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

BRIEF OF THE PRODUCT LIABILITY ADVISORY COUNCIL, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

The Product Liability Advisory Council, Inc. ("PLAC") will focus on the first question presented by petitioner, GlaxoSmithKline LLC ("GSK"):

1. Whether [a union benefit plan] states a plausible RICO injury by alleging that a manufacturer's failure to disclose risk information inflated the price of a medication.

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INTEREST OF *AMICUS CURIAE* [1]

The Product Liability Advisory Council, Inc. (PLAC) is a non-profit association with almost 100 corporate members representing a broad cross-section of American and international product manufacturers. PLAC seeks to contribute to the improvement and reform of law in the United States and elsewhere, with emphasis on achieving fairness and balance in the law governing the liability of manufacturers of products. PLAC's perspective is derived from the experiences of its corporate members, which span a diverse group of manufacturing industries, including pharmaceuticals. In addition, several hundred of the leading product liability defense attorneys in the country are sustaining (non-voting) members of PLAC. Since 1983 PLAC's briefs as *amicus curiae* have been accepted in over 1,075 cases in both state and federal courts, including this Court. A list of PLAC's corporate members is attached as Appendix 1.[2]

This case is of particular importance to PLAC's members, which seek to mitigate the threat to

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[1] Pursuant to Supreme Court Rule 37.6, *amicus curiae* states that this brief was not authored, in whole or in part, by counsel to a party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than the *amicus* or its counsel. Pursuant to Supreme Court Rule 37.2(a), *amicus curiae* further states that all parties received timely notice of the intent to file this brief, Petitioner and Respondents have consented to the filing of this brief.

[2] Except for this citation, all remaining appendix citations in this brief are to the Appendix filed with Petitioner's brief in support of its petition for a writ of certiorari.

pharmaceutical and other product manufacturers posed by the Third Circuit's expansive and unworkable interpretation of RICO's injury requirement for standing.[3] By permitting plaintiffs in this case to have standing, the Third Circuit is enabling plaintiffs to use implausible allegations of "price inflation" as a ruse to bring RICO class action claims for treble damages, even though prescription drug pricing is inelastic, the price in fact did not change after the allegedly undisclosed risks became public knowledge, the purported risks never materialized and were later disproven, and the drug performed as intended and did not physically harm the users.

The Third Circuit's ruling opens the door to claims premised on attenuated and speculative allegations of economic injury. Unmooring the requirement of a concrete injury to business or property from RICO standing would eliminate an essential statutory requirement and accelerate the trend of "no-injury" class actions against prescription drug and other product manufacturers. By allowing implausible claims to end-run standing requirements, courts would permit plaintiffs to coerce large settlements from defendants seeking to avoid the crushing financial burden of defending complex class action litigation and the risk of RICO treble damages.

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[3] Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962.

STATEMENT OF THE CASE

PLAC adopts Petitioner's Statement of the Case.

Avandia is a prescription drug originally protected by a patent. No other drug is chemically the same. Avandia is used to treat Type 2 diabetes. Other anti-diabetic drugs are on the market, but they differ in their chemistry and how they work.

Plaintiffs are health benefit plans. They pay for medications that physicians prescribe for plan beneficiaries. Plaintiffs assert that GSK falsely promoted Avandia's efficacy and failed to disclose its health risks compared to less expensive drugs. These purported misrepresentations allegedly caused Plaintiffs to "pay for Avandia, which is neither safer nor more effective than other less expensive anti-diabetic drugs." (App. 235a ¶ 168.) However, their allegation is implausible and contradicted by the fact that they continued to pay for Avandia after a 2007 study reported those risks.

Consequently, the Third Circuit relied on a different theory of "price inflation." However, the Complaint does not, and cannot, allege that Avandia's price declined after the 2007 study. While the reported risks of Avandia changed, its price did not. The allegations, as well as real world experience, reveal an inelastic market price for Avandia. This is typical of prescription drugs with no chemically equivalent competitor.

Moreover, the Complaint does not allege that a competing drug, Actos, cost less than Avandia. (*See generally* App. 172a-269a.) The Complaint's reliance on a cheaper drug, metformin, is misplaced, because Avandia was typically prescribed when other drugs,

such as metformin, fail to control a patient's diabetes. (3d Cir. JA 314.)

