No. ___

In the Supreme Court of the United States

SERGEANTS BENEVOLENT ASSOCIATION HEALTH AND WELFARE FUND, NEW ENGLAND CARPENTERS HEALTH BENEFITS FUND, ALLIED SERVICES DIVISION WELFARE FUND,
Petitioners,

v.

SANOFI-AVENTIS U.S. LLP, SANOFI-AVENTIS U.S., INC.,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The petitioners are health plans that cover the costs of prescription drugs. They brought this action under the Racketeering Influenced and Corrupt Organizations Act, 18 U.S.C. § 1964(c), against a drug manufacturer that allegedly misled doctors about a drug's safety to cause a boost in the drug's prescriptions. The Second Circuit held below that the doctors' prescribing decisions break the chain of causation between a drug manufacturer's fraud and a drug purchaser's economic injury, making a finding of causation under RICO impossible. The First and Third Circuits, by contrast, have held that the existence of prescribing doctors poses no bar to RICO causation.

The question presented is:

Where purchasers allege that a manufacturer misrepresented a drug's safety to prescribing doctors to increase sales, does the presence of the doctors break the causal chain—for purposes of RICO causation—between the misrepresentations and the purchasers' economic injuries?

PARTIES TO THE PROCEEDINGS

The petitioners, all plaintiffs below, are the Sergeants Benevolent Association Health and Welfare Fund, New England Carpenters Health Benefits Fund, and Allied Services Division Welfare Fund.

The State of Louisiana, Citizens of the State of Louisiana, Louisiana Department of Health and Hospital, and Charles C. Foti, in his official capacity as the Attorney General for the state of Louisiana were plaintiffs in the originally filed action in the district court, but Attorney General Foti filed a notice of voluntary dismissal of the Louisiana state plaintiffs' claims on May 21, 2008.

Respondents Sanofi-Aventis U.S. LLP and Sanofi-Aventius U.S., Inc. were defendants below.

CORPORATE DISCLOSURE STATEMENT

No publicly held corporation owns 10% or more of any petitioner's stock. Nor is any petitioner a subsidiary of any parent company.

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INTRODUCTION

Eight years ago, in *Bridge v. Phoenix Bond & Indemnity Co.*, this Court unanimously held that a RICO plaintiff who suffers economic injury "by reason of" a defendant's fraud may recover "even though it was a third party, and not the plaintiff, who relied on the defendant's misrepresentation." 553 U.S. 639, 647, 653, 656 (2008). In the wake of *Bridge*, however, a fundamental disagreement has arisen over what constitutes an intervening cause that snaps the chain of causation under RICO. The disagreement is far-reaching—it split even this Court 4-1-3 in *Hemi Group v. City of New York*, 559 U.S. 1 (2010). And it has developed most acutely in a context with enormous practical importance to our health care system and the national economy: When a drug company allegedly misleads doctors about a drug's safety to boost prescription sales, do the doctors break the causal chain between the misrepresentations and the purchasers' economic injuries?

Four circuits have squarely confronted this question and split right down the middle. On one side, the First and the Third Circuits hold that the "existence" of third-party doctors in the chain of causation does not "preclude[] a finding of causation" under RICO. *In re Neurontin Mktg. Sales Practices & Prod. Liability Litig.*, 712 F.3d 21, 45 (1st Cir. 2013); *see In re Avandia Mktg., Sales Practices & Prod. Liability Litig.*, 804 F.3d 633, 645 (3d Cir. 2015) ("[T]he presence of intermediaries, doctors and patients," does not "destroy[]" causation.). In these circuits, "*Bridge* forecloses th[e] argument" that, because the "supposed misrepresentations went to prescribing doctors," the "causal link . . . must have been broken." *Neurontin*, 712 F.3d at 37; *Avandia*, 804 F.3d at 645 ("*Bridge* precludes that argument.").

On the other side, in the Second and Ninth Circuits, the "intervening actions of prescribing physicians" interrupt the chain of causation and make a finding of RICO causation "impossible." App. 47a; *see United Food & Commercial Workers Cent. Pa. & Reg'l Health & Welfare Fund v. Amgen, Inc.*, 400 Fed. App'x 255, 257 (9th Cir. 2010) (holding that doctors' prescribing decisions render the causal chain "too attenuated" to satisfy RICO causation). In these circuits, a drug company's misrepresentations about a drug's safety cannot "be a but-for, much less proximate, cause of the plaintiffs' injury." App. 27a-28a. The upshot: the fate of high-stakes drug-fraud cases turns on nothing but geography.

This case marks the fourth time, since *Bridge*, that this Court has been asked to weigh in on this divisive and important question—and it presents the best opportunity yet to resolve the rift in the circuits. In earlier petitions, the circuit split was either plausibly inchoate (as with the First Circuit's decision in *Neurontin*) or the record was incomplete (as with the Third Circuit's decision at the pleadings stage in *Avandia*). But no such flaw exists here. The decision below eliminated any doubt that the circuits are hopelessly split over the RICO-causation standards. And the court below took sides on that split on a complete record—including an evidentiary hearing—at summary judgment.

