PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 14-1948

IN RE: AVANDIA MARKETING, SALES PRACTICES &
PRODUCT LIABILITY LITIGATION

GlaxoSmithKline, LLC,

Appellant

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D. C. Nos. 2-09-cv-00730, 2-10-cv-02475,
2-10-cv-05419, 2-07-md-01871)
District Judge: Honorable Cynthia M. Rufe

Argued on November 18, 2014

Before: AMBRO, SCIRICA and ROTH, Circuit Judges

(Opinion filed: October 26, 2015)

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O P I N I O N

ROTH, Circuit Judge:

This interlocutory appeal involves claims brought against GlaxoSmithKline LLC (GSK) by third-party payors (TPPs), based on GSK's alleged misrepresentation and concealment of the significant safety risks associated with use of Avandia, Avandamet, and Avandaryl (collectively, Avandia), Type II diabetes drugs. GSK argues that the District Court erred in finding that the TPPs adequately alleged the elements of standing under the Racketeer Influenced and Corrupt Organizations Act (RICO).[1] We agree with the District Court's analysis, finding standing, and therefore we will affirm.

I.

A.[2]

Plaintiffs, Allied Services Division Welfare Fund, UFCW Local 1776 and Participating Employers Health and Welfare Fund, and United Benefit Fund, are TPPs. They are union health and welfare funds and are suing GSK on behalf of themselves and other similarly situated TPPs. TPPs typically provide medical coverage, including prescription drug coverage, to their members and members' dependents.

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[1] 18 U.S.C. § 1961 *et seq*.

[2] These facts are taken from the Complaints and treated as true because, in reviewing a denial of a motion pursuant to Federal Rule of Civil Procedure 12(b)(6), we accept as true all well-pleaded allegations and construe the complaint in the light most favorable to the plaintiffs. *See Lewis v. Atlas Van Lines, Inc.*, 542 F.3d 403, 405 (3d Cir. 2008).

Whether a TPP will cover the cost of a member's prescription, in whole or in part, depends on whether that drug is listed in the TPP's "formulary." Pharmacy Benefit Managers (PBMs) prepare TPPs' formularies of drugs approved for use by the TPPs' members. The formularies are prepared by analyzing research regarding a drug's cost effectiveness, safety and efficacy. When a PBM determines that a drug offers advantages over a competing drug, it will give that drug preferred status on the formulary. A TPP will typically cover more of the cost of a particular drug when that drug has a higher preference status on the formulary. The greater coverage of cost by the TPP allows the member to pay a lower co-payment when prescribed that drug.

Type II diabetes is the most common form of diabetes and results from the body's failure to produce enough insulin or its inability to properly use insulin. Type II diabetes was first treated with oral medications, primarily metformin and sulfonylureas, or with injected insulin. In the 1990s, pharmaceutical companies began to develop a new form of Type II diabetes treatment known as thiazolidinediones (TZDs). On May 25, 1999, the Food and Drug Administration (FDA) approved Avandia, a TZD, for sale in the United States. GSK marketed Avandia as a more effective and safer alternative to the cheaper, existing Type II oral medications. In turn, TPPs included Avandia in their formularies and covered Avandia prescriptions at a favorable rate.

Soon after the FDA approved Avandia, concerns regarding its heart-related side effects began to surface. For example, in 2001, the FDA requested that GSK add a warning to the prescription label regarding the increased risk of fluid

retention resulting from Avandia use. Shortly thereafter, GSK's sales representatives denied the existence of this risk. As a result, the FDA instructed GSK to stop minimizing the risk of heart attacks and heart-related diseases in its marketing. In 2006, the FDA required GSK to update the warning to include new data about the potential increased occurrence of heart attack and heart-related chest pain in some Avandia patients.

In May 2007, Steven E. Nissen and Kathy Wolski published a paper in *The New England Journal of Medicine*, documenting the results of forty-two clinical trials of Avandia. The Nissen study concluded that, compared with the use of competing diabetes drugs, Avandia use was associated with a significant increase in the risk of myocardial infarction and a borderline-significant increase in the risk of death from heart-related diseases. According to the TPPs, GSK responded to the Nissen study with a marketing campaign designed to sway doctors and consumer confidence. This campaign included publishing full-page advertisements in more than a dozen newspapers and the release of promotional materials to prescribing physicians. Specifically, GSK challenged the Nissen study's methodology and conclusions and described the results of its own favorable study.

