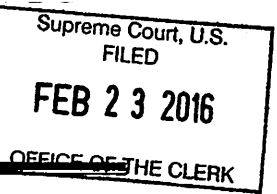


15 - No. 15-1078



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**

PETITION FOR A WRIT OF CERTIORARI

Nina M. Gussack
Anthony C.H. Vale
Yvonne M. McKenzie
PEPPER HAMILTON LLP
3000 Two Logan Square
Eighteenth & Arch Streets
Philadelphia, PA 19103
(215) 981-4000

John H. Beisner
Counsel of Record
Jessica D. Miller
Geoffrey M. Wyatt
SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP
1440 New York Ave., NW
Washington, DC 20005
(202) 371-7000
john.beisner@skadden.com

Attorneys for Petitioner

QUESTIONS PRESENTED

This case involves claims by third-party payors (“TPPs”) that they overpaid for Avandia, a prescription diabetes medication manufactured by petitioner, GlaxoSmithKline (“GSK”). The TPPs claim that GSK failed to disclose risk information, entitling them to recovery under the Racketeer Influenced and Corrupt Organizations Act, even though they do not allege that Avandia was ineffective; that it injured any one of their plan participants; or that they stopped covering it after learning about the drug’s alleged risks. The Third Circuit nevertheless held that the TPPs could plausibly allege that GSK’s representations had an “inflationary effect” on the drug’s price. In so ruling, the Third Circuit expressly declined to follow the Eleventh Circuit, which had previously rejected similar claims, and also departed from several other appellate decisions rejecting similar “fraud on the market” theories. The Third Circuit also concluded that the TPPs plausibly alleged proximate and factual causation, again contradicting the decisions of other circuits. The questions presented are:

1. Whether a TPP states a plausible RICO injury by alleging that a manufacturer’s failure to disclose risk information inflated the price of a medication.

2. a. Whether the independent decisions of prescribing doctors break the causal chain under RICO where a TPP alleges that it paid more because a manufacturer’s misrepresentations caused doctors to write more prescriptions for a medication.

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

CORPORATE DISCLOSURE STATEMENT

Petitioner GlaxoSmithKline LLC is owned, through several levels of wholly-owned subsidiaries, by GlaxoSmithKline plc, a publicly traded limited company organized under the laws of England. To the knowledge of GlaxoSmithKline LLC and GlaxoSmithKline plc, none of the shareholders of GlaxoSmithKline plc owns beneficially 10 percent or more of its outstanding shares. However, the Bank New York Mellon ("BNYM") acts as Depository in respect of Ordinary Share American Depositary Receipts ("ADRs") representing shares in GlaxoSmithKline plc. In that capacity, BNYM is the holder of more than 10 percent of the outstanding shares in GlaxoSmithKline plc.

TABLE OF CONTENTS

	<u>Page</u>
QUESTIONS PRESENTED.....	i
CORPORATE DISCLOSURE STATEMENT.....	ii
TABLE OF APPENDICES.....	v
TABLE OF AUTHORITIES.....	vii
PETITION FOR A WRIT OF CERTIORARI.....	1
OPINIONS BELOW	1
STATEMENT OF JURISDICTION.....	1
STATUTORY PROVISIONS INVOLVED.....	1
STATEMENT	1
A. Avandia.....	4
B. Respondents’ Allegations.....	6
C. GSK’s Motion To Dismiss	9
D. Rulings Below.....	10
REASONS FOR GRANTING THE WRIT	13
I. The Third Circuit’s Holding that Alleged Overpayments for an Effective Drug Suffice to Establish RICO Injury Directly Conflicts with Eleventh Circuit Precedent and Contravenes the Decisions of this Court and Other Circuits.	13

II.	The Third Circuit's Causation Rulings Directly Conflict with Other Circuits and Ignore this Court's Cases Governing Basic Pleading Requirements.	24
A.	The Courts Of Appeals Are Now Squarely Divided Over Whether Individualized Prescribing Decisions Defeat Proximate Causation.....	24
B.	The Third Circuit's Resolution of Respondents' Direct-Reliance Allegations Contravened this Court's Precedents Governing Pleading Requirements.....	31
	CONCLUSION	35

TABLE OF APPENDICES

	<i>Page</i>
APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT, FILED OCTOBER 26, 2015	1a
APPENDIX B — MEMORANDUM OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA, FILED OCTOBER 23, 2013	30a
APPENDIX C — CORRECTED ORDER OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA, FILED FEBRUARY 19, 2014	63a
APPENDIX D — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA, FILED FEBRUARY 19, 2014	66a
APPENDIX E — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT, FILED APRIL 15, 2014	70a
APPENDIX F — SUR PETITION FOR REHEARING OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT, FILED NOVEMBER 25, 2015	74a

Table of Appendices

	<i>Page</i>
APPENDIX G — CLASS ACTION COMPLAINT, <i>UNITED BENEFIT FUND V. GLAXOSMITHKLINE</i> , UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA, FILED OCTOBER 14, 2010	76a
APPENDIX H — FIRST AMENDED CLASS ACTION COMPLAINT, <i>ALLIED SERVICES DIVISION WELFARE FUND V. GLAXOSMITHKLINE</i> , UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA, FILED OCTOBER 12, 2010	172a
APPENDIX I — FIRST AMENDED CLASS ACTION COMPLAINT, <i>UFCW LOCAL 1776 AND PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND V. GLAXOSMITHKLINE</i> , UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA, FILED AUGUST 20, 2010.....	270a

TABLE OF AUTHORITIES

CASES

<i>In re Actimmune Marketing Litigation</i> , 614 F. Supp. 2d 1037 (N.D. Cal. 2009).....	33
<i>Anza v. Ideal Steel Supply Corp.</i> , 547 U.S. 451 (2006).....	passim
<i>Appletree Square I, Limited Partnership v. W.R. Grace & Co.</i> , 29 F.3d 1283 (8th Cir. 1994).....	20
<i>Ashcroft v. Iqbal</i> , 556 U.S. 662 (2009).....	31
<i>In re Avandia Marketing, Sales Practices & Product Liability Litigation</i> , 804 F.3d 633 (3d Cir. 2015)	1
<i>In re Avandia Marketing, Sales Practices & Products Liability Litigation</i> , No. 2007-MD-1871, 2013 U.S. Dist. LEXIS 152726 (E.D. Pa. Oct. 22, 2013)	1
<i>Bell Atlantic Corp. v. Twombly</i> , 550 U.S. 544 (2007).....	31, 32, 34
<i>Bridge v. Phoenix Bond & Indemnity Co.</i> , 553 U.S. 639 (2008).....	28, 29, 30
<i>District 1199P Health & Welfare Plan v. Janssen, L.P.</i> , 784 F. Supp. 2d 508 (D.N.J. 2011)	16, 33

<i>Employer Teamsters - Local Nos. 175/505 Health & Welfare Trust Fund v. Bristol Myers Squibb Co., 969 F. Supp. 2d 463 (S.D. W. Va. 2013).....</i>	<i>27</i>
<i>In re Epogen & Aranesp Off-Label Marketing & Sales Practices Litigation, No. MDL 08-1934 PSG (AGRx), 2009 WL 1703285 (C.D. Cal. June 17, 2009).....</i>	<i>28</i>
<i>Funk v. Stryker Corp., 631 F.3d 777 (5th Cir. 2011).....</i>	<i>6</i>
<i>Health Care Service Corp. v. Olivares, No. 2:10-CV-221-TJW-CE, 2011 WL 4591913 (E.D. Tex. Sept. 2, 2011).....</i>	<i>33</i>
<i>Health Care Service Corp. v. Pfizer, Inc., No. 2:10-cv-221, 2012 U.S. Dist. LEXIS 89759 (E.D. Tex. Apr. 23, 2012)</i>	<i>16</i>
<i>Hemi Group, LLC v. City of New York, 559 U.S. 1 (2010).....</i>	<i>26, 27, 30</i>
<i>Holmes v. Securities Investor Protection Corp., 503 U.S. 258 (1992).....</i>	<i>25, 26, 27, 31</i>
<i>Ironworkers Local Union 68 v. AstraZeneca Pharmaceuticals, LP, 634 F.3d 1352 (11th Cir. 2011).....</i>	<i>2, 14, 15, 16</i>
<i>McLaughlin v. American Tobacco Co., 522 F.3d 215 (2d Cir. 2008)</i>	<i>19, 20</i>

