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 United States Court of Appeals For the Third Circuit

REPLY BRIEF OF PETITIONER

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CASES

Respondents concede that the courts of appeals are divided over what qualifies as "injury to property" under the Racketeer Influenced and Corrupt Organizations Act ("RICO") in cases, like this one, involving allegations that a third-party payor ("TPP") overpaid for a drug even though it was effective. They also recognize that the issues presented have "important policy implications" for the entire "American health care" system. (Br. in Opp'n ("BIO") at 33.)

Nevertheless, respondents ask the Court to deny certiorari on the supposed ground that the Eleventh Circuit's ruling in *Ironworkers* was an "outlier" decision. This contention oversimplifies the appellate split on RICO injury, which became more fractured in light of the unique price-inflation theory minted by the decision below. While respondents focus on two decisions that have disagreed with the Eleventh Circuit's approach, other courts have acknowledged its logic. Moreover, several courts of appeals have expressly rejected reliance on price-inflation theories like the one endorsed by the Third Circuit here – a point that respondents barely address. Indeed, respondents *do not even attempt to defend the Third Circuit's theory that GSK somehow "inflated" the price of Avandia*, instead quietly framing their theory of injury along the lines they originally pled – that they would not have covered the drug or that doctors would not have prescribed it. (BIO 24.)

Respondents also raise for the first time GSK's 2012 plea agreement, as though it has some relevance to the questions before the Court. The plea agreement is a red herring. For one thing, it only addressed GSK's reporting obligation to the FDA, not its marketing to TPPs or physicians. (BIO App. 2a (referencing "failure to report data relating to clinical

experience" and "other data and information" with respect to Avandia).) In any event, the plea expressly states: "*No identifiable economic loss appears to have been suffered by the federal [FDA], and the parties were unable to determine any economic loss to others directly and proximately caused by this offense*." (BIO App. 8a (emphasis added).) Thus, respondents' assertion that the plea involved "the same harm of paying excess prices for excessive sales of a compromised product" (BIO 3) is *expressly disclaimed* by the plea itself. If anything, the plea's acknowledgment that economic loss is not easily established only serves to highlight the Third Circuit's errors, the importance of the questions presented, and the need for this Court's intervention.

Notably, respondents ignore the most salient fact in Avandia's regulatory history: since respondents filed suit, the FDA has *eliminated* the heightened, black-box warning about Avandia's alleged cardiovascular risks because the data do not support the existence of any increased risk. Thus, the TPPs seek to invoke RICO's treble-damages provision based on a supposed risk that has now been refuted, underscoring the danger of mischaracterizing ongoing scientific study and debate as actionable "fraud." (Pet. 3-6.)[1]

As amici point out, the ramifications of this tactic are significant. TPP RICO claims against drug man-

[1] Although respondents briefly reference a civil settlement relating to Avandia (BIO 1; BIO App. 37a), that settlement makes clear that GSK "expressly denie[d] the allegations" at issue, including allegations about certain cardiovascular issues (see *id.* 39a-42a), a position that was vindicated by the FDA's subsequent findings.

ufacturers comprise a significant and growing segment of the federal docket, and absent review, the decision below will only fuel this growth by lowering the pleading barriers to entry.

The Court should grant review to provide critical guidance for lower courts presiding over such cases and reverse the Third Circuit's erroneous decision.

ARGUMENT

As set forth in the petition, the Court should grant review for three reasons. First, as respondents concede, the courts of appeals are divided over whether a TPP states a RICO injury by alleging that it overpaid for a drug where there are no allegations that the drug was ineffective or that it injured any of the TPP's beneficiaries. Second, the courts are also split over application of this Court's RICO precedents concerning proximate causation in cases involving allegations that a manufacturer's misrepresentations about one of its drugs caused doctors to write more prescriptions paid for by the TPPs. And third, the Third Circuit's holding that respondents' conclusory allegations of reliance sufficed to establish causation in fact conflicts with this Court's precedents holding that a plaintiff has a burden of pleading *facts* that show entitlement to relief. For the reasons set forth below, respondents' contrary arguments on each of these points lack merit, and the Court should grant the petition.

I. The Court Should Resolve the Acknowledged Circuit Split as to Whether Overpayment for an Effective Drug Suffices to Establish RICO Injury.