On May 23, 2007, the FDA recommended that GSK add a "black box" warning to Avandia's label to warn of the risk of congestive heart failure in connection with the use of Avandia. On August 14, 2007, GSK added the warning, which stated that TZDs "cause or exacerbate congestive heart failure in some patients. . . . Avandia is not recommended in patients with symptomatic heart failure." Three months later, the FDA added a second black box warning, describing the

Nissen study's results as showing "Avandia to be associated with an increased risk of myocardial ischemic events such as angina or myocardial infarction."

In February 2010, the U.S. Senate Finance Committee released a report on Avandia. The Committee concluded that the "totality of the evidence suggests that GSK was aware of the possible cardiac risks associated with Avandia years before such evidence became public" and that GSK failed to notify the FDA and the public of these risks despite its duty to do so. The report also noted that GSK attempted to minimize or misrepresent those risks in order to contradict the Nissen study and to intimidate independent physicians.

Ultimately, on September 23, 2010, the FDA restricted access to Avandia in response to increasing evidence of its cardiovascular risks. Specifically, the FDA limited access to existing users and to new patients whose blood sugar could not be controlled with other medications and who had decided with their doctor not to take Actos, a competing TZD drug. Doctors were required to advise existing Avandia users of Avandia's cardiovascular risks before continuing to prescribe it.

Since its release, Avandia has been used on a regular basis by at least one million individuals in the United States and has generated billions of dollars in revenue for GSK. A one-month supply of Avandia has sold for $90 to $220, with the TPP covering between $135 and $140 per prescription and the patient paying the balance. This was a dramatic increase in the cost of Type II diabetes treatment. Previously, the most prevalent oral drug therapy, metformin, cost approximately $45 to $55 for a one-month supply, with the

TPP covering $40 to $50 of that amount. Although plaintiffs identify Actos as another alternative to Avandia, they do not provide the price which TPPs typically covered for Actos prescriptions.

B.

Plaintiffs bring this class action on behalf of themselves and other similarly situated TPPs that covered the cost of Avandia after May 25, 1999. They assert that GSK's failure to disclose Avandia's significant heart-related risks violated RICO based on predicate acts of mail fraud,[3] wire fraud,[4] tampering with witnesses,[5] and use of interstate facilities to conduct unlawful activity.[6] They also assert claims for unjust enrichment and violations of the Pennsylvania Unfair Trade Practices and Consumer Protection Law[7] and other states' consumer protection laws.

Plaintiffs allege that GSK deliberately concealed the significant safety risks associated with the use of Avandia and continued to promote Avandia as a safer treatment for diabetes despite the known risks of heart attack and disease. Specifically, plaintiffs allege that GSK selectively manipulated data and scientific literature, made false and misleading statements in its 2007 advertising campaign, and intimidated physicians to publish false and misleading articles—all in order to increase Avandia sales. According to

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[3] *See* 18 U.S.C. § 1341.
[4] *See id*. § 1343.
[5] *See id*. § 1512.
[6] *See id*. § 1952.
[7] *See* 73 Pa. Cons. Stat. §§ 201-1-201-9.3.

plaintiffs, TPPs and PBMs included Avandia in their formularies and covered Avandia at favorable rates in reliance on these misrepresentations by GSK. Plaintiffs allege that Avandia was worth less than the favorable rates at which they covered it (their "excess price" theory). Similarly, they allege that physicians relied on GSK's misrepresentations in deciding to prescribe Avandia and would have prescribed Avandia to fewer patients had GSK not concealed Avandia's risks (their "quantity effect" theory). Plaintiffs seek compensatory, punitive, and statutory damages for the financial harm they suffered as a result of GSK's conduct, and they seek injunctive relief to prevent GSK from continuing its allegedly unlawful activities.

On November 3, 2010, GSK moved to dismiss, in part, because plaintiffs failed to adequately allege standing under Section 1964(c) of RICO. The District Court rejected GSK's arguments, holding that plaintiffs plausibly alleged that they had suffered a concrete economic injury based on the substantial savings they would have experienced had they covered cheaper alternatives to Avandia. This was true regardless of whether any beneficiary who had ingested Avandia became ill.