<i>In re Neurontin Marketing & Sales Practices Litigation,</i> 712 F.3d 21 (1st Cir. 2013)	28, 29
<i>Prohias v. Pfizer, Inc.,</i> 485 F. Supp. 2d 1329 (S.D. Fla. 2007)	18
<i>Rivera v. Wyeth-Ayerst Laboratories,</i> 283 F.3d 315 (5th Cir. 2002).....	16
<i>In re Schering-Plough Corp. Intron/Temodar Consumer Class Action,</i> No. 2:06-cv-5774 (SRC), 2009 U.S. Dist. LEXIS 58900 (D.N.J. July 10, 2009).....	16
<i>Sedima, S.P.R.L. v. Imrex Co.,</i> 473 U.S. 479 (1985).....	14
<i>Sergeants Benevolent Association Health & Welfare Fund v. Sanofi-Aventis U.S. LLP,</i> 20 F. Supp. 3d 305 (E.D.N.Y. 2014)	27
<i>Southeast Laborers Health & Welfare Fund v. Bayer Corp.,</i> 444 F. App'x 401 (11th Cir. 2011)	19, 30, 33
<i>Southeast Laborers Health & Welfare Fund v. Bayer Corp.,</i> 655 F. Supp. 2d 1270 (S.D. Fla. 2009)	30
<i>Steele v. Hospital Corp. of America,</i> 36 F.3d 69 (9th Cir. 1994).....	14

<i>Summit Properties Inc. v. Hoechst Celanese Corp.</i> , 214 F.3d 556 (5th Cir. 2000).....	20
<i>UFCW Local 1776 v. Eli Lilly & Co.</i> , 620 F.3d 121 (2d Cir. 2010)	19, 27, 30
<i>United Food & Commercial Workers Central Pennsylvania & Regional Health & Welfare Fund v. Amgen, Inc.</i> , 400 F. App'x 255 (9th Cir. 2010)	26, 27, 28
<i>In re Warfarin Sodium Antitrust Litigation</i> , 391 F.3d 516 (3d Cir. 2004)	21, 22
<i>In re Yasmin & Yaz (Drospirenone) Marketing, Sales Practices & Products Liability Litigation</i> , No. 3:09-md-02100-DRH-PMF, 2010 U.S. Dist. LEXIS 80758 (S.D. Ill. Aug. 5, 2010)	28

STATUTES

18 U.S.C. § 1962	1
18 U.S.C. § 1964(c)	1, 14
28 U.S.C. § 1254(1)	1
28 U.S.C. § 1292(b)	7, 12
28 U.S.C. § 1331	7
28 U.S.C. § 1332(d)(2).....	7

RULE

Fed. R. Evid. 201(b)	6
----------------------------	---

OTHER AUTHORITIES

U. S. Food and Drug Administration, <i>FDA Drug Safety Communication: FDA eliminates the Risk Evaluation and Mitigation Strategy (REMS) for rosiglitazone-containing diabetes medicines</i> , (Dec. 16, 2015)	6
U. S. Food and Drug Administration, <i>FDA Drug Safety Communication: FDA requires removal of some prescribing and dispensing restrictions for rosiglitazone-containing diabetes medicines</i> , (Nov. 25, 2013)	6

PETITION FOR A WRIT OF CERTIORARI

Petitioner GlaxoSmithKline LLC (“GSK”) respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Third Circuit in this case.

OPINIONS BELOW

The opinion of the Court of Appeals (App. 1a-29a) is reported at 804 F.3d 633. The opinion of the United States District Court for the Eastern District of Pennsylvania (App. 30a-62a) is unpublished but available at 2013 U.S. Dist. LEXIS 152726.

STATEMENT OF JURISDICTION

The Court of Appeals issued its decision on October 26, 2015. On November 9, 2015, GSK filed a petition for panel rehearing or rehearing *en banc*. The Court of Appeals denied this request on November 25, 2015. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The Racketeer Influenced and Corrupt Organizations Act (“RICO”), states, in relevant part, that “[a]ny person injured in his business or property by reason of a violation of section 1962 of this chapter [18 U.S.C. § 1962] may sue therefore in any appropriate United States district court and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney’s fee” 18 U.S.C. § 1964(c).

STATEMENT

This case presents important and recurring questions that have divided the lower courts in cases involving RICO claims brought by third-party payors (“TPPs”) against drug manufacturers. In particular,

the decision below approved a theory of RICO injury based on allegations by TPPs that they paid too much for a drug – even though they do not allege that the drug was ineffective or injured any of their beneficiaries. The Third Circuit’s decision squarely conflicts with the Eleventh Circuit’s ruling in *Ironworkers Local Union 68 v. AstraZeneca Pharmaceuticals*, 634 F.3d 1352 (11th Cir. 2011), which expressly held that a plaintiff TPP cannot establish the requisite loss to support a RICO claim against a drug manufacturer based solely on an allegation that a drug was misrepresented and that cheaper alternatives were available, *id.* at 1363-64. The Court of Appeals acknowledged *Ironworkers* but declined to follow it, suggesting that *Ironworkers* was wrongly decided and concluding that the respondents could proceed on the theory that GSK’s alleged misrepresentations or omissions about cardiovascular safety caused them to pay more for the diabetes drug Avandia than they otherwise would have. This price-inflation theory – which was not pressed by respondents and was co-opted by the court below from the antitrust context – also conflicts with other courts of appeals that have rejected price-inflation theories in the prescription-drug context and is tantamount to a fraud-on-the-market theory that many other courts have rejected under RICO.

The decision below also contravened the holdings of this Court and many lower courts regarding the sufficiency of causation under RICO in two ways. First, the Third Circuit parted ways with the Second and Ninth Circuits, as well as several district courts, in failing to hold that the intervening decisions of prescribing doctors break the causal chain and render causation too attenuated under this Court’s

RICO precedents, which hold that proximate causation is lacking where the alleged causal connection between a RICO violation and injury is not sufficiently direct. Second, the Third Circuit permitted the TPPs to rest on conclusory allegations of reliance that did not offer any factual detail about the alleged misrepresentations they received or how the TPPs relied on them – contrary to an Eleventh Circuit ruling in a similar case and this Court’s decisions in *Twombly* and *Iqbal*, which expressly held that courts must not “unlock the doors of discovery for a plaintiff armed with nothing more than conclusions.”

These important issues repeatedly arise in TPP suits against drug manufacturers, which comprise a significant and growing segment of prescription-drug litigation in this country. The pattern in such cases is typically the following: a study raises questions about the risk-benefit profile of an FDA-approved drug, prompting a debate in the scientific community. As the debate continues, TPPs and others bring suit claiming that they would have refused to cover the drug or paid less for it if the risk had been discovered earlier. In nearly all such cases, including this one, the TPPs continue to cover the drug after filing their lawsuits, undermining their own claims that they were duped into paying for it. And additional studies are often published after a lawsuit is filed, refuting the initial study results that led to litigation in the first place. This case is a particularly compelling example of that pattern: over the course of the Avandia controversy, the FDA required a so-called “black box” warning and imposed a restrictive-prescription program, only to reverse course and eliminate both the warning and the restrictions a few years later.