Finally, the Complaint does not allege that Avandia injured any plan beneficiary or was not effective. In sum, the plan beneficiaries received the drug prescribed by their physicians, the drug worked, it caused no physical harm, and Plaintiffs paid the inelastic market price. There is no plausible allegation of facts showing that the purported misrepresentations affected the price paid by Plaintiffs.

Accordingly, the district court dismissed Plaintiffs' unjust enrichment claim, holding that "Plaintiffs have received the benefit of their bargains." (App. 62a.) Plaintiffs have not appealed that dismissal. Consistent with that ruling, the Third Circuit has since affirmed the dismissal of certain consumer fraud claims, finding that the Avandia users "received the drug [they were] prescribed, the drug did the job it was meant to do (i.e., controlled [. . .] blood sugar levels), and it caused no apparent physical injuries." *In re Avandia Mktg. Sales Practices & Prods. Liab. Litig.*, No. 15-2145, 2016 U.S. App. LEXIS 2463, at *7 (3d Cir. Feb. 12, 2016). These findings led the Third Circuit to hold that, "[u]nder such circumstances, *there could be no ascertainable loss*." *Id.* (emphasis added).

Despite finding that Avandia users had no ascertainable loss and had received the benefit of their bargain in a consumer class action, the Third Circuit affirmed the district court's ruling that the plaintiff benefit plans had sustained an "injury to their business or property" for purposes of RICO. It

created its own "price inflation" theory of injury not alleged by Plaintiff. It determined that Plaintiffs had alleged sufficient injury by theorizing that they had either paid too much or too often for Avandia prescribed for plan beneficiaries. *In re Avandia Mktg.*, 804 F.3d 633, 640, 645 (3d Cir. 2015).

SUMMARY OF ARGUMENT

This petition presents a conflict among the Courts of Appeals on an issue that this Court has not yet addressed: what constitutes a plausible "injury to business or property" sufficient to satisfy RICO's statutory standing requirement. In traditional RICO cases involving extortion or loan sharking, the injury is obvious. As plaintiffs attempt to import RICO's treble damage liability into areas governed by commercial and products liability law, the definition of an injury sufficient for RICO standing has become murky and controversial. Yet, that definition is an important limitation to prevent an unwarranted expansion of RICO liability.

The Third Circuit's determination that "inflated price" and "excess quantity" theories of injury for prescription drugs satisfy RICO's requirement of an "injury to business or property" conflicts with a decision of the Eleventh Circuit. Those theories are neither adequately alleged nor plausible in light of the inelastic pricing for prescription drugs. As the Eleventh Circuit recognized, prescription drug pricing is typically not responsive to product risk.

In addition, the Fifth Circuit has also rejected those theories of injury. It has not allowed claims of overpayment for prescription drugs in the absence of

allegations that the drugs either caused physical injury or were not effective.

The Circuit conflict raises an issue of nationwide importance. The statutory requirement of "injury to business or property" is essential to confine the permissible scope of RICO. By allowing generic, implausible allegations of "price inflation" to satisfy that element of a RICO claim, the Third Circuit's holding permits complaints premised on speculative, and implausible claims of injuries to proceed based on little more than statistical guesswork. When the inelastic market price for prescription drugs does not change after the allegedly undisclosed health risks are publicly reported, and the drugs work as intended and cause no harm, there is no cognizable RICO injury, and health benefit plans have no standing to bring claims that impose enormous time, expense, and risk on manufacturers.

By deferring any consequence for a failure of allegations until "another day," the Third Circuit is enabling the *in terrorem* impact of a civil RICO class action to coerce manufacturers to settle frivolous claims in order to avoid onerous discovery burdens and the threat of treble damages. Its decision is likely to exacerbate the proliferation of no-injury class action litigation in RICO and other contexts to the detriment of the judiciary's overcrowded docket as well as to manufacturing growth, employment, research, and product development.

ARGUMENT

I. THE THIRD CIRCUIT'S DECISION CONFLICTS WITH OTHER COURTS OF APPEALS REGARDING THE SCOPE OF RICO STANDING.

The Third Circuit's decision conflicts with other courts of appeals regarding what constitutes a plausible "injury to business or property" sufficient to establish standing for purposes of RICO.