The District Court also rejected GSK's argument that plaintiffs failed to adequately allege proximate causation. According to the District Court, it is sufficient that plaintiffs alleged that doctors relied upon GSK's misrepresentations in prescribing Avandia and that the TPPs themselves relied upon those misrepresentations in making formulary decisions. The District Court noted, however, that plaintiffs may have difficulty in proving causation at the next litigation stage because they did not restrict access to Avandia after the

Nissen study publicized Avandia's heart-related risks. The District Court also rejected GSK's argument that prescribing doctors' independent actions broke the chain of causation. The District Court relied on *In re Neurontin Marketing and Sales Practices Litigation*,[8] in which the First Circuit Court of Appeals held that, where a TPP is a primary and intended victim and the injury is foreseeable, the doctor's independent actions do not break the causal chain.[9]

On February 19, 2014, the District Court certified its decision for interlocutory appeal under 28 U.S.C. § 1292(b). The certified questions are the following:

> 1) Did the Court err in its application of *Maio v. AETNA, Inc.* [10]
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> 2) Did the TPPs sufficiently plead that Defendant's alleged misrepresentation about Avandia's safety caused their injuries, when the TPPs continued to include Avandia on their formularies and cover the cost of Avandia for

[8] 712 F.3d 21 (1st Cir. 2013).

[9] The District Court also made a number of other findings, including that plaintiffs failed to adequately allege a claim for unjust enrichment. Because plaintiffs did not allege that Avandia injured their beneficiaries or failed to perform as advertised, the District Court held that they "received the benefit of their bargains" and therefore could not maintain a claim for unjust enrichment. This holding is not currently on appeal.

[10] 221 F.3d 472 (3d Cir. 2000).

> their members after the alleged cardiovascular risks of Avandia were well-publicized, and
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> 3) Does the independent judgment of doctors and decision-making of the physicians who wrote the prescriptions for Avandia render the causal chain too attenuated to state a claim?[11]

We granted permission to appeal on April 15, 2014.

II.[12]

We exercise plenary review over a district court's denial of a motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6).[13] "A motion to dismiss pursuant to Rule 12(b)(6) may be granted only if, accepting all well pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief."[14] The facts alleged in the complaint must state a "plausible claim for relief."[15] "The issue is not whether a plaintiff will ultimately prevail but

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[11] We do not address plaintiffs' state-law claims in this appeal because they are not explicitly addressed within the questions that have been certified to us.

[12] The District Court had jurisdiction pursuant to 28 U.S.C. § 1331. We have appellate jurisdiction pursuant to 28 U.S.C. § 1292(b).

[13] *See Farber v. City of Paterson*, 440 F.3d 131, 134 (3d Cir. 2006).

[14] *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997).

[15] *See Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009).

whether the claimant is entitled to offer evidence to support the claims."[16] We also exercise plenary review over a district court's legal determination that plaintiffs have standing to pursue a civil RICO action.[17]

III.

The issue on appeal is whether plaintiffs have adequately pled standing to pursue a civil action under Section 1964(c) of RICO. Section 1964(c) provides that:

> Any person injured in his business or property by reason of a violation of section 1962 of this chapter may sue therefor 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]

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[16] *Maio*, 221 F.3d at 482 (quoting *In re Burlington*, 114 F.3d at 1420).

[17] *See id.*

[18] 18 U.S.C. § 1964(c). Section 1962 prohibits, in part, "any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce" from "conduct[ing] or participat[ing], directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." *Id.* § 1962(c). A "racketeering activity" can consist of a variety of predicate offenses, including, as alleged in this case, mail fraud, wire fraud, tampering with witnesses, and use of interstate facilities to conduct unlawful activity, *see id.* §

The language of § 1964(c) requires a RICO plaintiff to show that the plaintiff suffered an injury to business or property and that the plaintiff's injury was caused by the defendant's violation of 18 U.S.C. § 1962.[19] Section 1964(c)'s "limitation of RICO standing to persons 'injured in [their] 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.'"[20]

A.

We must first determine whether plaintiffs adequately alleged injury to business or property within the meaning of RICO. "'[A] showing of injury requires proof of a concrete financial loss, and not mere injury to a valuable intangible property interest.'"[21] This requirement "can be satisfied by allegations and proof of actual monetary loss, i.e., an out-of-pocket loss."[22]

GSK claims that the TPPs fail to assert a concrete injury, citing our decision in *Maio*. In that case, we considered whether health insurance beneficiaries could maintain a RICO claim for economic injury against their

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1961(1), and a "pattern" of such activity requires at least two acts, *id.* § 1961(5).

[19] *See Maio*, 221 F.3d at 483.

[20] *Maio*, 221 F.3d at 483 (quoting *Steele v. Hospital Corp. of Am.*, 36 F.3d 69, 70 (9th Cir. 1994)) (internal citation omitted).

[21] *Id.* (quoting *Steele*, 36 F.3d at 70).