As respondents concede, "[t]he Third Circuit . . . refused to credit" the Eleventh Circuit's decision in

Ironworkers Local Union No. 68 v. AstraZeneca Pharmaceuticals, LP, 634 F.3d 1352 (11th Cir. 2011), regarding the requirements for alleging RICO injury in TPP cases like this one. (BIO 21.) The Third Circuit did so even though, like this case, "*Ironworkers* also involved TPPs who sought damages because of [alleged] fraudulently induced payments for more expensive prescriptions." (*Id.* 20.) There is no way to reconcile the Third Circuit's determination that TPPs state a cognizable RICO injury by alleging that a drug manufacturer's behavior caused an "inflationary effect" on the drug's price, irrespective of the drug's "effectiveness" (Pet. App. 15a), with the Eleventh Circuit's determination that a TPP does *not* state a cognizable injury under RICO merely by paying for "a more expensive drug" without proof that the drug was "unsafe or ineffective," *Ironworkers*, 634 F.3d at 1363.

Despite conceding this clear conflict, respondents contend that review is unnecessary because "[th]e Eleventh Circuit [d]ecision in *Ironworkers* [i]s [i]ndefensible" and an "outlier." (See BIO 19-22.) These merits arguments, which parrot the language of the Third Circuit and other courts on respondents' side of the split, ignore the fact that other decisions have followed the Eleventh Circuit's approach to injury in TPP cases like this one. See, *e.g.*, *Health Care Serv. Corp. v. Olivares*, No. 2:10-CV-221-DF-CE, 2011 WL 4591915, at *1 (E.D. Tex. Sept. 30, 2011) (adopting report and recommendation dismissing TPP's claims for lack of injury; "the court concludes that the Fifth Circuit will most likely agree with the

Eleventh Circuit's reasoning in *Ironworkers*").[2] As such, respondents' arguments only amplify the need for this Court to resolve the split and provide guidance to the lower courts on whether allegations of overpayment are sufficient to state a cognizable injury under RICO when a drug is not alleged to have been ineffective or to have harmed the TPP's beneficiaries.

This is particularly so because the approach taken by the Third Circuit is wrong as a matter of law and logic. As the petition explains, the price-inflation theory adopted by the Third Circuit has been resoundingly rejected in the RICO context by other federal courts – including *several other courts of appeals*. (Pet. 18-20.) The Second Circuit, for instance, has explained that a "price impact" theory has no place in RICO cases involving prescription drugs because the "market for prescription drugs is quite inelastic, meaning that the price of a medication rarely has significant impact on the demand for that medication." *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 125 (2d Cir. 2010) (discussed in Pet. 19); see also *McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215, 228-29 (2d Cir. 2008) (holding that "loss of value" and "price impact" theories of injury are not susceptible to generalized proof); *Se. Laborers Health*

[2] This prediction was well founded in light of the Fifth Circuit's ruling in *Rivera v. Wyeth-Ayerst Laboratories*, 283 F.3d 315, 319-21 (5th Cir. 2002), that a consumer plaintiff cannot satisfy Article III standing by merely alleging that a drug poses undisclosed risks of harm that did not manifest in the plaintiff. Respondents brush *Rivera* aside as a non-RICO case (BIO 32 n.18), but it necessarily follows that a plaintiff who lacks *constitutional* standing to sue would also lack *statutory* standing to sue, whether under RICO or any other law.

& Welfare Fund v. Bayer Corp., 444 F. App'x 401, 405-410 & n.4 (11th Cir. 2011) (discussed in Pet. 19) (rejecting allegation that a TPP "paid too much" for a drug as an impermissible "fraud on the market" theory and explaining that the notion that there is a "market capable of efficiently digesting the truth [about a drug] and relaying it to [a TPP] in the form of a market price" is either too indirect or foreclosed by case law).