Unfortunately, plaintiffs rarely wait for the science to settle. The promise of treble damages increasingly drives many litigants – even TPPs, which face their own share of dubious RICO suits – to label ongoing scientific debate and differences of opinion as “fraud.” The implications for the entire pharmaceutical industry are enormous – threatening virtually limitless liability in many cases in which the *drug worked* and *none of the TPP’s beneficiaries is alleged to have been injured*. For these reasons, it is especially important that the questions presented in this case are resolved correctly and that RICO requirements are applied in the same way across the circuits.

A. Avandia

Avandia belongs to the class of drugs known as thiazolidinediones (“TZDs”). TZDs were developed in the 1990s as a new form of treatment for the most common form of diabetes: Type 2. Avandia was approved for sale in the United States by the Food and Drug Administration (“FDA”) on May 25, 1999.¹ Since Avandia’s introduction, more than one million individuals in the United States have used the drug on a regular basis. Prior to the introduction of TZDs, Type 2 diabetes was generally treated with metformin, sulfonylureas, or injected insulin.

¹ This case also involves two related drugs, Avandamet and Avandaryl. Avandamet, which combines Avandia and metformin in one pill, was approved by the FDA on October 10, 2002. Avandaryl, which combines Avandia and glimepiride in one pill, was approved by the FDA on November 23, 2005. Because the allegations do not meaningfully distinguish among these drugs, they are referred to collectively as “Avandia.”

Following Avandia's introduction to the market in 1999, the FDA required GSK to amend its warning for Avandia on several occasions. In 2001, GSK added a warning to its prescription label, cautioning doctors that use of Avandia could cause fluid retention. In 2006, GSK added data on a non-statistically-significant increased incidence of heart attack and heart-related chest pain in some patients taking Avandia. The following year, in November 2007, the FDA required GSK to add a "black box" warning regarding the potential increased risk of heart attacks and other ischemic events. The FDA's action in November followed publication of a meta-analysis in *The New England Journal of Medicine*, which reported that Avandia was associated with a statistically significant increase in the risk of myocardial infarction and a borderline-significant increase in the risk of death from heart-related diseases compared to competing diabetes medications. Although some TPPs discontinued coverage of Avandia following release of the May 2007 meta-analysis, the TPPs in this action did not remove Avandia from their formularies or restrict coverage of the drug. (App. 51a.)

In September 2010, after reviewing developing data regarding cardiovascular risks, the FDA went further, limiting Avandia to: (i) patients already using the medication (as long as the patient's doctor advised the patient of potential cardiovascular risks) or (ii) new patients whose blood sugar was inadequately controlled with other medications and who decided, in consultation with their physician, not to take Actos (another TZD). (App. 39a; see also App. 192a-193a.)

Then, in 2013, the FDA dramatically shifted course. After "determin[ing] that recent data" for

Avandia “do not show an increased risk of heart attack compared to the standard type 2 diabetes medicines metformin and sulfonylurea,” the FDA removed restrictions on the drug. See FDA, *Drug Safety Communication*, Nov. 25, 2013 (“FDA Nov. 25 Communication”), available at <http://www.fda.gov/Drugs/DrugSafety/ucm376389.htm> (last visited Feb. 23, 2016). And in December 2015, the FDA announced that it had “continued monitoring” Avandia, “identified no new pertinent safety information,” and determined that special regulatory oversight of the medication was no longer necessary. FDA, *Drug Safety Communication*, Dec. 16, 2015, available at <http://www.fda.gov/Drugs/DrugSafety/ucm476466.htm> (last visited Feb. 23, 2016). As a result of these developments, the Avandia label no longer contains a black-box warning about the risk of heart attacks, and the “Warnings and Precautions” section has been revised to include, in addition to the 2007 meta-analysis, the FDA’s latest conclusion that studies of Avandia “do not show an increased risk of heart attack compared to the standard type 2 diabetes medicines metformin and sulfonylurea.” See FDA Nov. 25 Communication.²

B. Respondents’ Allegations

Respondents are union health and welfare funds that provide medical and prescription drug coverage to their beneficiaries and their beneficiaries’ dependents. Most TPPs obtain administrative services from

² Although these developments post-dated the complaints at issue here, the Court may take judicial notice of the statements of a federal agency. See Fed. R. Evid. 201(b); see, e.g., *Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (affirming judicial notice of FDA letter).

companies known as Pharmacy Benefit Managers (“PBMs”), which are responsible for preparing a formulary – a list of drugs that are approved for coverage when prescribed to the TPP’s beneficiaries.

Respondents, which covered Avandia under their formularies, filed putative class actions against GSK, alleging that it failed to disclose the heart-related risks of Avandia and asserting claims for: (1) violations of RICO and state consumer protection laws; and (2) unjust enrichment. Respondents alleged subject-matter jurisdiction under the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2). (App. 86a, 180a, 279a.)³

The thrust of respondents’ allegations is that GSK failed to disclose that Avandia poses an alleged heart-attack risk. Respondents further allege that “PBMs and pharmacy and therapeutic committees relied on Defendant’s misrepresentations regarding Avandia’s safety when approving and/or placing Avandia on formularies” and that “[TPPs] relied on the Defendant’s misrepresentations regarding Avandia’s safety in reimbursing and/or paying for prescriptions of Avandia for their” beneficiaries. (App. 141a-142a, 235a (same), 332a (same).) Respondents also contend that (i) “[b]ut for Defendant’s actions, [TPPs] would not have paid for Avandia but would instead have paid for safer, equally efficacious drugs like metformin and/or sulfonylureas” (App. 142a, 235a (same), 332a (same)); and (ii) “Defendants’ deceptive and misleading marketing scheme increased the number of prescriptions of Avandia

³ The Court of Appeals determined that the district court had jurisdiction pursuant to 28 U.S.C. § 1331, and that it had appellate jurisdiction pursuant to 28 U.S.C. § 1292(b).

written and filled during the Class Period” (App. 139a-140a, 233a (same), 330a (same)).

Notably, respondents did not plead *any facts* in support of *their* generalized allegations of reliance on GSK’s alleged misrepresentations; instead, they made only broad statements about *all* purchasers of Avandia.⁴ Nor did respondents allege that, after learning about Avandia’s alleged risks, they refused to pay for Avandia prescriptions – or that they restricted its coverage in any way. For example, although respondents’ complaints focus on safety concerns raised by Dr. Steven Nissen in 2007, there is no allegation that *any one* of the respondents restricted coverage of Avandia or removed it from their formularies after being informed of the alleged risks. Respondents also failed to allege that Avandia was ineffective, that it injured any of their beneficiaries, or that the physicians who prescribed Avandia to their beneficiaries stopped prescribing Avandia when additional risk information became available in 2007 or at any time thereafter.

Importantly, respondents also failed to plead facts in support of their assertion that they would have saved money if their beneficiaries had used an alternative medication. Respondents alleged that a one-

⁴ (See, e.g., App. 235a (“Patients, physicians, PBMs, pharmacy and therapeutic committee members, and third-party payors relied on the Defendants’ misrepresentations of Avandia’s safety. . . . PBMs and pharmacy and therapeutic committees relied on the Defendants’ misrepresentations of Avandia’s safety when approving and/or placing on their formularies. Third-party payors relied on the Defendants’ misrepresentations of Avandia’s safety in reimbursing and/or paying for prescriptions of Avandia for their [beneficiaries].”); App. 332a (same); App. 141a (same).)

month supply of Avandia sold for \$90 to \$220, with TPPs typically covering \$135 to \$140 per prescription and the patient paying the balance. Although respondents also alleged that a one-month supply of metformin (an older diabetes drug) cost approximately \$45 to \$55, with a TPP covering \$40 to \$50 of that amount, they did not provide the cost of any other TZD (such as Actos – the drug that respondents themselves alleged to be an “alternative” to Avandia). This omission is significant because, as the district court noted, Avandia was generally only prescribed when older medications such as metformin were unsuccessful for a patient. (3d Cir. JA 314.) And although respondents’ complaints contain bland allegations that they “overpaid” for Avandia (see App. 252a; App. 349a; App. 158a), there is no allegation that the price of Avandia declined after the alleged risks were disclosed in 2007 or in subsequent years. As such, plaintiffs did not allege facts sufficient to support the conclusory allegation that they would have paid less but for GSK’s supposed misconduct.