[22] *Id.*

insurer, Aetna, based on alleged misrepresentations regarding the services included in their HMO plans.[23] The insured parties claimed that the insurer's failure to disclose restrictive internal policies caused them injury by causing them to "pa[y] too much in premiums for an 'inferior' health care product."[24] They alleged that the internal policies were designed to improve profitability at the expense of quality of care, whereas the insurer's marketing campaign represented that the purchased policy focused on quality of care.[25] The insured parties also claimed that the internal policies "restrict[ed] the physicians' ability to provide the high quality health care . . . promised."[26]

We rejected the plaintiffs' claims, finding that the insured parties suffered no cognizable injury. We construed the insured parties' property interests as the intangible "contractual right to receive benefits in the form of covered medical services," and found that the insured parties had suffered no injury absent allegations that they had received "inadequate, inferior delayed care, personal injuries resulting therefrom, or [the] denial of benefits due under the insurance arrangement.[27] Because the insured parties specifically disclaimed any contractual shortcoming on the part of the insurer, they "simply c[ould not] establish as a factual matter that they received anything less than what they bargained for."[28] Instead, the alleged economic harm was "contingent

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[23] *See id.* at 483-84.
[24] *Id.* at 484-85.
[25] *Id.* at 474.
[26] *Id.* at 475.
[27] *Id.* at 490.
[28] *Id.* at 494.

upon the impact of events in the future" – namely, inadequate care produced by the insurer's internal policies.[29] We concluded that plaintiffs could not establish that they had suffered a tangible economic harm because their theory of injury was premised solely on the possibility that they *might* receive inadequate healthcare in the future.[30]

GSK argues that here too, the TPPs' injury is predicated on the possibility that future events might occur – namely, that the drugs purchased by the TPPs will prove to be unsafe or ineffective. However, because the TPPs do not allege that they received unsafe or ineffective prescriptions, GSK argues that they have received exactly what they bargained for and that they have not suffered a concrete injury.

The TPPs respond that their injury is one which has long been considered concrete: overpayment due to illegal or deceptive marketing practices. They cite our decision in *In re Warfarin Sodium Antitrust Litigation*,[31] in which TPPs alleged that DuPont violated antitrust law by disseminating false and misleading information about a cheaper generic drug, causing the TPPs to cover the cost of duPont's more expensive brand name drug.[32] We held that "TPPs, like

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[29] *Id.* at 494-95.

[30] *Id.* at 495.

[31] 391F.3d 516 (3d Cir. 2004).

[32] Although *Warfarin* was an antitrust case, it is applicable here because RICO's standing requirements were modeled on antitrust law. In drafting Section 1964(c), Congress "used the same words [as § 7 of the Sherman Act and § 4 of the Clayton Act], and we can only assume it intended them to have the

individual consumers, suffer[] direct economic harm when, as a result of [a pharmaceutical company's] alleged misrepresentations, they pa[y] supracompetitive prices for [brand drugs] instead of purchasing lower-priced generic [drugs]."[33] According to the TPPs, if allegedly anticompetitive behavior that leads to overpayment establishes a concrete injury, then so should allegedly fraudulent behaviorthat leads to overpayment.

We agree with the TPPs that *Warfarin* offers the closest analogy to the facts of this case and that GSK's reliance on *Maio* is distinguishable in one crucial respect: unlike the injury suffered by plaintiffs in *Maio*, the injury suffered by the TPPs here is *not* contingent on future events. The TPPs' damages do not depend on the effectiveness of the Avandia that they purchased, but rather on the inflationary effect that GSK's allegedly fraudulent behavior had on the price of Avandia. By contrast, the damages suffered by the plaintiffs in *Maio* were entirely dependent on the quality of the health care they received. Because the plaintiffs in that case did not allege that they had received inadequate care, their "theory of present economic loss require[d] a significant degree of factual speculation,"[34] and was thus insufficient to establish standing.

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same meaning that courts had already given them." *See Holmes*, 503 U.S. at 266-68; *see also Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 921, 932 (3d Cir. 1999).

[33] *Warfarin*, 391 F.3d at 531.

[34] *Maio*, 221 F.3d at 495.

To further illustrate the point, suppose that the defendants in *Warfarin* had asserted that the TPPS had failed to establish standing because they had not alleged that the drugs they had purchased were ineffective. That argument would have been rejected by the court: the injury suffered by the TPPs in that case did not depend on the drug's ineffectiveness but rather on the defendant's anticompetitive behavior. That same logic would apply here. The injury suffered by the TPPs in this case does not depend on Avandia's ineffectiveness, but rather on GSK's fraudulent behavior. As such, the TPPs' theory of economic loss does not require factual speculation. If we accept the plausible allegations in the complaint as true, the fraudulent behavior alleged in their complaint has already occurred, and its effect on the price of Avandia is not contingent on future events.