This Court should step in now. This fundamental question of RICO causation has serious consequences for our health care system and the broader economy. For patients, consumers, and health plans alike, fraud, waste, and abuse in the sale and promotion of prescription drugs impose massive costs. And because the medical community relies on accurate information about drugs from the companies that make them, unchecked drug

fraud places the safety and lives of thousands of patients in jeopardy. *Id*; CA2 JA 1099-1101.

For those in the drug industry, the issue is no less crucial. As GlaxoSmithKline put it earlier this year when it sought review on this exact question, the circuit split's "implications for the entire pharmaceutical industry are enormous." Pet. for Cert. at 4, *GlaxoSmithKline LLC v. Allied Servs. Division Welfare Fund* (No. 15-1078) (*Avandia*), *cert. denied*, —S. Ct.—, 2016 WL 740942. As a result, a key industry voice explained earlier this year, the "uncertainty" over this question makes it "vital for this Court to grant review" to resolve this "deeply unsettled area of law." PhRMA Amicus Br. Supporting Petrs. at 2, *GlaxoSmithKline LLC v. Allied Servs. Division Welfare Fund* (No. 15-1078).

OPINIONS BELOW

The district court's decision and order is reported at 20 F. Supp. 3d 305 and reproduced at App. 49a. The Second Circuit's opinion and order is reported at 806 F.3d 71 and reproduced at App. 1a.

JURISDICTION

The Second Circuit entered judgment on November 13, 2015. App. 1a. On February 18, 2016, the court of appeals denied a timely petition for rehearing. App. 127a. On May 5, 2016, Justice Ginsburg granted an extension of time to file a petition for certiorari until June 17, 2016. This Court's jurisdiction rests on 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Section 1964(c) of the Racketeering Influenced and Corrupt Organizations Act (RICO), codified at 18 U.S.C. § 1964(c), provides:

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

STATEMENT OF THE CASE

I. The antibiotics market

Millions of patients every year walk into a doctor's office after experiencing a chronic cough, only to discover that they are suffering from a respiratory infection. While potentially serious, the treatment is straightforward: a prescription antibiotic usually eliminates the symptoms in a week or two. "[N]umerous antibiotics and other anti-infective" medications have been available to treat these conditions for many years, many of which already exist in generic form. Petrs. CA2 Br. 14. This crowded field includes household names like amoxicillin (Augmentin) and azithromycin (Zithromax), plus dozens of other brand-name and generic drugs. *Id.*; App. 4a

In most cases, "there is little or no advantage for using one antibiotic over another." Petrs. CA2 Br. 1, 14. "[N]one of the currently available" antibiotics possesses any "clinical superiority" over any of the others. CA2 JA 1244.[1] And all of the various classes of antibiotics used to treat respiratory infections "exhibit similar effectiveness and thus offer a similar benefit." App. 5a. As one expert explained, "there's no particular antibiotic that has really been proven to be of any more benefit than another." JA 1066.

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[1] The Second Circuit joint appendix will be referred to as "JA."

How, then, does a doctor decide which antibiotic to prescribe? When antibiotics are "equal in efficacy," the "differentiating factor" is "safety." JA 1089-90. Before prescribing antibiotics, doctors pore over "all available clinical safety . . . information," Petrs. CA2 Br. 12; Resps. CA2 Br. 5, and consider "rare but serious side effects" of a drug "every time they make a prescribing decision," JA 1089-90. Doctors "place substantial reliance upon the FDA label," which is the "the single go-to source" for ascertaining a drug's safety. JA 1089. Because "safety is paramount," JA 1060, companies that sell antibiotics understand its importance to prescribing decisions.

II. Ketek's rise and fall.

A. The FDA approves Ketek to treat respiratory infections.

In 2000, Aventis submitted an application to the FDA seeking approval to market an antibiotic telithromycin, known as Ketek, to treat four types of respiratory infections. *See* App. 6a. The next year, an FDA expert committee recommended limited approval for Ketek provided that Aventis conduct further studies to assess safety and efficacy. App. 7a-8a. The FDA expressed concerns about the possibility of serious but rare side effects—including liver damage—that may not have been fully revealed by the initial, small-scale studies. *Id.*; JA 1089-90. The FDA warned Aventis that "further studies . . . to assess Ketek's potential side effects" were necessary for Ketek to be "approvable." App. 7a-8a.

Although Aventis "downplay[ed] Ketek's risks," JA 83, it nonetheless complied with the FDA's request by planning for "a large-scale clinical study" "to assess Ketek's potential side effects, known in the medical community as 'adverse events.'" App. 7a-8a. Through a program dubbed "Study 3014," Aventis began collecting

data to "reveal rarer side effects that might not have appeared in trials of a few hundred or few thousand subjects." JA 647; App. 8a.

Aventis's study did not go well, and Aventis became aware of "serious problems" compromising the integrity of the data. JA 654. But in an effort to persuade the FDA that "Ketek was safe and effective," Aventis told regulators that Study 3014 identified "no new significant safety signals," JA 1096, and did not report any "detectable difference" in the incidence of liver-related side effects between Ketek and a control antibiotic. Petrs. CA2 Br. 15.