The statement of the rule is straightforward: to establish standing under RICO, a putative plaintiff must allege a direct, concrete injury to business or property. *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 279 (1992) ("Of course, a RICO plaintiff only has standing if, and can only recover to the extent that, he has been injured in his business or property by reason of the conduct constituting the violation interest." (internal citations and quotation omitted)). However, the interpretation and application of that rule have caused confusion and conflict in the lower courts, particularly in the context of prescription drugs.

Congress enacted RICO to provide criminal and civil remedies for the injuries to business and property wrought by organized crime. The injuries from criminal activities, such as extortion, loan sharking, and other criminal frauds, were obvious and palpable. For example, if an individual purchased a painting represented to be an original Monet but was in fact a fake copy, those injuries would undoubtedly fit RICO's definition of an "injury to business or property." *E.g.*, *De Sole v. Knoedler Gallery, LLC*, 974 F. Supp. 2d 274, 310 (S.D.N.Y.

2013) (holding that plaintiffs stated a RICO injury where they "purchased a painting for $8.4 million that was represented to be a genuine Mark Rothko, but which turned out to be a forgery").

However, RICO's remedy of treble damages has given clever plaintiffs the incentive to prospect for bigger paydays in areas traditionally governed by products liability and commercial law. This prospecting has stretched the definition of an "injury to business or property," among other elements of a RICO claim. As shown by the Third Circuit's ruling, the scope of a RICO injury is no longer obvious, but controversial.

The Third Circuit determined that Plaintiffs have standing to proceed with a RICO claim premised on a reported risk, now disproven by later studies,[4] that did not manifest and did not affect the market price of the prescription drug. In the Third Circuit's view, "[t]he injury suffered by the TPPs [third party payors] in this case does not depend on Avandia's ineffectiveness, but rather on GSK's fraudulent behavior." *In re Avandia*, 804 F.3d at 640; *see also id.* at 645 (holding that plaintiffs could show a tangible economic injury "regardless of whether cheaper drugs existed on the market").

While the Third Circuit's ruling might have some merit in the abstract in other circumstances, its reasoning overlooks whether the Complaint alleges any plausible injury in this case. Fraudulent conduct alone, even if proven, does not constitute a RICO claim. Plaintiffs must allege and prove an injury

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[4] *See* http://ww.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm477601.htm.

caused by that conduct. It is black letter law that alleged tortious conduct but with no harm or damages does not amount to a claim for relief. A putative fraud plaintiff with no injury has no standing to sue. *E.g.*, *Montana-Dakota Utils. Co. v. Nw. Pub. Serv. Co.*, 341 U.S. 246, 254 (1951) ("Injury is an essential element of remediable fraud. Deceit and injury must concur." (internal citation omitted)); *Palsgraf v. Long Island R.R. Co.*, 248 N.Y. 339, 341 (1928) (Cardozo, J.) ("Proof of negligence in the air, so to speak, will not do." (internal citation omitted)). Likewise, RICO's requirement of an "injury to business or property" is an essential element to allege standing and a claim. It is no surprise, therefore, that the Third Circuit's ruling, which does not require a plausible allegation of injury, has created a conflict among the courts of appeals.

The Third Circuit's ruling is directly contrary to a recent Eleventh Circuit decision. In that case, third party payors asserted civil RICO claims against a pharmaceutical company alleging that the company made "false representations concerning [a] drug's safety and efficacy." *Ironworkers Local Union 68 v. AstraZeneca Pharms., LP*, 634 F.3d 1352, 1363 (11th Cir. 2011). Plaintiffs sought to recover the difference between the amount they paid and the amount they would have paid for less expensive substitutes. The Eleventh Circuit dismissed the claim, holding that, "to assert a plausible economic injury arising from the purchase of prescription drugs, the plaintiffs must have alleged that the purchased drugs either

were medically unnecessary or inappropriate for their prescribed use." *Id.* at 1360, 1363.[5]

The Second Circuit has similarly concluded that a plaintiff cannot state a RICO injury based on speculation that more fulsome disclosures of a product's risks would have led to a market-wide decrease in price. *McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215, 228 (2d Cir. 2008) ("[T]he loss of value model is designed to award plaintiffs damages based on the benefit of their bargain. Such damages are generally unavailable in RICO suits."); *accord Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 2d 508, 521, 522 n.23, 523 (D.N.J. 2011) (dismissing RICO claims by third party payors for