Reliance on our decisions in *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*,[35] and *Horvath v. Keystone Health Plan East, Inc.*,[36] is similarly misplaced. In *Schering-Plough*, TPPs alleged that Schering's off-label promotional activities of certain drugs caused them economic injury. Relying on *Maio*, the District Court held that the plaintiffs lacked standing to assert this injury because they failed to allege that any consumers or beneficiaries received inadequate drugs or suffered personal injuries.[37] On appeal, we affirmed the District Court on causation grounds. To the

[35] 678 F.3d 235 (3d Cir. 2012).
[36] 333 F.3d 450 (3d Cir. 2003).
[37] *See* No. 2:06-cv-5774, 2009 WL 2043605, at *16 (D.N.J. July 10, 2009).

extent we agreed with the District Court's injury analysis in that case, we did so in *dictum*, not in binding precedent.[38]

Horvath, an ERISA case, is distinguishable on the same basis as *Maio*. In *Horvath*, as in *Maio*, the plaintiff alleged that she overpaid for the healthcare provided by an HMO due to the HMO's misleading statements.[39] But the plaintiff "d[id] not allege . . . that the care she received from the Keystone HMO was defective or substandard in any way."[40] Accordingly, we noted that the plaintiff"'s claims "rest not only on the troublesome assumption that a factfinder can accurately determine the amount her [employer] allegedly overpaid [the HMO], but also on the notion that the [employer] would have passed these savings on to its employees in the form of a higher salary or additional benefits.[41] We determined that such a claim was too speculative to establish standing.[42] In this case, however, if we accept the TPPs' plausible allegations as true – as we are required to do at this stage – then no speculation is required to determine whether they suffered an injury.

GSK advances one final argument for its position that the TPPs have not suffered a concrete injury. Relying on the Eleventh Circuit Court of Appeals' decision in *Ironworkers Local Union 68 v. AstraZeneca Pharm., LP.*, [43] GSK argues that TPPs can statistically anticipate a certain level of fraud

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[38] *See Schering-Plough*, 678 F.3d at 246.
[39] *Horvath*, 333 F.3d at 452.
[40] *Id.* at 453.
[41] *Id.* at 457.
[42] *Id.*
[43] 634 F.3d 1352 (11th Cir. 2011).

and pass this risk on to their beneficiaries in the form of higher premiums. In *Ironworkers*, a case with facts similar to these, the court found the plaintiff insurance companies suffered no injury because they "adjust[] their premiums upward to reflect the projected value of claims" for payment of "medically unnecessary or inappropriate prescriptions of formulary drugs" – "even those caused by fraudulent marketing.[44] Although GSK says that the TPPs "presumably" adjusted their premiums in this way, we are not entitled to make such a presumption at the motion-to-dismiss stage. Furthermore, the argument lacks a limiting principle.[45]

B.

In addition to cognizable injury, a RICO plaintiff must satisfy RICO's proximate causation requirements. In evaluating the requirement for proximate cause in a RICO case, we cannot look only to the language of § 1964(c). It is too broad: "Any person injured in his business or property by reason of a violation of section 1962 of this chapter . . . shall recover . . .." The Supreme Court has been concerned about this breadth of language, which on its face might "be read to mean that a plaintiff is injured 'by reason of' a RICO violation, and therefore may recover, simply on showing that the defendant violated § 1962, the plaintiff was injured, and

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[44] *Id.* at 1364, 1368.

[45] Were it "[t]aken to its ultimate conclusion . . a retailer would be unable to claim injury from shoplifting, or a bank from robbery, on the ground that their business models presumably accounted for such losses in pricing their products and services." Br. Amicus Curiae Third Party Payors at 10.

the defendant's violation was a 'but for' cause of plaintiff's injury."[46]

The Court addressed this overbreadth concern in *Holmes v. Securities Investor Protection Corp.*[47] Noting that Congress had modeled the broad language of § 1964(c) on the language of the federal antitrust laws, the Court pointed out that historically the lower federal courts had read § 4 of the Clayton Act with the intent of adopting "the judicial gloss that avoided a simple literal interpretation . . .."[48] Thus, the Court had held in the antitrust case of *Associated General Contractors* that "the judicial remedy cannot encompass every conceivable harm that can be traced to alleged wrongdoing."[49]

The *Holmes* Court found the remedy for this overbreadth in the doctrine of "proximate cause." The Court specified that "we use 'proximate cause' to label generically the judicial tools used to limit a person's responsibility for the consequences of that person's acts."[50] Because of the common language of § 1964(c) and of § 4 of the Clayton Act, the Court in *Holmes* then discussed the elements of proximate cause developed in the common law and, in doing so, referred

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[46] *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258, 265-66 (1992) (comparing *Associated General Contractors of California, Inc. v. California State Council of Carpenters*, 459 U.S. 519, 529 (1983).