C. GSK’s Motion To Dismiss

GSK moved to dismiss the respondents’ complaints in the district court, arguing, among other things, that respondents lacked standing to pursue their RICO claims because they had not adequately alleged injury and causation.

With respect to injury, GSK argued that paying for a drug that allegedly contains undisclosed risks does not amount to an economic injury under RICO unless the drug is alleged to have been ineffective or harmful. GSK further contended that even if such a theory were generally cognizable, plaintiffs’ allegations failed to set forth sufficient facts to show that

their beneficiaries' doctors would have prescribed cheaper alternative drugs instead of Avandia.

GSK also argued that respondents failed to state plausible theories of causation. With respect to respondents' first causation theory – that they would have refused to pay for Avandia but for GSK's allegedly fraudulent conduct – GSK argued that respondents did not plead any *facts* to support this theory, rendering their conclusory allegations implausible. With respect to respondents' alternative causation theory – that they were injured because physicians would have written fewer Avandia prescriptions but for GSK's fraudulent conduct – GSK argued that this theory of causation was too attenuated and failed due to, among other things, the intervening independent judgment of the prescribing physicians. GSK further argued for dismissal of respondents' consumer-fraud and unjust-enrichment claims for similar reasons – specifically, that these claims (like the RICO claims) require allegations of causation and injury, which were not sufficiently alleged for the same reasons set forth in support of dismissal of the RICO claims.

D. Rulings Below

The district court largely rejected GSK's arguments, denying the motion to dismiss as to all of the TPPs' claims except their claims for unjust enrichment. The district court first held that the TPPs "sufficiently allege[d] economic injury at th[e] pleading stage of the litigation" to support their RICO and consumer protection claims by asserting that, if GSK had not misled them about the safety of Avandia,

they would not have covered the drug. (App. 44a.)⁵ The court asserted, without explanation, that this conclusion was “unaffected by whether any given patient who ingested Avandia became ill.” (*Id.*) At the same time, however, the district court dismissed the TPPs’ unjust enrichment claims on the ground that they “received the benefit of their bargains” in the form of an effective diabetes medication that was not alleged to have injured any of their beneficiaries. (App. 62a.) The court did not attempt to reconcile those two rulings.

The district court also rejected GSK’s causation arguments. While noting that “it is not clear from the Complaints the extent to which [GSK’s] alleged misrepresentations and concealments were directed at the TPPs or their PBMs,” the court found that respondents had adequately alleged causation because their complaints generally alleged that “PBMs routinely rely upon existing scientific literature when making formulary decisions, and that they did rely upon such literature when making formulary decisions about Avandia” – notwithstanding respondents’ failure to allege what scientific literature they purportedly relied on or when they considered it.

The district court also rejected GSK’s argument that the intervening decisions of doctors destroyed proximate causation. According to the court, “first-party reliance is not a necessary element of proximate cause in every private RICO claim.” (App. 46a.)

⁵ The district court acknowledged that the TPPs had failed to allege that they would have saved money by covering another TZD (*e.g.*, Actos) instead of Avandia, but held that this “argument is more relevant to summary judgment or the calculation of damages.” (App. 44a.)

Thus, “[w]here misrepresentations are directed at prescribing doctors, rather than TPPs, but a TPP, as payor, is a primary and intended victim,” “the doctor’s independent actions do not break the causal chain” because injury to the TPP is foreseeable. (App. 46a-47a (internal quotation marks omitted).)

On interlocutory review under 28 U.S.C. § 1292(b), the Court of Appeals affirmed. Relying on inapposite antitrust case law, the Court of Appeals determined that respondents had alleged a tangible economic harm under RICO based “on the inflationary effect that GSK’s allegedly fraudulent behavior had on the price of Avandia” – an injury that the Court of Appeals determined “d[id] not depend on the effectiveness of the Avandia that [respondents] purchased.” (App. 15a.) The Court of Appeals further determined that “the presence of intermediaries, doctors and patients” did not destroy proximate causation. (App. 27a.) Despite concluding that “many of these issues will resurface in the future” and declining to “opine on the likelihood of plaintiffs’ success down the road,” the Court of Appeals allowed the case to proceed, explaining that “[a]t this stage in the litigation, plaintiffs ‘need only put forth allegations that raise a reasonable expectation that discovery will reveal evidence’ of proximate causation.” (App. 29a (quoting *Fowler v. UPMC Shadyside*, 578 F.3d 203, 213 (3d Cir. 2009)).)

Following this decision, GSK filed a petition for panel rehearing or rehearing en banc. In its petition, GSK argued that the Court of Appeals erred in three significant ways. First, the court adopted an “inflationary effect” injury that was not advanced by respondents and is not cognizable under RICO. Second, the panel opinion ignored one of GSK’s key

arguments on appeal: that respondents' complaints did not plead facts sufficient to establish but-for causation because the allegations sounded in reliance but failed to set forth facts showing how any reliance by respondents or anyone else caused *their* alleged injuries. The TPPs did not allege that they actually received and acted on an alleged misrepresentation by GSK or that doctors relied on the alleged misrepresentations in prescribing Avandia to the three TPPs' beneficiaries. Third, the panel's proximate-causation analysis ignored plaintiffs' "quantity-effect" theory, which depends on the independent decisions of third-party physicians.

The Court of Appeals denied the request for rehearing on November 25, 2015. This petition for certiorari timely follows.

REASONS FOR GRANTING THE WRIT

I. The Third Circuit's Holding that Alleged Overpayments for an Effective Drug Suffice to Establish RICO Injury Directly Conflicts with Eleventh Circuit Precedent and Contravenes the Decisions of this Court and Other Circuits.

First, the decision below squarely disagreed with the Eleventh Circuit over whether a TPP sustains a cognizable RICO injury by allegedly paying too much for a drug even though there is no allegation that the drug was ineffective or injured any of the TPP's beneficiaries. According to the Third Circuit, the TPPs stated an injury irrespective of "the effectiveness of the Avandia that they purchased" (App. 15a), a ruling that directly conflicts with the Eleventh Circuit's contrary holding in a similar case.

RICO confers standing only upon a person claiming to be “injured in his business or property by reason of a violation of section 1962.” 18 U.S.C. § 1964(c); see *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 496 (1985) (“the plaintiff only has standing if, and can only recover to the extent that, he has been injured in his business or property by the conduct constituting the violation”). A “defendant who violates section 1962 is not liable for treble damages to everyone he might have injured by other conduct, nor is the defendant liable to those who have not been injured.” *Sedima*, 473 U.S. at 496-97 (internal quotation marks and citation omitted). Thus, section 1964(c)’s “limitation to a person ‘injured in his business or property’ has a ‘restrictive significance,’ . . . which helps to assure that RICO is not expanded to provide a federal cause of action and treble damages to every tort plaintiff.” *Steele v. Hospital Corp. of Am.*, 36 F.3d 69, 70 (9th Cir. 1994) (quoting *Reiter v. Sonotone Corp.*, 442 U.S. 330, 339 (1979); other internal quotation marks and citation omitted).