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[5] This Court has required plaintiffs to demonstrate, at the outset, a "plausible" claim for relief before allowing a lawsuit to "'take up the time of a number of other people, with the right to do so representing an in terrorem increment of the settlement value.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007). The Third Circuit's dismissal of GSK's objection that plaintiffs' claims are inherently speculative and incapable of proof as "a question for another day," *In re Avandia*, 804 F.3d at 644, contradicts the protections of Rule 8 and Rule 9(b) of the Federal Rules of Civil Procedure. *See, e.g.*, *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 347 (2005) (holding that a mere allegation that the purchase price of a security was inflated on the day of purchase does not sufficiently plead an "economic loss" for purposes of private securities fraud actions and dismissing plaintiffs' complaint). The Third Circuit's rejection of GSK's standing arguments also conflicts with the Eleventh Circuit's decision in *Ironworkers*, which placed the burden on third party payors to allege a "plausible economic injury" by pleading that "they did not charge their enrollees premiums or, in turn, adjust those premiums to compensate for [the] known risk" of paying for all prescription drugs covered by their policies, even those that are medically inappropriate or prescribed because of fraud. *Ironworkers*, 634 F.3d at 1364.

lack of injury because they "do not identify any participant in their health plans who received an ineffective or unsafe off-label [drug] prescription" and holding that allegations that "alternative medications were more effective or safer" were insufficient to confer standing).

While their contexts vary, the Second and Eleventh Circuit decisions hold that there is no fraudulent injury when benefit plans and consumers received the benefit of their bargain. Despite knowing of the 2007 study, Plaintiffs continued to pay the same price and did not remove Avandia from their list of approved drugs. Their actions make implausible any theory of "price inflation," and reflect the inelastic prices of prescription drugs.[6]

Accordingly, PLAC urges this Court to grant the petition for writ of certiorari to resolve the conflict among the Second, Third, and Eleventh Circuits on the issue of RICO standing.

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[6] In a different context, the Fifth Circuit has also rejected a "price inflation" theory of injury. In *Rivera*, a putative class of union funds (like Plaintiffs here) and individual patients brought an action seeking a return of money they paid for an effective painkiller. The Fifth Circuit held that a class of "patients who were prescribed, had purchased, and had ingested [a prescription drug] but suffered *no* physical or emotional injury," yet claimed they overpaid for the drug, "have asserted no concrete injury." "By plaintiffs' own admission, [the named plaintiff] paid for an effective pain killer, and she received just that—the benefit of her bargain." *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 317, 320-321 (5th Cir. 2002) (reversing class certification due to lack of standing).

II. THE THIRD CIRCUIT'S IMPLAUSIBLE THEORIES OF INJURY, IF PERMITTED, WOULD OPEN THE DOOR TO INHERENTLY SPECULATIVE RICO CLAIMS.

The petition raises recurring questions of nationwide importance for prescription drug and other manufacturers. Speculative RICO class action claims of economic harm resulting from some allegedly undisclosed product risk or characteristic, despite no physical injury to the user or performance problem, are a growing wildfire.

A. The "Price Inflation" Theory Is Implausible, Because Prescription Drug Pricing Is Inelastic To Risk.

The Third Circuit's generic "price inflation" theory attempts to conjure up a purported injury when none in fact exists. In this case, physicians prescribed Avandia to plan beneficiaries, and those beneficiaries received Avandia as prescribed. Plaintiffs acknowledge that Avandia is typically prescribed when other less expensive, less risky drugs fail to control patients' diabetes. Plaintiffs point to only one comparable drug, Actos, but never allege its price. And Plaintiffs continued to pay for Avandia and to pay the same price after a 2007 study reported new cardiovascular risks. Consequently, whether Plaintiffs proceed on a price inflation or excess quantity theory, the fundamental fact remains, as the district court held when dismissing the unjust enrichment claims, that Plaintiffs received exactly what they agreed to pay for: Avandia prescribed for

their plan beneficiaries at a market price unaffected by the nondisclosure of that purported health risk.