In April 2004, the FDA formally approved Ketek to treat three respiratory infections. Given Aventis's statements on Study 3014's results, the FDA allowed Aventis to market Ketek without requiring any information concerning the risk of liver failure to be included in the "Warning" section of the drug's label. Aventis therefore falsely represented on Ketek's label that the risk of liver problems was no greater than that of other competitor antibiotics. JA 119-20. And it promoted the drug to doctors as safe even for patients with a history of liver problems. App. 11a.

Following FDA approval, several health plans—including petitioners here—placed Ketek on their formularies, meaning that it would be reimbursable for those covered patients who received it. App. 14a.

B. Sales of Ketek reach blockbuster status.

Aventis's launch of Ketek in July 2004 "was the most successful antibiotic launch ever." Petrs. CA2 Br. 17. Although Ketek "only became available halfway through the year," it was "prescribed 859,696 times in 2004." App. 14a-15a. This dominance turned Ketek into a revenue-generating blockbuster: It grossed $209 million in 2005

alone and was set to exceed that number in 2006. App. 15a.

For Aventis, Ketek's launch was part of a strategic plan, formulated years before the drug's approval, to generate massive sales. To reach this goal, Aventis promoted "a marketing campaign designed to expand its market share across all anti-microbial drugs." CA2 Special App. 6. Aventis understood that it would "face extensive competition from established medications" already on the market, and so it falsely told doctors that Ketek was "as safe" as other antibiotics." CA2 Special App. 6. This campaign was a success: Less than two years after hitting the market, "a Ketek prescription was written every four or five seconds." App. 15a.

C. Deaths and other injuries linked to Ketek cause the FDA to pull approval for most uses.

With Ketek's market success, real-world data began to reveal the drug's hazards. Just seven months after it first launched, the FDA began receiving reports of liver-failure deaths linked to Ketek. JA 649. By the end of January 2006 (about 18 months after launch), ten cases of serious liver damage "closely associated" with Ketek had been reported—prompting the FDA to issue a public-health advisory warning physicians to "monitor patients taking [Ketek] for signs or symptoms of liver problems." App. 16a. A major journal, *Annals of Internal Medicine*, published an article that same month detailing Ketek-related liver failures. App. 16a; JA 651.

By mid-2006, the FDA was forced to step in. At first, the "spike in reports of hepatic adverse events associated with Ketek," App. 17a, prompted the FDA to issue a "strong warning" that Ketek could "cause serious liver injury, liver failure and even death," Harris, *F.D.A. Warns of Liver Failure After Antibiotic*, N.Y. Times,

June 30, 2006, at A14. Then, as the number of incidents continued to rise, the FDA demanded that Aventis change its label to call attention to the risks of liver toxicity and issued a letter to physicians alerting them to these changes. App. 17a-18a.

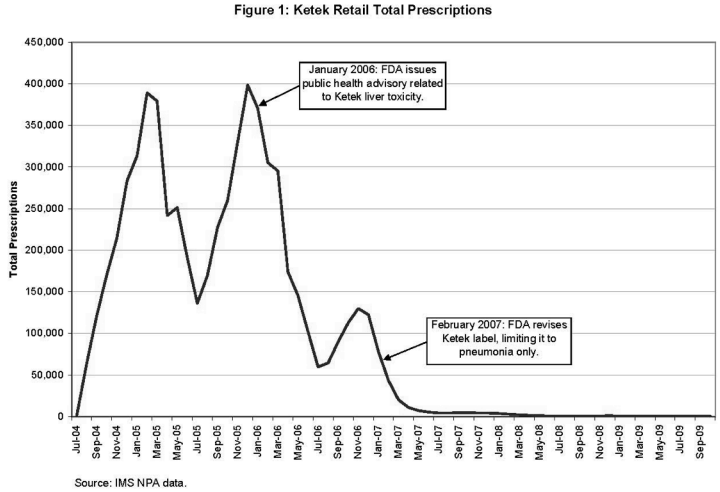
Even with these changes, though, regulators remained concerned. One FDA official cautioned that the agency didn't "really know if the drug works" and was "flying blind as far as safety goes." Harris, *Approval of Antibiotic Worried Safety Officials*, N.Y. Times, July 18, 2006, at A15. He warned that internal agency data suggested that Ketek "is uniquely more toxic than most other drugs." *Id.* Another echoed these concerns, calling Ketek a "time bomb"—a drug "far more dangerous than other drugs that fight the same infections." McNamara, *Doctor: FDA-Approved Drug A 'Time Bomb'*, CBS News, Dec. 13, 2006, http://cbsn.ws/1UlnDyM.

These safety concerns prompted the FDA to withdraw Ketek's approval, effective February 2007, for the two most commonly prescribed respiratory conditions. It concluded that "available safety data did not support the continued marketing of Ketek." JA 589. *See also* Zwillich, *FDA Curbs Use of Ketek*, CBS News, Feb. 13, 2007, http://cbsn.ws/1rs9Gos.