Consistent with this important statutory limitation, some courts have rejected RICO theories of injury in cases, such as this one, alleging that a drug was fraudulently marketed, where the plaintiff does not allege that the drug failed to work or that it suffered injury from any of those risks. In *Ironworkers Local Union No. 68 v. AstraZeneca Pharmaceuticals, LP*, 634 F.3d 1352, 1356 (11th Cir. 2011), for example, the Eleventh Circuit reviewed the dismissal of a RICO action brought by several TPPs (and others) against AstraZeneca, in which the TPPs alleged that the drug manufacturer had fraudulently induced physicians to prescribe the medication Seroquel for numerous off-label uses. *Id.* The TPPs claimed that

AstraZeneca's allegedly fraudulent off-label marketing campaign caused them "to unnecessarily pay for [the more expensive] Seroquel off-label prescriptions." *Id.* at 1357 (quoting complaint). The TPPs sought to recover the difference between the price of the off-label Seroquel prescriptions and the amount that they would have paid for the less expensive alternatives. *Id.* On appeal, the Eleventh Circuit affirmed the dismissal, finding, among other things, that the TPPs failed to allege a cognizable economic injury under RICO.

In its ruling, the Eleventh Circuit concluded that a TPP does not suffer economic injury merely by paying for "a more expensive drug." *Id.* at 1363. As the court explained, because prescriptions are based on the medical judgment of doctors, "a patient suffers no economic injury" by being prescribed one drug simply because cheaper alternatives are available. *Id.* Neither, by extension, does a TPP suffer injury in such circumstances. *Id.* at 1366. After all, TPPs and PBMs make actuarial calculations in establishing premiums to ensure that they can cover a predicted number of prescriptions of a drug and still make a profit – calculations that are not affected by a drug manufacturer's representations to doctors because TPPs "ha[ve] to pay regardless of the facts surrounding [a] prescription." *Id.* at 1365-66. Thus, to state a cognizable injury under RICO, a plaintiff must show something more – e.g., that its beneficiaries' physicians, "would not have prescribed the drug under the standards of sound medical practice" if they had known the allegedly undisclosed information, "because [it] was unsafe or ineffective in treating the [enrollees] condition." *Id.* at 1363.

Several other decisions have applied similar logic. See, e.g., *Health Care Servs. Corp. v. Pfizer, Inc.*, No. 2:10-cv-221, 2012 U.S. Dist. LEXIS 89759, at *7-8 (E.D. Tex. Apr. 23, 2012) (recommending dismissal of RICO claim by TPP for lack of a RICO injury because, *inter alia*, there was no allegation that the purchased drugs were “either unsafe or ineffective for their prescribed use”), *report and recommendation adopted*, 2012 U.S. Dist. LEXIS 89758 (E.D. Tex. June 28, 2012). As the U.S. Court of Appeals for the Fifth Circuit explained in applying Article III’s injury requirement, a plaintiff does not allege a plausible economic injury by claiming that a drug contained a risk that only affected *other* individuals. *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 320 (5th Cir. 2002); see also *Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 2d 508, 521, 523 & n.23 (D.N.J. 2011) (dismissing RICO claims by TPPs for lack of injury where they “d[id] not identify any participant in their health plans who received an ineffective or off-label Risperdal prescription”; allegations that “alternative medications were more effective or safer than Risperdal” were insufficient); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-cv-4774, 2009 U.S. Dist. LEXIS 58900, at *67 (D.N.J. July 10, 2009) (TPPs lacked standing under RICO where they failed to plead that any beneficiaries “received inadequate [or] inferior [drugs] or even worse, suffered personal injuries as a result of [d]efendants’ alleged misrepresentations”) (internal quotation marks and citation omitted).

The Third Circuit acknowledged the Eleventh Circuit’s ruling in *Ironworkers* – and indeed expressly noted that the case involved “facts similar to these”

(App. 17a-18a) – but declined to follow it. According to the Third Circuit, it is improper to make any “presumption at the motion-to-dismiss” stage regarding the manner in which TPPs set their premiums (App. 18a) – even though it was the *plaintiffs’* burden to plead facts showing that they sustained injury. The Third Circuit also expressed its concern that the Eleventh Circuit’s holding “lacks a limiting principle” and would give a green light to fraudulent conduct by drug manufacturers (*id.*), ignoring the fact that the heavily regulated drug industry already has several disincentives to engage in fraud, in the form of FDA sanctions, Medicaid fraud suits brought by state attorneys general, and consumer and personal injury suits, to name a few.

Instead, the Third Circuit chose to part ways with its sister circuit and create an entirely new theory of RICO injury for drug cases that respondents had not even advocated: i.e., that an insurer can recover for the supposed “inflationary effect that [a drug manufacturer’s] allegedly fraudulent behavior had on the price of” a drug. (App. 15a.)⁶ The Court of Appeals

⁶ The Third Circuit did not appear to embrace either of the theories of injury that respondents actually advanced – i.e., that they were injured by paying for Avandia because cheaper drugs were available or that they were injured because physicians prescribed the medication with more frequency than they otherwise would have. These theories of injury would also fail as a matter of law under *Ironworkers* because the TPPs do not allege that the drug was ineffective or that it caused physical injury to their beneficiaries. In addition, the TPPs’ first theory – that the TPPs would have covered cheaper drugs – lacks sufficient support in the pleadings. As noted above, the TPPs alleged that metformin was cheaper than Avandia, but they did not offer any allegations comparing the price of Avandia to that of Actos – the only drug in the same class as Avandia that is mentioned in the

did not cite any RICO precedent from its own decisions or those of any other court in support of its conclusion, presumably because courts have rejected this theory time and again. As this Court held in *Anza*, the price a defendant sets for its products is “entirely distinct” conduct from the same party’s allegedly fraudulent statements; after all, the decision to set a particular price “in no sense require[s] [a company] to defraud” anyone. *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 458-59 (2006). Thus, a theory of injury that depends on the notion that a defendant’s alleged fraud allowed it to set a certain price for its products is too attenuated to be sustainable under RICO. See *id.* As one court put it, “such a theory is patently absurd” because it “depend[s] on the faulty premise that the price of [a medicine] fluctuates based on the public’s knowledge of [the medicine’s] benefits, even though drug prices (unlike stock prices which are necessarily set by the price at which buyers are willing to buy, or sellers willing to sell) are fixed by the product’s manufacturer.” *Prohias v. Pfizer, Inc.*, 485 F. Supp. 2d 1329, 1337 (S.D. Fla. 2007) (quoting *Heindel v. Pfizer, Inc.*, 381 F. Supp. 2d 364, 380 (D.N.J. 2004)).

Consistent with this reasoning, other federal courts – including several other courts of appeals – have squarely rejected price-inflation theories under RICO. As the Second Circuit has explained, such a

complaints. The Third Circuit dismissed this deficiency as a “factual dispute” (App. 27a), but the TPPs have the burden of pleading sufficient facts to show an injury, and absent allegations that Actos was cheaper or that the TPPs would only have covered metformin, it is not plausible that they sustained the claimed injury.

theory of injury would require “a series of speculative calculations to ascertain whether, and in what amount, plaintiffs suffered a loss,” when the reality is “that damages could have resulted from factors unrelated to the defendant’s alleged acts of fraud.” *McLaughlin v. American Tobacco Co.*, 522 F.3d 215, 230 (2d Cir. 2008) (citing *Anza*, 547 U.S. at 458-59).

The same principle applies with even greater force to RICO claims asserted by TPPs against drug manufacturers; as the Second Circuit has explained, a “price impact” theory has no place in such cases 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). Indeed, a “drug company may even *increase* the price of a drug when it is expected that negative information will lower the demand,” further highlighting the unsuitability of price-impact theories of injury in such cases. *Id.* The Eleventh Circuit has likewise expressly rejected a price-impact theory in a drug case, explaining that an allegation that a TPP “paid too much” for a drug is an impermissible “fraud on the market” theory that cannot establish injury or causation because 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. *Se. Laborers Health & Welfare Fund v. Bayer Corp.*, 444 F. App’x 401, 405-10 & n.4 (11th Cir. 2011) (analyzing the proposed injury under state law and then adopting the same reasoning in rejecting the TPP’s RICO claim).