[47] 503 U.S. 258 (1992).

[48] *Id.* at 267-68 (quoting *Associated General Contractors*, 459 U.S. at 534.

[49] *Associated General Contractors*, 459 U.S. at 537.

[50] *Holmes*, 503 U.S. at 268.

to *Associated General Contractors*.[51] Among the "many shapes" that the doctrine of proximate cause took at common law "was a demand for some direct relation between the injury asserted and the injurious conduct alleged. Thus, a plaintiff who complained of harm flowing merely from the misfortunes visited upon a third person by the defendant's acts was generally said to stand at too remote a distance to recover."[52]

The *Holmes* Court stated that there are three reasons behind the requirement of a directness of relationship between the injury and conduct alleged. First, the directness of the injury: indirect injuries make it difficult "to ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent factors."[53] Second, the risk of multiple recoveries: indirect injuries may present such a risk and courts would have to adopt complicated rules apportioning damages to guard against this risk.[54] Third, the likelihood of vindication by others: the need to grapple with the problems presented by indirect claims may be unjustified "since directly injured victims can generally be counted on to vindicate the law as private attorneys general."[55]

In *Holmes*, the Court concluded that the Securities Investor Protection Corporation (SIPC) had failed to satisfy

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[51] 459 U.S. 519.
[52] *Holmes* at 268-69 (citing 1 J. Sutherland, Law of Damages 55-56 (1882)).
[53] *Id.* at 269.
[54] *Id.*
[55] *Id.* at 269-70.

the proximate cause requirement.[56] The SIPC, as a subrogee, alleged that the defendant engaged in a stock manipulation scheme, which caused two broker-dealers to become insolvent and, in turn, required that the SIPC reimburse the broker-dealers' customers' losses.[57] The Supreme Court held that, even if plaintiffs stood in the shoes of the customers, "the link is too remote between the stock manipulation alleged and the customers' harm, being purely contingent on the harm suffered by the broker-dealers."[58]

Since *Holmes*, the Court has found proximate cause lacking in RICO cases when the conduct directly causing the harm was distinct from the actions that gave rise to the fraud. In *Anza v. Ideal Steel Supply Corp.*,[59] plaintiff alleged that a competing business caused it harm by defrauding the State tax authority and using the proceeds to offer lower prices to attract more customers.[60] The Court held that the cause of plaintiff's harm was "a set of actions (offering lower prices) entirely distinct from the alleged RICO violation (defrauding the State.)."[61] A plurality of the justices reached a similar decision in *Hemi Group, LLC v. City of New York*,[62] where New York City alleged that out-of-state cigarette sellers failed to file Jenkins Act reports with the State, and asserted injury in the form of lost taxes from City residents.[63] The

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[56] *See id.* at 261-63.
[57] *See id.*
[58] *Id.* at 271.
[59] 547 U.S. 451 (2006).
[60] *Id.* at 457-58.
[61] *Id*. at 458.
[62] 559 U.S. 1 (2010).
[63] *Id.* at 4-5.

plurality concluded that causation was even more attenuated than in *Anza* because "the City's theory of liability rest[ed] not just on separate *actions*, but separate actions carried out by separate *parties*."[64] "Put simply, Hemi's obligation was to file the Jenkins Act reports with the State, not the City, and the City's harm was directly caused by the customers, not Hemi."[65]

In contrast, however, if there is a sufficiently direct relationship between the defendant's wrongful conduct and the plaintiffs' injury, the Court has held that a RICO plaintiff who did not directly rely on a defendant's misrepresentation can still establish proximate causation.[66] In *Bridge v. Phoenix Bond & Indemnity Co.*, bidders at a county tax lien auction alleged that they were directly harmed by other bidders' fraudulent scheme to win more bids at the auction.[67] The defendants argued that the plaintiffs could not establish proximate causation because even though the county may have relied on defendants' misrepresentations, plaintiffs did not.[68] Rejecting this argument, the Court held that the "alleged injury—the loss of valuable liens—[was] the direct result of petitioners' fraud [because] . . . . [i]t was a foreseeable and natural consequence of petitioners' scheme to obtain more liens for themselves that other bidders would obtain fewer liens."[69]

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[64] *Id.* at 11.
[65] *Id.*
[66] 553 U.S. 639, 657-58 (2008).
[67] *See id.* at 642.
[68] *See id.* at 653.
[69] *Id.* at 658.