D. After the FDA's advisory and withdrawal, Ketek sales plummet.

Following the FDA's public health advisory in early 2006, Ketek sales began to decrease dramatically. And by mid-2006, sales of Ketek had taken "an unmistakable dive." App. 15a-16a.

In fact, as the graph below shows, once the risks "were made known to the market"—in mid-2006—"nearly all Ketek prescriptions stopped." JA 1362.



JA 373. And Ketek's domestic sales "continued their downward trend" following the FDA's withdrawal of approval. App. 21a; *see also* Saul, *Antibiotic Receives Low Grade From Federal Panel, Which Urges Limits and Warnings*, N.Y. Times, Dec. 16, 2006, at A11 (observing that Ketek "sales dropped sharply after safety issues were raised" and were "down substantially" in 2006).

By 2007, more than three-quarters of drug-payors had removed Ketek from their formularies or moved the drug to a "nonpreferred" status. JA 138, 1362. Although Ketek remains available today, it "is rarely prescribed." App. 21a.[2]

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[2] The graph, *supra*, charts Ketek's sales from its 2004 launch through its ultimate decline. Because sales of antibiotics for respiratory infections follow the seasonality of cold weather, *see* App. 15a, Ketek's sales initially spiked during the two seasonal cold periods in late 2004 and 2005. After the FDA's 2006 health-risk disclosures, however, sales dropped precipitously during the 2006-07 season.

E. Regulators discover that Aventis knew about Ketek's safety problems for years.

Ketek's rapid fall from grace sparked intense scrutiny from regulators. Congress and the FDA launched independent investigations—including a criminal inquiry. JA 647-48. These investigations uncovered "unprecedented" fraud in both "scope and scale." App. 8a.

In particular, the investigations revealed that Aventis intentionally kept the FDA in the dark about Ketek. It made sure that the FDA's experts were "[u]naware of the unreliability of Study 3014's results." App. 10a; JA 654. And, even though the FDA specifically directed Aventis to perform the study to identify the risk of serious but rare side effects, Aventis obscured the study's true safety findings, which revealed a *threefold* increase in the risk of those serious side effects. Petrs. CA2 Br. 15. It also dismissed the rates of such side effects, despite evidence that thousands of "unnecessary serious adverse events" would occur among Americans treated with Ketek just "over the first year" on the market. JA 1099.

Ultimately, as Congress's investigation concluded, in the case of Ketek, "there were sirens, red flags and bull horns, but it looks like [Aventis] kept ear plugs and blinders on." JA 656.

III. This litigation.

A. The petitioners are health-benefits plans that filed this action soon after the fraud came to light, alleging that Aventis violated RICO and state consumer-protection laws by omitting and misrepresenting Ketek's serious safety risks. If doctors had been aware of these risks, the petitioners alleged, they would not have prescribed Ketek. The petitioner health-benefit plans thus

paid hundreds of millions of dollars for Ketek prescriptions that, absent Aventis's fraud, they would not have.

In support of their claims, the petitioners' experts testified that doctors, who "did not have information about Ketek's increased risks of serious" liver toxicity side effects until January 2006 (at the earliest), would not have prescribed the drug had they been aware of that information—particularly in light of the fact that numerous similarly efficacious antibiotics were available. JA 1367. As one expert explained, because Ketek offered "no therapeutic advantages," once its true risks became known doctors understood that "there was absolutely no reason to choose [Ketek]." JA 1105.

And the experts clearly saw the causal relationship between the public revelation of Ketek's safety risks and its sales nosedive. One expert, Dr. Meredith Rosenthal, a professor of health economics at Harvard, considered what factors might have triggered the steep decrease in Ketek's prescriptions and sales and determined that the "predominant factor in the drop in sales of Ketek"—and the "only plausible explanation for this decline"—was the disclosure of Ketek's rare but serious side effects "allegedly suppressed by [Aventis]." JA 1131-32, 1134-36. Specifically, she "attribute[d] the precipitous drop in Ketek prescriptions beginning in the winter [of] 2005-06 as due to (1) the FDA's January 2006 public health advisory regarding Ketek's liver toxicity, (2) the FDA's June 2006 strengthening of Ketek's label to include the risk of liver damage, and (3) the FDA's February 2007 withdrawal of approval for two of Ketek's three indications." JA 1364.[3] In her many years of studying the industry,

[3] As Dr. Rosenthal explained, the 2006-07 seasonal sales fluctuations should not be misinterpreted as an "increase," *see* graph, (continued …)

she "had never [before] seen a situation where a brand name drug sales at this point in the life cycle dropped so precipitously in response to safety information." JA 1134-35.

For its part, Aventis chose not to "directly attack[] Dr. Rosenthal's proffered statistics." JA 1370. Instead, it argued that proof of causation was impossible "because physicians' decisions to prescribe Ketek . . . are inherently individual and based on a multitude of factors." JA 1138.