The Third Circuit's error results from a fundamental misunderstanding of the marketplace for prescription drugs. Even when aimed at controlling the same health problem, prescription drugs take different approaches and are not chemically equivalent. Avandia is not the same chemically as metformin or Actos. Consequently, pricing in the prescription drug market is inelastic. Opderbeck, *Patents, Essential Medicines, and the Innovation Game*, 58 Vand. L. Rev. 501, 525-26 (2005). "The initial price set by a pharmaceutical company is 'sticky' in that the price does not respond to market demand. Rather, the price is generally increased over time as a routine matter by the manufacturer." *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 125 (2d Cir. 2010) "Even if negative information is released about a medication, the demand for the drug may go down, but the price generally remains the same." *Id.*

Further, a prescription drug is purchased only if a physician, exercising independent medical judgment regarding safety and efficacy, determines it is in the patient's best medical interest. *E.g.*, *Ironworkers*, 634 F.3d at 1362 (citing *UFCW Local 1776*, 620 F.3d at 135); *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974)). "Physicians generally do not take the price of a drug into account when deciding among treatment options, and often do not even know the price of the drugs they prescribe." *UFCW Local 1776*, 620 F.3d at 126-27. As such, a plaintiff's claim that additional warnings would have led to a decrease in price is particularly implausible for a prescription

drug. And, as the Complaint and real world experience demonstrates, in fact the price of Avandia did not decline after a 2007 study reported purportedly serious, previously undisclosed risks.

By permitting the claims to proceed, the Third Circuit opens the door to civil RICO suits based on a claim that plaintiffs would not have paid as much if they had known of some allegedly undisclosed risk or characteristic—when the claim is inherently implausible and contradicted by real world experience of inelastic prescription drug pricing. Moreover, the same claim could be made, after the fact, about virtually every product, as experience reveals new, unanticipated risks. But when the product was effective and did no harm, such a claim amounts to "buyers' remorse" that a more favorable price was not negotiated; it should not suffice to state a civil RICO class action.

In addition, any such claim is inherently subjective and rife with speculation. Is the product appropriately priced for one user, who has no concern about the risk, but not for another user, who became unduly concerned? Does the injury-in-fact requirement for standing depend on the subjective reaction of each individual? That result would not set any principled basis for a determination of injury and standing. Eviscerating the standing requirement would open the door to an untold number of claims with no objective, concrete injury.

B. Eroding The Standing Requirement Would Cause Other Legal Problems To Arise.

Adherence to the standing requirement avoids other intractable legal issues, some of constitutional dimension. The purported proof for any class action dispute over a product's "real" worth to payors or users could only lead to a battle of experts using generalized statistics. Plaintiffs will not call as witnesses, one by one, the physicians who prescribed Avandia, or the plan beneficiaries who took the drug. Nor is it likely Plaintiffs will attempt to discover the true facts from individual physicians and consumers.

In the class action context, plaintiffs will use a statistical approach to attempt to prove counter-factual unknowns: (1) the number of pills prescribed by doctors that would not have been prescribed; (2) the market impact on price that would have resulted from more fulsome disclosures; (3) the impact of more fulsome disclosures on payors' negotiations with manufacturers; or (4) how many pharmacy benefit managers or pharmacy and therapeutics committees would have changed their recommendations regarding the drugs? *See generally UFCW Local 1776*, 620 F.3d 121 (reversing district court and dismissing RICO class action based on "excess price" and "quantity effect" theories because such theories are not "demonstrable with generalized proof"); *Ironworkers,* 634 F.3d at 1364-69 (dismissing RICO claims and outlining the speculative nature of the payors' alleged injuries). The standing and injury requirements have the salutary effect of shielding the courts from such inherently speculative litigation

based on questionable assumptions built into statistical models.

Moreover, the Third Circuit's decision undermines this Court's jurisprudence requiring a RICO plaintiff to plead a direct injury:

> First, the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent factors. Second, quite apart from problems of proving factual causation, recognizing claims of the indirectly injured would force courts to adopt complicated rules apportioning damages among plaintiffs removed at different levels of injury from the violative acts, to obviate the risk of multiple recoveries. And, finally, the need to grapple with these problems is simply unjustified by the general interest in deterring injurious conduct, since directly injured victims can generally be counted on to vindicate the law as private attorneys general, without any of the problems attendant upon suits by plaintiffs injured more remotely.