Keeping in mind that at the motion-to-dismiss stage we must accept all plausible allegations in the complaint as true, we view the case before us as more akin to *Bridge* than to *Holmes*, *Anza*, or *Hemi*. The Court in *Holmes*, *Anza*, and *Hemi* was concerned that the conduct causing plaintiffs' injuries was different than the conduct allegedly constituting a RICO violation.[70] Each of those cases featured plaintiffs alleging harm that was derivative of harm suffered by a more immediate victim of the RICO activity. Here, GSK focuses on the presence of intermediaries—physicians and patients—in the causal chain. But GSK does not argue that a doctor's decision to prescribe Avandia or a patient's decision to take Avandia caused plaintiffs' injuries. The conduct that allegedly caused plaintiffs' injuries is the same conduct

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[70] *See, e.g.*, *Holmes*, 503 U.S. at 272 ("[T]he link is too remote between the stock manipulation alleged and the customers' harm, being purely contingent on the harm suffered by the broker-dealers . . .. The broker-dealers simply cannot pay their bills, and only that intervening insolvency connects the conspirators' acts to the losses suffered by the nonpurchasing customers and general creditors."); *Anza*, 547 U.S. at 458 ("Ideal asserts it suffered its own harms when the Anzas failed to charge customers for the applicable sales tax. The cause of Ideal's asserted harms, however, is a set of actions (offering lower prices) entirely distinct from the alleged RICO violation (defrauding the State)."); *Hemi*, 559 U.S. at 11 ("[T]he conduct directly responsible for the City's harm was the customers' failure to pay their taxes. And the conduct constituting the alleged fraud was Hemi's failure to file Jenkins Act reports. Thus, as in *Anza,* the conduct directly causing the harm was distinct from the conduct giving rise to the fraud.").

forming the basis of the RICO scheme alleged in the complaint – the misrepresentation of the heart-related risks of taking Avandia that caused TPPs and PBMs to place Avandia in the formulary. The injury alleged by the TPPs is an economic injury independent of any physical injury suffered by Avandia users.[71] And, as far as we can tell, prescribing physicians did not suffer RICO injury from GSK's marketing of Avandia.

Nor should there be difficulty in distinguishing between the amount of damages attributable to a defendant's violation and to other, independent factors. The amount of damages is either the difference between what Avandia coverage cost and the cost of coverage of cheaper, safer drugs and/or the overvaluation of Avandia caused by GSK's misrepresentations. This issue of damages, rather than demonstrating a lack of proximate causation, raises an issue of proof regarding the overall number of prescriptions (under the "quantity effect" theory) or amount of price inflation (under the "excess price" theory) attributable to GSK's actions. This is a question of damages and, more specifically, a question for another day.

GSK, however, claims that plaintiffs' theory of causation—that TPPs relied on GSK's misrepresentations when including Avandia on formularies—fails as a matter of law. According to GSK, plaintiffs cannot establish causation

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[71] *See Warfarin,* 391 F.3d at 531 (holding that TPPs had standing to assert antitrust claims because they suffered "direct and independent harm" as a result of paying supracompetitive prices for the defendant's drug regardless of any injury suffered by the consumer plaintiffs).

because they continued to cover Avandia prescriptions after its safety risks were publicly exposed in May 2007. But this argument is based on two faulty assumptions. GSK first asks us to assume, in the absence of contrary allegations, that plaintiffs did not change their coverage of Avandia in 2007.[72] At this stage, however, we do not know that this is true.

In addition, GSK's argument assumes that plaintiffs knew the full scope of GSK's alleged fraud based on the Nissen study. Other TPPs, however, may have chosen to remove Avandia from their formularies in May 2007 simply out of an abundance of caution, not due to knowledge of Avandia's full scope of risks. In fact, GSK responded to the Nissen study with a marketing campaign, which plaintiffs allege was specifically designed to minimize the report's effects on the medical community. Furthermore, the FDA merely added black box warnings to Avandia in 2007 and did not restrict Avandia usage until September 2010, over three years after the Nissen study's release. Viewing these facts in the light most favorable to plaintiffs, we cannot conclude at this stage that Avandia's cardiovascular risks were fully known in May 2007.