B. The district court granted Aventis's motion for summary judgment, denied the health plans' motion for class certification, and dismissed the RICO claims. The district court held that, under governing Second Circuit law, the "intervening acts" of third-party doctors "interrupt the causal chain between Defendants' RICO violations and Plaintiffs' injuries." App. 80a. The court explained that the "alleged misconduct"—Aventis's "fraudulently exaggerating the safety and efficacy of a prescription antibiotic"—would "not result in injury . . . unless doctors relied on the fraudulent information in prescribing the antibiotic to patients." App. 80a. And, given the independent nature of doctors' prescribing decisions, it determined that the purchasers could not meet this standard. In reaching this conclusion, the district court rejected as "not controlling" the First Circuit's contrary "view." App. 90a n.1.

C. The Second Circuit affirmed. It held that the plaintiffs' "theory of injury"—that third-party doctors relied "on Aventis's alleged misrepresentation" to over-

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supra, because "there is a monotonic and steep decline in Ketek sales in this seasonally-adjusted way," JA 1132.

prescribe Ketek, which, in turn, "caused [health plans] to pay for Ketek prescriptions that would not have been written otherwise"—was "foreclose[d]" by its previous decision in *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010) ("*Zyprexa*"). App. 34a. In *Zyprexa*, the Second Circuit had ruled that, in drug-fraud RICO cases, "generalized proof is insufficient to establish RICO causation" because "the prescribing decisions" of doctors are "multifaceted and therefore call[] for individualized determinations as to whether the prescriptions had in fact been written because of [the defendant's] alleged fraud." App. 34a. As the court explained, "[t]he same is true here." App. 36a.[4]

Under RICO, the Second Circuit reiterated, both but-for and proximate cause require that the doctors "all face[] 'the same more or less one-dimensional decisionmaking process' such that the alleged misrepresentations would have been 'essentially determinative.'" App. 30a. In the court's view, the evidence must establish that every doctor's prescribing decision is based "entirely on safety," and "truly . . . one-dimensional"—that "the safety information allegedly withheld" was "so significant that it would dictate every physician's decisionmaking." App. 41a. That standard, the Second Circuit explained, can only be satisfied by proof that "*all* predisclosure [drug] prescriptions were written in reliance

[4] The court "set to the side" other possible arguments that Aventis raised in defense, including the chance that "the FDA was aware of Study 3014" and "did not rely on it in approving Ketek." App. 35a n.6. These potential "problems" with the purchasers' "theory of causation" did not bear on the Court's analysis of but-for and proximate causation, which turned entirely on the intervening prescribing decisions of doctors.

on [a defendant's] alleged fraud." App. 36a (emphasis added). Thus, as in *Zyprexa*, testimony by individual doctors who were not misled by the misinformation will securely defeat the claims. App. 33a.

The Second Circuit thought its conclusions could be "distinguishe[d]" from the First Circuit's in *Neurontin*. App. 45a. True, it admitted, *Neurontin* "indicate[s] that where individual physicians' reliance on a pharmaceutical company's misrepresentations forms a necessary link in the causal chain," "individualized inquiries as to each prescribing physician's actual decisionmaking" will not necessarily defeat causation. App. 46a. But the court suggested that the existence of a "regression analysis" in *Neurontin* offered a "far more sophisticated" approach to proving causation that the purchasers here—"apparently by their own choice"—opted not to perform; instead, the court concluded, the purchasers' evidence here was too "simplistic" to establish causation. App. 46a-47a.

To support this view, the Second Circuit dismissed the purchasers' evidence in exchange for its own, speculating (without record support) that "other factors," like "larger changes in the market for anti-infectives" could have played a role in the "drop in sales" and defeated any "inference that the drop in sale was actually attributable to the safety disclosures." App. 37a. Even so, the court offered no theory explaining how a factor like changes in the broader "anti-infective market" could trigger a near-complete drop in Ketek's—but no other similar drug's—sales.

The court did hypothesize that, even in the absence of a regression analysis, some drug might be "so dangerous that no physician would ever prescribe it" if that doctor

had been "aware of its true risks." App. 37a. But it did not consider Ketek's risk of serious liver damage or death sufficient; the "dangerousness of the drug" must "speak for itself"—*i.e.*, "cause certain death" or "blindness in a tenth of the patients"—to make the "tradeoff . . . never be worth the risk." App. 38a. Only then could a jury "infer" that a prescription "was necessarily written in reliance on the defendant's concealment of the drug's risks." App. 37a. Unless *no doctor* would ever prescribe it, the court held, misrepresentations about a drug's safety could not, under RICO, cause compensable harm to purchasers.

REASONS FOR GRANTING THE WRIT

I. The circuits are divided over causation in third-party-reliance RICO cases.

The Second Circuit holds that, in cases alleging that a drug company fraudulently exaggerated a drug's safety and efficacy to boost its sales, the "intervening actions of prescribing physicians" interrupt the chain of causation to make a finding of causation under RICO "impossible." App. 47a. That rule has created a "sharp division[] between the circuits," breeding "uncertainty" and promoting arbitrary "geographic divergence." PhRMA Amicus Br., *supra*, at 3, 16.