Holmes, 503 U.S. at 269-70 (citations omitted); *accord Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 459-60 (2006); *see also Assoc. Gen. Contractors v. Cal. State Council of Carpenters*, 459 U.S. 519, 536-46 (1983); *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 730-35, 740-45 (1977) (only direct purchaser may bring Clayton Act claim for damages).

Although *Holmes* addressed the proximate cause requirement, the policy rationale of dismissing cases premised on speculative theories of injury to "prevent these types of intricate, uncertain inquiries from

overrunning RICO litigation," *Anza*, 547 U.S. at 460, applies here. As the Second Circuit recognized, the theories of injury endorsed by the Third Circuit necessarily require courts "to engage in a series of speculative calculations to ascertain whether, and in what amount, plaintiffs suffered a loss." *McLaughlin*, 522 F.3d at 230 (dismissing plaintiffs' RICO class action complaint). These concerns apply with even greater force to prescription drugs, where pricing is inelastic, physicians and consumers make the purchasing decisions, and a doctor's decision to prescribe a drug is rarely related to price. *E.g.*, *UFCW Local 1776*, 620 F.3d at 133-36.

When standing is not enforced, as in this case, difficult problems of causation arise. Embedded in plaintiffs' RICO class action claim is an impermissible "fraud-on-the market" theory. *See generally Summit Props. v. Hoechst Celanese Corp.*, 214 F.3d 556, 561 (5th Cir. 2000) ("No court has accepted the use of [the fraud-on-the market] theory outside of the context of securities fraud, and one circuit has expressly rejected its use in the context of a similar civil RICO case."); *Se. Laborers Health & Welfare Fund v. Bayer Corp.*, 444 F. App'x 401, 410 n.4 (11th Cir. 2011) (holding a third party payor "may not rely on a fraud-on-the-market or fraud-on-the-FDA theory of causation for its RICO claim").

Under Plaintiffs' aggregate approach, patients and their physicians would be divorced from the lawsuit, and therefore it would be the height of speculation for any court to try to determine which physicians, if any, were misled by GSK's marketing; which physicians never saw Avandia's marketing but prescribed the drug based on other medical

literature; which physicians understood the potential risks yet chose to prescribe Avandia; which physicians were initially misled but then continued to prescribe Avandia after learning of the cardiovascular risks; which physicians would have prescribed Avandia regardless of the risks, or which physicians would have prescribed which (presumably cheaper) alternative drug; and which users would have chosen to follow or not follow their physicians' advice.

The mischief of this speculative approach is underscored by the fact that the FDA, after exhaustive study, has determined "that data did not demonstrate an increased risk of heart attack with [Avandia] compared to the standard type 2 diabetes medicines metformin and sulfonylurea." http:// www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm477601.htm. Statistical analyses, reliant on assumptions, cannot overcome the uncertainty inherent in Plaintiffs' speculative theories of injury and causation. *E.g.*, *Wal-Mart Stores v. Dukes*, 131 S. Ct. 2541, 2561 (2011) (disapproving trial by formula); *McLaughlin*, 522 F.3d at 227-28, 231-32 (holding that "loss of value" and "price impact" theories of injury are not susceptible to generalized proof).

C. The Petition Raises Recurring Issues Of Nationwide Significance Warranting Immediate Consideration.

The Third Circuit dismisses GSK's concerns as "a question of damages and, more specifically, a question for another day." *In re Avandia*, 804 F.3d at 644. As a practical matter, however, these issues will

not be decided on "another day." And as a legal matter, they should not be.

As a practical matter, "[a] civil RICO lawsuit has vast implications for the defendants because of the specter of treble damages and the possibility of permanent reputational injury to defendants from the allegation that they are 'racketeers.'" *Nichols v. Mahoney*, 608 F. Supp. 2d 526, 536 (S.D.N.Y. 2009). As a result of substantial discovery costs and the litigation risk of treble damages, a civil RICO action engenders "in terrorem" settlements, long before issues of proof of injury and damages can be resolved at trial. *Id.* This incentive to settle even groundless civil RICO actions is compounded in alleged class actions. *See, e.g.*, *AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 350 (2011) (noting the "'in terrorem' settlements that class actions entail").