For similar reasons, other courts of appeal have repeatedly rejected RICO claims that rest on the theory that a defendant's alleged fraud inflated prices. In one case involving the sale of polybutylene plumbing, for example, the Fifth Circuit rejected a theory that the allegedly fraudulent statements were "incorporated into the market price." *Summit Properties 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). As the court explained, "[a]n efficient market is a critical element" of such a theory and is lacking in the context of mass-marketed products. *Id.* As a result, the Fifth Circuit observed, "[n]o court has accepted the use of this theory outside the context of securities fraud, and one circuit has expressly rejected its use in the context of a similar RICO case." *Id.* at 561 & n.24 (emphasis added) (citing *Appletree Square I v. W.R. Grace & Co.*, 29 F.3d 1283, 1287 (8th Cir. 1994)); see also *Appletree*, 29 F.3d at 1287 (rejecting the theory that an alleged fraud caused injury by inflating the price of a building).⁷

⁷ These cases and the Eleventh Circuit's decision in *South-east Laborers* were decided under the auspices of RICO's proximate-causation requirement rather than injury, but the concepts are closely related in this context, as evidenced in the Second Circuit's injury analysis in *McLaughlin*, which drew on its analysis of the price-inflation theory under the causation requirement. Compare 522 F.3d at 222-27 (concluding that it was not possible to establish loss causation based on a supposed "fraud on the market" given the inefficient market for consumer goods), with *id.* at 229-30 (citing similar considerations in explaining why the price-impact theory failed).

The Third Circuit did not even acknowledge this authority, relying instead on its statement in *In re Warfarin Sodium Antitrust Litigation*, 391 F.3d 516 (3d Cir. 2004) – an appeal involving the certifiability and fairness of a *class settlement* in an *antitrust* suit – that “TPPs, like individual consumers, suffer direct economic harm when, as a result of a pharmaceutical company’s alleged misrepresentations, they pay supracompetitive prices for brand drugs instead of purchasing lower-priced generic drugs.” (App. 14a-15a (quoting *Warfarin*, 391 F.3d at 531) (alteration marks omitted).)

The logic of *Warfarin* makes no sense in the product liability context. In *Warfarin*, TPPs alleged that the defendant, DuPont, which manufactured a drug called Coumadin, violated § 2 of the Sherman Act by making false safety claims about the drug’s generic equivalent (warfarin sodium), which had entered the market at a much lower price when Coumadin’s patent expired. 391 F.3d at 528. According to the TPPs, these misrepresentations “permit[ed] DuPont to monopolize the market for warfarin sodium and charge supracompetitive prices for Coumadin” 391 F.3d at 528. In order to demonstrate that DuPont’s misrepresentations and conduct had an anticompetitive effect, plaintiffs cited evidence that “more than 75% of prescriptions for sodium warfarin were still filled with Coumadin a year after [the competitor] introduced a generic version,” even though the generic version had been approved by the FDA as the “bioequivalent and therapeutic equivalent to Coumadin.” *Id.* at 522-23.⁸ Accordingly, the TPPs argued that

⁸ This rate was notable because “[g]enerally, about 40-70% of prescriptions for drugs available from multiple sources are filled

they were entitled to the difference in price between the two allegedly fungible products. See *id.* at 531. In the Third Circuit’s view, the “same logic would apply here” – even though *Warfarin* “was an antitrust case” involving two fungible drugs – because “RICO’s standing requirements were modeled on antitrust law.” (See App. 14a-17a & n.32.)

The Third Circuit’s analysis conflicts with this Court’s precedent and basic logic. This Court expressly warned in *Anza* that courts should be wary of “blur[ring] the line between RICO and the antitrust laws,” because antitrust theories of injury could entail “intricate, uncertain inquiries” when transplanted to the RICO context. 547 U.S. at 459-60 (highlighting the difficulty in ascertaining the causes and extent of an alleged drop in prices). After all, in the antitrust arena, consumers can be injured simply because they purchased a product “in a market where competition has been wrongfully restrained.” *Warfarin*, 391 F.3d at 531. Thus, TPPs could plausibly allege that they would have paid for the cheaper of two *chemically-identical* drug products but for an antitrust violation.

Here, by contrast, the theory of injury is far more complicated because there is no chemically equivalent drug to Avandia. As such, it cannot be assumed that GSK’s alleged fraud allowed it charge more for the drug than some theorized “market” price. To the contrary, the pricing of an innovative product with no equivalent counterpart is influenced by many factors. In the case of drugs, for example, a new product

with less expensive generic products within one year of generic availability.” *Warfarin*, 391 F.3d at 523.

might be more promising than older drugs, either generally or for specific patient populations. In such cases, the new drug is not in direct competition with other drugs, and its price will not be tied to theirs. Because there is no way to demonstrate that a TPP was financially injured under these circumstances, litigating such a theory of injury is barred under *Anza*. 547 U.S. at 460.

In short, the Third Circuit's decision is deeply in conflict with this Court's precedents and the decisions of other circuits. The Third Circuit's recognition of TPP injury where there is no allegation that the drug was ineffective or that it injured any of the TPPs' beneficiaries squarely conflicts with the Eleventh Circuit's decision in *Ironworkers*, as the Third Circuit tacitly acknowledged. Its adoption of an "inflated price" theory of injury has been rejected by the Second Circuit in another TPP case, repeatedly rejected in other RICO cases in other circuits, and conflicts with this Court's decision in *Anza*. And its reliance on antitrust precedents to support an inflated-price theory of injury separately conflicts with *Anza* because it ignores the Court's express warning not to conflate antitrust and RICO theories of injury. Absent review by this Court, the Third Circuit's decision paves the way for TPPs to establish RICO injury based solely on allegations of "overpayment" any time a scientific debate emerges over the safety and efficacy of a drug – a result that could produce a significant deterrent to research and development of new drugs and restrict patient access to beneficial medications. (See App. 14a.) For all of these reasons, the Court should grant review and reverse the decision below.

II. The Third Circuit's Causation Rulings Directly Conflict with Other Circuits and Ignore this Court's Cases Governing Basic Pleading Requirements.

The Third Circuit's resolution of the causation issues in this case also merits review. As noted previously, respondents proffered two theories of causation: (1) that GSK's alleged misrepresentations led doctors to write more Avandia prescriptions than they otherwise would have, causing respondents to reimburse more Avandia prescriptions; and (2) that respondents relied on the alleged misrepresentations in giving Avandia more favorable formulary placement than it would have otherwise received. The Third Circuit's acceptance of the first theory deepens a split between the First and Third Circuits on the one hand and the Second and Ninth Circuits on the other, over whether a theory of causation that depends on the individual decisions of thousands of prescribing doctors is too attenuated to satisfy proximate causation. And its acceptance of the second theory is inconsistent with this Court's rulings and those of various federal courts, including the Eleventh Circuit, because it condoned allegations of but-for causation that offer nothing more than "bare legal conclusions" and lack any "factual heft."

A. The Courts Of Appeals Are Now Squarely Divided Over Whether Individualized Prescribing Decisions Defeat Proximate Causation.