A. On one side of the split stand the First and Third Circuits, which have held that RICO's causation requirement can be satisfied even where the injury "rests on the actions of independent actors—the prescribing doctors." *Neurontin*, 712 F.3d at 34. In these circuits, both elements of RICO causation—"but-for causation" and "proximate causation"—survive the existence of third-party doctors who exercise independent judgment when it comes to prescribing drugs.

In *Neurontin*, for example, a class of purchasers brought suit against Pfizer for "fraudulent[ly] marketing . . . Neurontin for off-label uses" that caused purchasers to pay for more prescriptions than they would have otherwise. *Id.* at 26. "At the heart of the appeal" was whether, "as a matter of law," the purchasers could meet RICO's "causation requirements." *Id.* at 33. Pfizer argued that the purchasers' claims failed both elements of RICO causation: "As to but-for causation," Pfizer insisted that the purchasers' "theories of causation" were defeated by (among other things) the "patient-specific, idiosyncratic decisions of individual prescribing physicians." *Id.* at 34, 45. And it claimed that there could be "no proximate causation" because "there are too many steps in the causal chain connecting its misrepresentations to the injury." *Id.* at 34.

The First Circuit rejected both of Pfizer's causation challenges. The court explained that Pfizer's evidence that some doctors "said that their decisions to prescribe Neurontin were not influenced by Pfizer's fraudulent marketing" was insufficient to "preclude[] a finding" of but-for causation because it set the bar too high. *Id.* at 45. "A tort plaintiff need not . . . 'offer evidence which positively excludes every other possible cause of the [injury],'" the court observed. *Id.* (quoting *BCS Servs., Inc. v. Heartwood 88, LLC*, 637 F.3d 750, 757 (7th Cir. 2011)). Rather than proving that a drug company's misinformation led every doctor to prescribe the drug in *every* case, the court held, a plaintiff must show only that the misinformation "had a *significant influence* on prescribing decisions" that, in turn, injured the plaintiff. *Id.* (emphasis added). Once a plaintiff satisfies this requirement, the case must be allowed to proceed; "the burden of proving an intervening cause . . . is on the defendant,"

and "[w]eighing" that evidence against the plaintiff's is "a task for the jury." *Id.* at 45-46.

On proximate causation, the First Circuit reached a similar result. "[T]he causal chain" was "anything but attenuated" because Pfizer's scheme "was designed to fraudulently inflate the number of Neurontin prescriptions for which [drug purchasers] paid." *Id.* at 37, 39. As a result, Neurontin purchasers were not only the "primary and intended victim[s]" of the scheme to defraud but their injuries were also a "foreseeable and natural consequence." *Id.* at 37 (quoting *Bridge*, 128 S. Ct. at 2144).

Dismissing Pfizer's claim that "doctors are independent intervening causes," the First Circuit held that "[t]he fact that some physicians may have considered factors other than Pfizer's detailing materials in making their prescribing decisions does not add such attenuation to the causal chain as to eliminate proximate cause." *Id.* at 39. To the contrary: "Pfizer's scheme relied on the expectation that physicians would base their prescribing decisions *in part* on Pfizer's fraudulent marketing"—so "[r]ather than showing a lack of proximate causation," the court explained, "this argument presents a question of proof regarding the total number of prescriptions that were attributable to Pfizer's actions." *Id.* at 39.

The Third Circuit agrees. In *Avandia*, GSK (like Pfizer) argued "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." 804 F.3d at 645. Like the First Circuit, the Third Circuit concluded that the purchaser plaintiffs 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." *Id.* GSK "deliberately misrepresent[ed] the safety of Avandia" so that drug purchasers "paid for this drug." *Id.* That "fraudulent scheme could have been successful only if plaintiffs paid for Avandia, and this is the very injury that plaintiffs seek recovery for." *Id.* As a result, the Third Circuit, citing *Neurontin*, held that the plaintiffs' "alleged injury is sufficiently direct to satisfy the RICO proximate cause requirement." *Id.*[5]

B. The Second Circuit has adopted the exact opposite view. In a pair of decisions—first *Zyprexa* and now the decision below—it has firmly held that a drug company's misrepresentations "cannot be a but-for, much less proximate, cause of the plaintiffs' injury." App. 27a-28a.

The Second Circuit first considered the issue in *Zyprexa*. There, much like in *Neurontin*, drug purchasers brought suit under RICO alleging that another drug company, Eli Lilly, "became aware of harmful side effects associated with the drug [Zyprexa]," and "did not disclose" those effects "once Zyprexa went on the market." 620 F.3d at 124. The purchasers sought to recover the costs incurred when they paid for Zyprexa prescriptions that would not have been prescribed had the safety concerns been disclosed. *Id.* at 135.

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[5] Although the Third Circuit omitted any discussion of but-for causation, in allowing the claims to proceed it necessarily agreed that the plaintiffs had satisfied their burden on this element as well. *Cf. Hemi Group*, 559 U.S. at 22 (Breyer, J., dissenting) (explaining that "no one denies that Hemi's misrepresentation was a 'but-for' condition of New York City's loss" where majority's analysis focused on proximate cause).