GSK further argues that plaintiffs' claim, that doctors relied on GSK's misrepresentations when prescribing Avandia, fails because there are no allegations that alternative prescriptions would have been cheaper. As a preliminary matter, plaintiffs' injury is not entirely contingent on the

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[72] *See* Oral Arg. Tr. at 9:19-10:2 ("There's no allegation in the complaint [Plaintiffs] changed any behavior [in 2007]. And so I think the Court should assume that no change in behavior occurred.").

existence of cheaper alternative drugs. Although these allegations are central to plaintiffs' "quantity effect" theory, they are less important to an "excess price" theory. Under that theory, plaintiffs may be able to show that Avandia cost too much regardless of whether cheaper drugs existed on the market.

In any event, plaintiffs identify metformin as a cheaper alternative drug, which they allege was the most prevalent oral drug therapy for Type II diabetes prior to Avandia and cost substantially less than Avandia. Despite GSK's contention, it was not necessary for plaintiffs to have included a price comparison between Avandia and Actos, another Type II diabetes drug. Although metformin may belong to an older class of drugs, it is not entirely clear when -- or even if -- Actos was a more popular alternative to Avandia than metformin. Again, GSK seeks a dismissal as a matter of law when there is a factual dispute between plaintiffs and GSK on the existence of alternative therapies. It is sufficient that a plaintiff identify in the pleadings a specific alternative drug that doctors would have prescribed and that would have cost less.

Finally, GSK argues 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. But *Bridge* precludes that argument. The plaintiffs in *Bridge* were the "primary and intended victims of the scheme to defraud" and their injury was a "foreseeable and natural consequence of [the] scheme," regardless of whether they relied on the

misrepresentations.[73] The same is true here. Plaintiffs allege that drug manufacturers are well aware that TPPs cover the cost of their drugs and describe the alleged RICO scheme as consisting of "deliberately misrepresenting the safety of Avandia so that Plaintiff and members of the Class paid for this drug."[74] This fraudulent scheme could have been successful only if plaintiffs paid for Avandia, and this is the very injury that plaintiffs seek recovery for. We conclude therefore that plaintiffs' alleged injury is sufficiently direct to satisfy the RICO proximate cause requirement at this stage.[75]

Nor does this decision conflict with our holding in *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*[76] There, we held that proximate causation was lacking where TPPs sued cigarette manufacturers based on alleged misrepresentations and sought damages for the money spent treating beneficiaries' smoking-related health conditions.[77] Analogizing to *Holmes*, we concluded that the smokers, like the broker-dealers there, were the "third party linking the plaintiffs and defendants."[78] In both cases, plaintiffs only "suffered a loss because of the harm that the defendants brought upon th[at] third party."[79] That is not

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[73] *See* 553 U.S. at 650, 658.
[74] J.A.120, ¶ 184 (Allied Services Compl.); J.A.193, ¶ 178 (UFCW Local 1776 Compl.); J.A.265, ¶ 235 (United Benefit Compl.).
[75] *See Neurontin*, 712 F.3d at 37-38.
[76] 171 F.3d 912 (3d Cir. 1999).
[77] *Id.* at 930.
[78] *Id.* at 932.
[79] *Id.*

what happened here. Although GSK identifies third parties, doctors and patients, within the causal chain, plaintiffs did not suffer economic harm because those third parties were injured.

To sum up, this case does not present any of the three fundamental causation concerns expressed in *Holmes*. At least for the purposes of this motion to dismiss, the injury is sufficiently direct. There is no risk of duplicative recovery here. And, no one is better suited to sue GSK for its alleged fraud.[80] At this stage in the litigation, plaintiffs "need only put forth allegations that raise a reasonable expectation that discovery will reveal evidence" of proximate causation.[81] They have done that here.

IV.

Plaintiffs have plausibly alleged the elements of RICO standing, and GSK has not offered a valid justification for limiting the claims at this stage of the litigation. While many of these issues will resurface in the future, we will not opine on the likelihood of plaintiffs' success down the road. We simply hold that it would be premature to dismiss plaintiffs' well-pled RICO allegations at this juncture. Accordingly, we will affirm the judgment of the District Court.

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[80] *See Bridge*, 553 U.S. at 658.

[81] *See Fowler v. UPMC Shadyside*, 578 F.3d 203, 213 (3d Cir. 2009) (internal quotations omitted).