The Third Circuit's decision solidified a split over whether a TPP plausibly alleges causation under RICO by averring that a drug manufacturer's misrepresentations defrauded doctors, causing them to

write “excess prescriptions” for the medication. The majority of federal courts to consider the issue have held that the attenuated link between alleged misrepresentations made to doctors and any ultimate injury to TPPs is insufficiently *direct* to establish proximate causation. A small number of courts – including the Court of Appeals here – have disagreed, however, concluding that the alleged *foreseeability* of the injury to the TPPs suffices to establish proximate causation notwithstanding the lack of directness. The Court should intervene to resolve this split and clarify, consistent with the Court’s prior rulings, that lack of directness defeats proximate causation even where harm to the plaintiff was allegedly foreseeable.

In *Holmes v. Securities Investor Protection Corporation*, 503 U.S. 258 (1992), this Court held that RICO’s requirement that a private individual suing under the statute be injured “by reason of” a statutory violation is a “demand for some *direct* relation between the injury asserted and the injurious conduct alleged.” *Id.* at 268 (emphasis added).

The Court reaffirmed this “direct relation” test for RICO proximate causation in *Anza*. See 547 U.S. at 461 (describing the proper inquiry as “whether the alleged violation led directly to the plaintiff’s injuries”). The *Anza* ruling also expressly established that foreseeability does not satisfy proximate causation where directness is lacking, rejecting the Second Circuit’s conclusion that, “because the [defendants] allegedly sought to gain a competitive advantage over [the plaintiff], it is immaterial whether they took an indirect route to accomplish their goal.” *Id.* at 460. As this Court explained, that “rationale [did] not accord with *Holmes*,” and a “RICO plaintiff cannot circumvent the proximate-cause requirement by

simply claiming that the defendant's aim was to increase market share at a competitor's expense." *Id.* at 461. Thus, "[w]hen a court evaluates a RICO claim for proximate causation, *the central question it must ask is whether the alleged violation led directly to the plaintiff's injuries.*" *Id.* (emphases added).⁹

Consistent with the directness requirement emphasized in these decisions, most courts addressing TPP claims, like those here, that depend on an "excess prescriptions" or "quantity effect" theory of causation – i.e., that a drug manufacturer's alleged misrepresentations caused doctors to write more TPP-covered prescriptions – have rejected the claims as too attenuated to satisfy RICO's proximate-causation requirement. Indeed, both the Second and Ninth Circuits have rejected such theories on precisely this ground.

In *United Food & Commercial Workers Central Pennsylvania & Regional Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255 (9th Cir. 2010), the Ninth Circuit affirmed the dismissal of RICO and state consumer protection claims involving a defendant's allegedly fraudulent marketing of two prescription medications for off-label uses. *Id.* at 257. According to the Ninth Circuit, the plaintiffs "failed to plead a cognizable theory of proximate causation that links [the defendant's] alleged misconduct to

⁹ As a plurality of this Court recognized in *Hemi Group, LLC v. City of New York*, 559 U.S. 1 (2010), while the "concepts of direct relationship and foreseeability are of course two of the 'many shapes [proximate cause] took at common law,'" this Court's "precedents make clear that *in the RICO context*, the focus is on the directness of the relationship between the conduct and the harm." *Id.* at 12 (quoting *Holmes*, 503 U.S. at 268) (emphases added).

[the TPPs'] alleged injury." *Amgen*, 400 F. App'x at 257. In particular, "the complaint proffered an attenuated causal chain" involving physician prescription decisions. *Id.* In light of the multiple steps necessary to tie the defendant's alleged misconduct to the plaintiff's claimed injuries, the Ninth Circuit concluded that plaintiffs failed "to satisfy the Supreme Court's proximate causation requirement in the RICO context." *Id.* (citing *Hemi Grp.*, 559 U.S. at 9, and *Holmes*, 503 U.S. at 268, 271, 274).

Likewise, in *Lilly*, 620 F.3d at 134, the Second Circuit affirmed the denial of class certification in a RICO suit brought by TPPs alleging that fraudulent marketing of the drug Zyprexa had caused them to pay for prescriptions they otherwise would not have covered. According to the court, the "attenuated link between the alleged misrepresentations made to doctors and ultimate injury to the TPPs" made it impossible for the TPPs to establish proximate causation. This was so because the TPPs' "theory of liability rest[ed] on the independent actions of third and even fourth parties" that "play[ed] a role in the chain between [the manufacturer] and the TPPs." *Id.* (internal quotation marks and citation omitted); see also, e.g., *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 20 F. Supp. 3d 305, 323 (E.D.N.Y. 2014) (rejecting similar allegations in a putative class action; "[a]s recognized by the Second Circuit in *Zyprexa* . . . the prescribing decisions of physicians are based on so many factors as to defy any efforts to categorically attribute them to a particular cause"), *aff'd*, 806 F.3d 71 (2d Cir. 2015); *Emp'r Teamsters-Local Nos. 175/505 Health & Welfare Trust Fund v. Bristol Myers Squibb Co.*, 969 F. Supp. 2d 463, 475 (S.D. W. Va. 2013); *In re Yasmin*

& Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig., No. 3:09-md-02100-DRH-PMF, 2010 U.S. Dist. LEXIS 80758, at *23 (S.D. Ill. Aug. 5, 2010); *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, No. 08-1934 PSG (AGRx), 2009 WL 1703285, at *6 (C.D. Cal. June 17, 2009), *aff'd*, 400 F. App'x 255 (9th Cir. 2010).

The Third Circuit did not address any of this authority in its proximate-causation analysis. Indeed, the court spent much of its proximate-causation analysis discussing respondents' *direct-reliance* theory rather than the excess-prescriptions theory – even though GSK only challenged proximate causation with respect to the latter theory. As a result, it barely addressed the proximate-cause argument GSK actually made.

In its short postscript addressing the excess-prescriptions theory, the Third Circuit said only that the “presence of intermediaries, doctors and patients” does not defeat proximate causation because the requisite directness is established where the plaintiffs are “the ‘primary and intended victims of the scheme to defraud’ and their injury was a ‘foreseeable and natural consequence of the scheme,’” citing this Court’s holding in *Bridge v. Phoenix Bond & Indemnity Company*, 553 U.S. 639 (2008). (App. 27a (quoting *Bridge*, 553 U.S. at 650, 658).) The court also mentioned in a footnote that the First Circuit had reached a similar conclusion in a case brought by TPPs alleging fraudulent marketing of the drug Neurontin. (See App. 28a n.75 (citing *In re Neurontin Mktg. and Sales Practices Litig.*, 712 F.3d 21, 37-38

(1st Cir. 2013)).¹⁰ But the minority view of proximate causation reflected in the *Neurontin* decision and embraced by the Court of Appeals in this case significantly over-reads *Bridge*. *Bridge* involved allegations that the defendants had committed mail fraud by falsely certifying compliance with a county rule imposing restrictions on bidders at tax lien sales. 553 U.S. at 642-44. The plaintiffs sued under RICO, alleging that the defendants had obtained a disproportionate share of tax sales by violating the rule. *Id.* at 644. The defendants argued that this Court's proximate-causation precedents defeated the claims because the alleged fraud was on the county, meaning that the plaintiffs could not have directly relied on the certifications of compliance. *Id.* at 653-54. This Court disagreed, explaining that there was a "sufficiently direct relationship" because: (1) the alleged injury was "a foreseeable and natural consequence of" the alleged scheme; (2) "no independent factors [could] account for [plaintiffs'] injury";

¹⁰ GSK acknowledges that the Court denied a petition for certiorari in *Neurontin*, but this case presents a far better vehicle for review because *Neurontin* involved allegations that the drug did not work at all and that no physicians would have prescribed it. See Brief in Opposition for Harden Respondents at 29-30, *Pfizer Inc. v. Harden Mfg. Corp.*, No. 13-289 (U.S. filed Nov. 4, 2013) (arguing that the allegation that Neurontin did not work at all for the uses at issue distinguished the case from others, like *Lilly*, that involved a "misrepresented drug [that was] still efficacious" because in cases involving effective drugs "it is much more difficult to determine whether the physician would have prescribed it"); see also *Neurontin*, 712 F.3d at 47 (specifically noting that the TPP plaintiff had "staked much of its case on proving that Neurontin was ineffective for the promoted off-label uses"). Moreover, the *Neurontin* petition, unlike this one, did not involve the additional issue of RICO injury that is presented in Part I of this petition.