In contrast to the First and Third Circuits, the Second Circuit held that "proof of but-for causation [is] impossible." 620 F.3d at 135. In reaching this conclusion, the court explained that several factors inherent in the "nature of prescriptions" impaired a plaintiff's ability to establish but-for causation. *Id.* For example, if "at least some doctors were not misled by [the defendant's] alleged misrepresentations," then they "would not have written" prescriptions that "actually caused loss" to the purchasers. *Id.* at 135-36.

Following *Zyprexa*, the Second Circuit in this case hammered this point home. Doctors' prescribing decisions, the Second Circuit wrote, are inherently "multifaceted and individualized," and involve a "multitude of factors" like "the age and sex of the patient, the availability of generics, or the patient's past reaction to a drug." App. 37a-38a. As a result, "given the number of factors that enter into doctors' prescribing decision," the misrepresentations could not be a but-for cause. App. 41a.

The Second Circuit's view of proximate causation is likewise at odds with its sister circuits. In *Zyprexa*, the Second Circuit ruled that the "link between the alleged misrepresentations made to doctors and the ultimate injury to [purchasers]" is too "attenuated" to satisfy RICO's proximate-causation requirement; "the independent actions of prescribing physicians" "interrupted" this "theory of causation" and "thwart[ed]" proximate cause. 620 F.3d at 134-35. When prescribing drugs, the court reasoned, doctors consider other "source[s] of information," including an "individual patient's diagnosis, past and current medications," etc. *Id.* at 135. "The nature of prescriptions," therefore, meant that Lilly was not "the *only* source of information on which doctors

based their prescribing decisions." *Id.* (emphasis in original).

In this case, the Second Circuit reaffirmed this view: A "theory of injury" requiring proof of "third-party reliance by doctors" on a company's "alleged misrepresentations" will founder on the premise that "a doctor's decision to prescribe" a drug is "made for any number of a multitude of reasons." App. 33a-34a. According to the Second Circuit, "if the person who was allegedly deceived by the misrepresentation"—*i.e.*, a doctor—"would have acted in the same way regardless of the misrepresentation," then the misrepresentation (in addition to failing RICO's but-for causation standard) could also not be a "proximate[] cause of the plaintiffs' injury." App. 27a-28a.

And the Ninth Circuit, too, shares this understanding. In *United Food*, the court held, as a matter of law, that doctors' prescribing decisions render the causal chain "too attenuated" to satisfy RICO's causation requirements. 400 Fed. App'x at 257. There, citing *Bridge*, the Ninth Circuit ruled that drug purchasers who alleged that a drug company, Amgen, had "concealed adverse test results" while promoting a pair of drugs to doctors could not "plead a cognizable theory of proximate causation that links Amgen's alleged misconduct to [the purchasers'] alleged injury." *Id.*

C. Until this Court steps in, the split in the circuits will continue to control the outcomes of drug-fraud cases. In the Second Circuit, evidence that "at least some doctors were not misled" by the alleged fraud, *Zyprexa*, 620 F.3d at 135, or proof that some doctors "may have considered factors other than" the misrepresentations in prescribing the drug, *Neurontin*, 712 F.3d at 39, will preclude these claims from reaching a jury. In the First

and Third Circuits, it will not. And in the Ninth Circuit, these claims will likely be dismissed outright. *See United Food*, 400 Fed. App'x at 257.

This divergence exists despite the Second Circuit's attempt to reconcile its decision here with *Neurontin*. In ruling that the decisions of prescribing doctors defeated causation, the court appeared to leave open the possibility that not every case in this "context" would likewise fail. App. 30a. It suggested that a hypothetical RICO drug-fraud case might survive if it involved "a drug so dangerous that no physician would ever prescribe it to treat a non-fatal condition if that physician were aware of its true risks." App. 37a. Such "an extraordinary case," the court wrote, "might well" meet RICO's causation requirements—assuming that "any prescription for the drug was necessarily written in reliance on the defendant's concealment of the drug's risks." App. 37a.

But that unachievable standard merely proves the existence, and impact, of the current split. If any case should have met the Second Circuit's "hypothetical drug" test it was this one. After all, once doctors learned that Ketek increased the risk of serious liver damage threefold, they simply stopped prescribing it; given the perfectly effective alternatives, the choice was easy. But the Second Circuit ruled otherwise, refusing to infer that "*all* pre-disclosure Ketek prescriptions were written in reliance on Aventis's alleged fraud" and posing a series of invented alternative explanations—divorced from the record—for why doctors might have stopped prescribing Ketek. App. 36a. In the First and Third Circuits, by contrast, evidence that doctors considered factors other than the misrepresentations is relevant only for the "damages question." *Neurontin*, 712 F.3d at 39; *Avandia*, 804 F.3d at 644. So long as the alleged fraud had a

"significant influence on prescribing decisions," RICO's causation standard is satisfied. *Neurontin*, 712 F.3d at 45. The Second Circuit's "hypothetical" case is just another way of emphasizing the difference in these rules.