As a legal matter, the standing requirement serves to protect defendants from costly litigation and the threat of catastrophic verdicts and to protect the courts from expending time and resources resolving hypothetical disputes for persons without an actual, concrete injury. The Third Circuit's decision, if allowed to stand, would permit putative plaintiffs to bypass statutory and prudential gates for entry to the federal courts.

Unlike the Third Circuit, this Court should not leave these legal and practical concerns for "another day." Prescription drug manufacturers are increasingly targeted by civil RICO lawsuits alleging conjectural "price inflation" or "excess quantity" theories of economic injury even when the drugs are effective and cause no physical harm. *See*, *e.g.*,

Ironworkers, 634 F.3d 1352 (11th Cir. 2011); *UFCW Local 1776*, 620 F.3d 121 (2d Cir. 2010); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235 (3d Cir. 2012); *Se. Laborers Health & Welfare Fund*, 444 F. App'x 401 (11th Cir. 2011); *Med. Mut. of Ohio v. Abbvie Inc.*, Nos. 14C1748, 14C8857, 2016 U.S. Dist. LEXIS 13043 (N.D. Ill. Feb. 4, 2016); *Arapahoe Surgery Ctr., LLC v. Cigna Healthcare, Inc.*, No. 13-cv-3422, 2015 U.S. Dist. LEXIS 28375 (D. Colo. Mar. 6, 2015); *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 65 F. Supp. 3d 283 (D. Mass. 2014); *Travelers Indem. Co. v. Cephalon, Inc.*, 32 F. Supp. 3d 538 (E.D. Pa. 2014); *Ind./Ky./Ohio Reg'l Council of Carpenters Welfare Fund v. Cephalon, Inc.*, No. 13-7167, 2014 U.S. Dist. LEXIS 69526 (E.D. Pa. May 21, 2014); *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 20 F. Supp. 3d 305 (E.D.N.Y. 2014); *Plumbers & Pipefitters Local 572 Health & Welfare Fund v. Merck & Co.*, Nos. 12-1379, -3652, -7027, 2013 U.S. Dist. LEXIS 61051 (D.N.J. Apr. 29, 2013); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. 05-CV-01699, 2012 U.S. Dist. LEXIS 111446 (N.D. Cal. Aug. 2, 2012); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, Nos. 3:09–md–02100–DRH–PMF, 3:09–cv–20071–DRH–PMF, 2010 WL 3119499 (S.D. Ill. Aug. 5, 2010).

Commentators have noted the growing trend of cases in which plaintiffs "generally allege," as Plaintiffs did here, "that a drug is simply not as safe or effective as patients (or their doctors) were led to believe, or that the patient would not have purchased the drug, or spent less for it had she fully appreciated

the risks, even when the medicine worked for that individual." Schwartz & Silverman, *Where Should Tort Law Draw the Line*, 80 Brooklyn L. Rev. 599, 630-33 (2015). Allowing the expansion of RICO standing would multiply the already costly and burdensome pharmaceutical litigation in the federal courts. *E.g.*, *id.* at 630 n.171 (noting that as of 2015 more than 20,000 pharmaceutical product liability cases were pending in federal multi-district litigation).

The harm would not be confined to pharmaceutical litigation. It would stimulate the filing of similar RICO class action claims not only against prescription drug manufacturers but also against sellers of other products. With the demise of class certification for persons allegedly physically injured by products, a growing number of class action suits allege that consumers paid too much for a product, though it functioned as advertised.

Loosening RICO standing would illogically allow "inflated price" or "excess quantity" claims, even where consumers received the benefit of their bargain and were not physically harmed by a defective product. The standing requirement serves to screen out frivolous claims brought by the wrong persons.

Relaxing standing, as the Third Circuit did, would encourage more litigation over non-defective products, jamming courthouse doors to legitimate claimants, diverting scarce judicial resources, imposing burdensome discovery and judgments based on speculative theories, and ultimately leading to increased consumer prices and fewer prescription drugs and other products. *See generally In re*

Bridgestone/Firestone Tires Prods. Liab. Litig., 288 F.3d 1012, 1017 (7th Cir. 2002); Polinksy & Shavell, *The Uneasy Case for Product Liability*, 123 Harv. L. Rev. 1437, 1475 (2010) (explaining that pharmaceutical products litigation creates little added value to consumers but results in billions of dollars in litigation-related costs added to the price of drugs).

