' previous decision to include Avandia was *not* made in reliance

on GSK's alleged misrepresentations.

The Third Circuit cited two grounds for rejecting GSK's assertion that the TPPs had inadequately alleged reliance. Pet. App. 25a-26a. First, it was unwilling to accept as truthful GSK's assertion that the TPPs continued to cover Avandia following 2007:

> GSK first asks us to assume in the absence of contrary allegations, that plaintiffs did not change their coverage of Avandia in 2007. At this stage, however, we do not know that this is true.

Pet. App. 25a. Second, the Third Circuit surmised that if the TPPs did not drop their coverage of Avandia in 2007, perhaps they delayed doing so because they were not yet fully aware of Avandia's risks until some later date. *Id.* at 25a-26a.

That rationale directly conflicts with this Court's decisions in *Twombly* and *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Those decisions direct federal court claimants to present at the pleadings stage factual allegations that render plausible each element of their claims. The TPPs' reliance claim simply is not plausible in the absence of a factual allegation that they altered their conduct once they learned the truth about the alleged misrepresentations on which they supposedly had been relying. Absent such factual allegations, the complaint fails to "raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555.

In conflict with those decisions, the Third Circuit

concluded that the absence of specific factual allegations regarding the TPPs' reliance was grounds for *denying* dismissal of the TPPs' claims at the pleadings stage. It reasoned that a determination regarding the viability of the TPPs' reliance claims should be delayed until later stages of the litigation. Pet. App. at 25a-26a. Given the extreme importance of this issue to the pharmaceutical industry and the likelihood that the number of similar TPP lawsuits will balloon if the Third Circuit's decision is allowed to stand, review is warranted to resolve the conflict between the decision below and this Court's Rule 8 case law.

CONCLUSION

The Court should grant the Petition.

Respectfully submitted,

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