Respondents all but ignore the price-inflation theory adopted by the Third Circuit and barely address these cases, instead attempting to brush them aside because (as GSK acknowledged in the petition) they were decided "'under the auspices of RICO's proximate-causation requirement rather than injury.'" (BIO 23 (quoting Pet. 20 n.7).) But this argument is formalistic in the extreme. At bottom, the cases all rejected price-inflation theories because the notion that a RICO violation could distort market prices is implausible, a conclusion that applies whether the problem is described as one of "causation" or "injury." Either way, the notion that "the market [is] an efficient translator of data to price" is not tenable outside securities markets. *Summit Props. Inc. v. Hoechst Celanese Corp.*, 214 F.3d 556, 561 (5th Cir. 2000), *recognized as overruled on other grounds by Haley v. Merial, Ltd.*, 292 F.R.D. 339, 356-58 & n.11 (N.D. Miss. 2013) (cited in Pet. 20). Notably, the Second Circuit's decision in *McLaughlin v. American Tobacco Co.*, 522 F.3d 215 (2d Cir. 2008), followed essentially the same logic in rejecting price inflation both as a theory of proximate causation and as a theory of injury (see Pet. 20 n.7) – a point respondents do not even attempt to address.

The Third Circuit likewise ignored the many cases rejecting price-inflation theories in RICO cases, instead importing a price-inflation theory from *In re Warfarin Sodium Antitrust Litigation*, 391 F.3d 516 (3d Cir. 2004), which addressed the classwide settlement of an antitrust case. (See Pet. 21-22.) Respondents relegate *Warfarin – the lynchpin of the decision below* – to a *footnote*, briefly referencing "the relationship between RICO and antitrust theories" that "this Court has repeatedly noted." (BIO 23.) But as the petition detailed, *Warfarin* involved price differences between chemically identical drugs (a brand-name drug and its generic equivalent). Here, by contrast, the alternatives to Avandia were different drugs with varying risk-benefit profiles and price points – and prescribing physicians considered a number of patient-specific factors in selecting appropriate diabetes medications for their patients. As such, a price-inflation theory would involve far more "'intricate [and] uncertain inquiries,'" as the Court foresaw in advising caution when importing antitrust injury principles into the RICO context. (Pet. 22 (quoting *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 459-60 (2006)).)

In short, respondents' effort to cast the law in this area as settled is belied by the caselaw. The Court should grant review to address the acknowledged divide over whether a TPP can suffer RICO injury based solely on alleged overpayments for an effective drug where there are no allegations that it harmed any of the TPP's beneficiaries.

II. The Court Should Resolve the Circuit Split over Whether Physicians' Individualized Prescribing Decisions Defeat Proximate Causation.

Respondents' opposition also confirms the need for this Court to resolve a growing split over whether a TPP's allegations that a drug manufacturer's misrepresentations caused physicians to write "excess prescriptions" for the medication is too attenuated to satisfy RICO's proximate-causation requirement.

As GSK explained in its petition (Pet. 26-30), the Second and Ninth Circuits – guided by this Court's decisions in *Hemi Group, LLC v. City of New York*, 559 U.S. 1 (2010) and *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258 (1992) – have held that the attenuated link between alleged misrepresentations to doctors and any ultimate injury to TPPs is insufficiently direct to establish proximate causation. *United Food & Commercial Workers Cent. Pa. & Reg'l Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255, 257 (9th Cir. 2010); *UFCW Local 1776*, 620 F.3d at 134. By contrast, the First and Third Circuits – relying principally on this Court's decision in *Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639 (2008) – have held that the alleged foreseeability of injury to TPPs is sufficient to establish proximate causation, notwithstanding the lack of directness. *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21 (1st Cir. 2013).

Respondents nevertheless claim that "[n]o [c]onflict [e]xists," ignoring the Second Circuit's decision in *Eli Lilly* and summarily dismissing the Ninth Circuit's decision in *Amgen* as unpublished. (See BIO 25-29.) But the split is a real one and likely to

get worse. The division between the courts of appeals stems from a perceived tension between this Court's decisions in *Holmes* – which described proximate causation as fundamentally a question about directness – and its decision in *Bridge*, which some courts have interpreted to mean that the foreseeability of injury alone can satisfy RICO's proximate-causation requirement. This tension was explored by several Justices of the Court in *Hemi Group*, but it was not resolved because *Hemi* did not produce a majority opinion. See, *e.g., Hemi Group*, 559 U.S. at 12 (Roberts, C.J.) (rejecting the dissent's view that "RICO's proximate cause requirement turn[s] on foreseeability, rather than on the existence of a sufficiently 'direct relationship' between the fraud and the harm"); *id.* at 19 (Ginsburg, J., concurring) (declining to "subscrib[e] to the broader range of the Court's proximate cause analysis"); *id.* at 25 (Breyer, J., dissenting) (criticizing the majority's claim that "'directness,' rather than foreseeability, should be [the] guide in assessing proximate cause, and that the lack of a 'direct' relationship . . . precludes a finding of proximate causation").