(3) “there is no risk of duplicative recoveries by plaintiffs removed at different levels of injury from the violation”; and (4) “no more immediate victim is better situated to sue. Indeed . . . the [plaintiffs] and other losing bidders were the *only* parties injured by [defendants’] misrepresentations.” *Id.* at 658.

The causal theory in this case is different in every critical respect. First, many “independent factors [could] account for [the TPPs’ alleged] injury.” As other courts have recognized, doctors receive information from numerous sources and may prescribe drugs for reasons unrelated to the drug manufacturer’s alleged misrepresentations. *E.g.*, *Lilly*, 620 F.3d at 135. Moreover, there is a clear and substantial risk of “duplicative recoveries” because there are “more immediate victim[s] . . . better situated to sue” – i.e., those claiming to have actually sustained cardiovascular injuries as a result of ingesting Avandia. *E.g.*, *Se. Laborers Health & Welfare Fund v. Bayer Corp.*, 655 F. Supp. 2d 1270, 1284 (S.D. Fla. 2009) (explaining that the “proper parties to vindicate the law would be those persons physically injured by the deception,” regardless of whether they could bring such claims under RICO), *aff’d*, 444 F. App’x 401 (11th Cir. 2011). To the extent any of respondents’ beneficiaries bring and prevail on such claims, the TPPs could be made whole through liens, subrogation, or whatever other provisions govern such cases under the relevant plan documents. For all of these reasons, TPP cases like this one stand “in contrast to *Bridge*.” *Hemi Grp.*, 559 U.S. at 15.

**B. The Third Circuit’s Resolution of
Respondents’ Direct-Reliance
Allegations Contravened this Court’s
Precedents Governing Pleading
Requirements.**

Finally, the Court of Appeals contravened this Court’s precedents by ignoring GSK’s argument that respondents had failed to allege *facts* to support their conclusory allegations of direct reliance – i.e., that GSK’s alleged misrepresentations caused them to make formulary decisions with respect to Avandia that they otherwise would not have made.

A RICO plaintiff must assert plausible allegations of but-for causation to make out a claim under the statute. *Holmes*, 503 U.S. at 265-66 (requiring that a defendant’s alleged RICO violation be the “but for” cause of the plaintiff’s injury). As a matter of basic pleading requirements, such a plausible allegation must include more than a mere conclusory assertion, without any factual detail, that the plaintiff relied on the defendant’s alleged misrepresentations. As this Court made clear in *Bell Atlantic Corporation v. Twombly*, 550 U.S. 544, 555 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), a plaintiff must plead sufficient “[f]actual allegations” to “raise a right to relief above the speculative level.” *Twombly*, 550 U.S. at 555. This requirement ensures that defendants are not forced to finance speculative fishing expeditions in cases where plaintiffs lack a strong factual basis for their claims – a protection that is especially important in the context of complex suits like this one. See *id.* at 558-59. Thus, where a plaintiff provides only a “naked assertion” that a required element is satisfied, without “further factual enhancement,” the allegations “stop[] short of the line

between possibility and plausibility of ‘entitle[ment] to relief,’” and a complaint must be dismissed. *Twombly*, 550 U.S. at 557.

Here, respondents’ allegations of but-for causation are nothing more than “naked assertion[s]” of “legal conclusions” that the “elements of a cause of action” are met. Respondents generally alleged in their complaints that “PBMs and pharmacy and therapeutic committees relied on the Defendants’ misrepresentations of Avandia’s safety when approving and/or placing Avandia on formularies”; that “[t]hird-party payors relied on the Defendants’ misrepresentations of Avandia’s safety in reimbursing and/or paying for prescriptions of Avandia for their” beneficiaries; and that “[b]ut for Defendants actions, third-party payors would not have paid for Avandia.” (App. 141a-142a.) But respondents did not provide any “*factual enhancement*” to these allegations. Most critically, they did not identify the specific “misrepresentations of Avandia’s safety” that *they* allegedly relied upon, or state how those alleged misrepresentations affected *their* formulary placement and reimbursement decisions. Indeed, the Third Circuit essentially acknowledged the absence of specific allegations concerning the TPPs’ formulary decisions but deemed them irrelevant, saying only that their absence means that “we do not know” what decisions were made. (App. 25a-26a.)

The Third Circuit’s conclusion that the TPPs’ “[t]hreadbare recitals” sufficed not only contravenes this Court’s precedents but also conflicts with the decisions of other federal courts in TPP cases – including the Eleventh Circuit – recognizing the need for plaintiffs to plead the factual details of reliance. In *Southeast Laborers Health and Welfare Fund v.*

Bayer Corp., 444 F. App'x 401 (11th Cir. 2011), for instance, the Eleventh Circuit affirmed the district court's dismissal of a TPP's RICO claim on causation grounds where the TPP "failed to allege facts plausibly demonstrating that [the TPP] would have independently determined that [the drug] was not 'medically necessary' if the [the drug manufacturer] had disclosed the allegedly suppressed material information." *Id.* at 410.¹¹ See also, *e.g.*, *Health Care Serv. Corp. v. Olivares*, No. 10-cv-221, 2011 WL 4591913, at *7 (E.D. Tex. Sept. 2, 2011), *adopted by* 2011 WL 4591915 (E.D. Tex. Sept. 30, 2011) (rejecting TPP's RICO and consumer-fraud claims based on allegations that drug manufacturer had caused it to cover prescriptions of various drugs by misrepresenting their safety and efficacy where the pleadings failed to include key facts; "although [the TPP] contends that [the drug manufacturers]' conduct caused [the TPP] to add [certain drugs] to its formulary, [the TPP] does not identify when it added those drugs to its formulary and under what circumstances those drugs were added"); *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037, 1050, 1052 (N.D. Cal. 2009) (dismissing RICO claims by TPPs where they failed to "allege what *specific*" statements they relied on) (emphasis added); *Dist. 1199P*, 784 F. Supp. 2d at 525 (reasoning that "without sufficient allegations of direct reliance, [TPPs] have not properly alleged that [d]efendants' misrepresentations were the 'but for' cause of their injuries"). The Court of Appeals did

¹¹ Although the Eleventh Circuit used the words "proximate causation," 444 F. App'x at 409-10, its analysis focused on the insufficiency of the factual pleadings and sounded in but-for causation.

not even address this error in the district court's ruling.

As a result of the lower courts' rulings, GSK will be forced to incur the enormous expenses associated with discovery in this complex litigation, notwithstanding the glaring deficiencies in respondents' complaints, precisely the danger the Court sought to avoid in *Twombly*. See 550 U.S. at 558-59. This result is particularly troublesome because the omissions in respondents' complaints suggest that the facts needed to properly allege their claims simply do not exist. For this reason too, the Court should grant review and reverse the lower courts' holdings.

CONCLUSION

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

February 23, 2016

Respectfully submitted,

Nina M. Gussack
 Anthony C.H. Vale
 Yvonne M. McKenzie
 PEPPER HAMILTON LLP
 3000 Two Logan Square
 Eighteenth & Arch Streets
 Philadelphia, PA 19103
 (215) 981-4000

John H. Beisner
Counsel of Record
 Jessica D. Miller
 Geoffrey M. Wyatt
 SKADDEN, ARPS, SLATE,
 MEAGHER & FLOM LLP
 1440 New York Ave., NW
 Washington, DC 20005
 (202) 371-7000
 john.beisner@skadden.com

Attorneys for Petitioner