Congress did not intend through RICO to regulate product design, warnings, or pricing. RICO should not become a mechanism to coerce price rebates or undeserved settlements. RICO standing rules do not allow these Plaintiffs to proceed with an implausible, speculative claim of inflated prescription drug prices supposedly caused by an undisclosed risk, now disproven, that did not materialize. The plan beneficiaries received exactly what their doctors ordered and that is what Plaintiffs agreed to pay for.

CONCLUSION

This Court should grant the petition for writ of certiorari in order to resolve a conflict among the courts of appeals on important issues of federal constitutional and statutory standing in RICO class actions.

Respectfully submitted,

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March 2016 *Counsel for Amicus Curiae*

APPENDIX

Corporate Members of the
Product Liability Advisory Council
as of 3/3/2016
Total: 97

3M
Altec, Inc.
Altria Client Services LLC
Astec Industries
Bayer Corporation
BIC Corporation
Biro Manufacturing Company, Inc.
BMW of North America, LLC
The Boeing Company
Bombardier Recreational Products, Inc.
Boston Scientific Corporation
Bridgestone Americas, Inc.
Bristol-Myers Squibb Company
C. R. Bard, Inc.
Caterpillar Inc.
CC Industries, Inc.
Celgene Corporation
Chevron Corporation
Cirrus Design Corporation
Continental Tire the Americas, LLC
Cooper Tire & Rubber Company
Crane Co.
Crown Cork & Seal Company, Inc.
Crown Equipment Corporation
Daimler Trucks North America LLC
Deere & Company
Delphi Automotive Systems
Discount Tire
The Dow Chemical Company
E.I. duPont de Nemours and Company
Emerson Electric Co.
Exxon Mobil Corporation
FCA US LLC
Ford Motor Company
Fresenius Kabi USA, LLC
General Motors LLC
Georgia-Pacific LLC
GlaxoSmithKline
The Goodyear Tire & Rubber Company

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Product Liability Advisory Council
as of 3/3/2016
Total: 97

Americas LLC	Microsoft Corporation
Great Dane Limited Partnership	Mine Safety Appliances Company
Harley-Davidson Motor Company	Mitsubishi Motors North America, Inc.
The Home Depot	Mueller Water Products
Honda North America, Inc.	Novartis Pharmaceuticals Corporation
Hyundai Motor America	Novo Nordisk, Inc.
Illinois Tool Works Inc.	Pella Corporation
Isuzu North America Corporation	Pfizer Inc.
Jaguar Land Rover North America, LLC	Pirelli Tire, LLC
Jarden Corporation	Polaris Industries, Inc.
Johnson & Johnson	Porsche Cars North America, Inc.
Kawasaki Motors Corp., U.S.A.	RJ Reynolds Tobacco Company
KBR, Inc.	Robert Bosch LLC
Kia Motors America, Inc.	SABMiller Plc
Kolcraft Enterprises, Inc.	The Sherwin-Williams Company
Lincoln Electric Company	St. Jude Medical, Inc.
Magna International Inc.	Stryker Corporation
Mazak Corporation	Subaru of America, Inc.
Mazda Motor of America, Inc.	Takeda Pharmaceuticals U.S.A., Inc.
Medtronic, Inc.	TAMKO Building Products, Inc.
Merck & Co., Inc.	TASER International, Inc.
Meritor WABCO	Teleflex Incorporated
Michelin North America,	

Corporate Members of the
Product Liability Advisory Council
as of 3/3/2016
Total: 97

Inc.

TK Holdings Inc.
Toyota Motor Sales, USA, Inc.
U-Haul International
Vermeer Manufacturing Company
The Viking Corporation
Volkswagen Group of America, Inc.
Volvo Cars of North America, Inc.
Wal-Mart Stores, Inc.
Western Digital Corporation
Whirlpool Corporation
Yamaha Motor Corporation, U.S.A.
Yokohama Tire Corporation
ZF TRW
Zimmer Biomet