These fault lines have been echoed in the courts of appeals that have addressed the proximate-causation question in TPP cases. Compare, *e.g.*, *Amgen*, 400 F. App'x at 257 (citing *Hemi Group* and *Holmes*, and explaining that a causal chain that involved doctors' prescribing decisions, among other "independent links," was "too attenuated to satisfy the Supreme Court's proximate causation requirement in the RICO context"), with Pet. App. 27a-28a (concluding that "*Bridge* precludes th[e] argument" that "the presence of intermediaries, doctors and patients, destroys proximate causation"). Absent this Court's

definitive resolution of the issue, these disagreements are likely to persist.

Respondents also contend that the Court's denial of review in *Neurontin* should be dispositive. (See BIO 28 (claiming that "[n]othing has changed since" then).) But the Third Circuit's decision deepened the split created by *Neurontin* and, because Avandia was indisputably an effective drug, provides a better vehicle to resolve it. (See Pet. 29 n.10.) Thus, *Neurontin* provides more reason to grant review than to deny it.

III. Review is Necessary to Ensure that the Lower Courts Faithfully Apply *Twombly* and *Iqbal* to the Rising Tide of RICO Claims.

Finally, the Court should also grant review because the decision below conflicts with this Court's rulings in *Twombly* and *Iqbal* regarding basic federal pleading requirements. Respondents cannot deny that they failed to allege any facts supporting their conclusory allegations that they relied on GSK's alleged misrepresentations in determining how and when to reimburse Avandia prescriptions. (Pet. 31-32.) Nor do any of their attempts to excuse this failure undermine the case for review.

First, GSK's four-year-old plea agreement does not give respondents a free pass at the pleading stage. (See BIO 29.) Contrary to respondents' contention that the plea involved the "same harm of paying excess prices for excessive sales of a compromised product," the plea expressly stipulated that "*the parties were unable to determine any economic loss to others directly and proximately caused by this offense*." (BIO App. 8a (emphasis added).) Thus, the plea undermines respondents' position that GSK's conduct

caused injury and certainly cannot substitute for a well pled complaint in this *civil* action.

Second, respondents' assertion that "questions of factual sufficiency . . . have nothing to do with legal sufficiency of a complaint under Rule 12(b)(6)" (BIO 30) is nothing less than a repudiation of *Twombly* and *Iqbal*, which held that plaintiffs must plead sufficient "factual matter" to provide "plausible grounds" to infer that the allegations in the complaint are true, *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007). Here, respondents pled *no facts* demonstrating that they relied on GSK's alleged misrepresentations in making their formulary decisions – an argument that the Third Circuit completely ignored. Nor do respondents acknowledge (much less respond to) the numerous cases that have dismissed RICO claims by TPPs on Rule 12(b)(6) grounds for failing – as the TPPs did here – to properly plead reliance. (Pet. 32-33 (discussing cases).)

Third, respondents' contention that review is unnecessary because "[t]his is merely a motion to dismiss" (BIO 5) also contradicts *Twombly* and *Iqbal*, which made it clear that defendants should not have to incur the enormous expenses associated with discovery in complex litigation where there are glaring factual deficiencies in a complaint. *Twombly*, 550 U.S. at 559 ("It is no answer to say that a claim just shy of a plausible entitlement to relief can, if groundless, be weeded out early in the discovery process" in light of the expenses of litigation.). "Rule 8 . . . does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Ashcroft v. Iq-*

bal, 556 U.S. 662, 678-79 (2009). Civil RICO suits are no exception.[3]

CONCLUSION

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

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Respectfully submitted,

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[3] Respondents' contention that review is unwarranted because they also alleged state consumer protection act claims that are not on appeal (BIO 32 n.19) is absurd. The RICO questions presented here are sufficiently important and compelling to justify review even absent assurance that they would resolve the entire case. And because the district court's resolution of the state law claims was clearly informed by its RICO analysis (see Pet. App. 57a-60a (referencing "the reasons set forth in its discussion of RICO claims" in addressing state claims)), resolution of the RICO issues could well resolve the state-law claims as well.