And the Second Circuit's effort to trivialize the split as merely a question of proof is likewise unavailing. The court suggested that the purchasers here produced only "weak[]" and "simplistic" "correlation-based" evidence to prove their case, attempting to contrast that with the evidence in *Neurontin*, which it labeled "sophisticated" because it employed regression analysis. App. 36a, 46a. In the Second Circuit's view, the absence of regression analysis barred any inference that the misrepresentations "caused doctors to write excess prescriptions paid Neurontin for by the [purchasers]." App. 45a. But, as Dr. Rosenthal explained here, because Ketek's sales declined so "rapidly and completely" "in response to safety information," a regression was statistically unwarranted. JA 1130-31, 1134-35, 1161. More to the point, the First Circuit itself dismissed exactly this kind of lazy logic, explaining that a "company's choice to undertake [a] marketing campaign" would be "inexplicable" if it didn't believe that its "information could affect a single doctor's decisionmaking." *Neurontin*, 712 F.3d at 46.

Unless this Court intervenes, the sharp conflict between the circuits will only fester, with intolerable practical consequences. The Court should not defer a reckoning any longer.

II. The division over causation in RICO drug-fraud cases is important and warrants review now.

This Court has already recognized the importance of deciding what constitutes an intervening cause under RICO, but has failed to provide the necessary guidance. Six years ago in *Hemi Group*, the Court tried to resolve

whether the "intervening voluntary acts of third parties" "cut[] the causal chain" under RICO. 559 U.S. at 25 (Breyer, J., dissenting). It could not. The Court split 4-1-3 on the question and disagreed over *Bridge*'s significance, with the controlling concurrence disavowing the plurality's causation analysis. *Id.* at 15 (plurality); *id.* at 28 (Breyer, J., dissenting); *id.* at 19 (Ginsburg, J., concurring in part and concurring in the judgment).[6] Although *Hemi* left the lower courts without a governing third-party causation framework, the importance of the question remains.

A. Given the current uncertainty over what constitutes an intervening cause after *Bridge*, it is no wonder that all relevant stakeholders in the drug-fraud context have urged this Court to weigh in. Today's petition marks the fourth time, since *Bridge* (and *Hemi Group*), that this Court has been asked to clarify causation in healthcare-fraud RICO cases. The Court should take this opportunity to resolve the issue. Allowing the conflict in the lower courts to linger will have negative consequences for all: patients, health-benefit plans, other private prescription-drug payers, and even the pharmaceutical industry itself.

Indeed, major pharmaceutical companies and health-benefit plans alike have, in recent terms, repeatedly sought this Court's guidance on this issue. Earlier this year, in *Avandia*, GSK (one of the world's largest pharmaceutical companies) sought review on the very question presented here. *See* Pet. for Cert. at i, *GlaxoSmithKline LLC v. Allied Servs. Division Welfare*

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[6] Justice Sotomayor was recused. *See Hemi Group*, 559 U.S. at 18.

Fund (No. 15-1078) (Question 2a). In support of that petition, PhRMA (the pharmaceutical industry's leading trade association) made clear that "[t]he lack of clarity on the issue has resulted in widely divergent results among the lower courts," and that these "sharp divisions between the circuits" warrant "this Court's immediate review." PhRMA Amicus Br., *supra*, at 3-5, 16. And several terms earlier, in *Neurontin*, Pfizer, too, argued that the "conflict among the courts of appeals" on this question presented "warrants the Court's review." Pet. for Cert. at 25, *Pfizer, Inc. v. Kaiser Found. Health Plan, Inc.* (No. 13-289).

Health-benefit plans have also repeatedly raised the alarm over the divergent standards between the circuits. In petitioning from the Second Circuit's decision in *Zyprexa*, for instance, health plans argued that, absent this Court's review, "a third-party payor's [RICO fraud] claim succeed[s] or fail[s] depending on the forum in which it is brought." Pet. for Cert. at 4, *Sergeants Benevolent Ass'n Health & Welfare Fund v. Eli Lilly* (No. 10-1173). This uncertainty, the petitioners explained, "severely limits the ability of third-party payors to pursue federal remedies for health-care fraud resulting in unnecessary and overpriced prescriptions." *Id.* at 3.

Leaving the split in place helps nobody. As PhRMA put it, "the uncertainty [caused by] the geographic divergence on the legal issue" imposes significant costs on the pharmaceutical industry as whole. PhRMA Amicus Br., *supra*, at 16. And the negative consequences for patients and private health-benefit providers are even more stark. The latter spent almost a trillion dollars in 2014 (or 33% of total U.S. health care spending) to pay for prescription drugs and other treatments for their beneficiaries, *see National Health Expenditures 2014*

Highlights, Ctr. For Medicare and Medicaid Servs. (last modified Dec. 3, 2015), http://go.cms.gov/1V5YDcI, and drug-marketing fraud only increases the costs for these payers. Moreover, as this case demonstrates, unchecked fraud and aggressive marketing misinformation risks the safety (and sometimes the lives) of thousands of patients.

RICO's private remedy was intended to hold companies accountable for engaging in just this kind of fraud. But, given the outcome-determinative split over RICO's causation standards, the fate of identical RICO drug-fraud cases now turns entirely on geography. That stark divergence on such an important matter for the healthcare sector is intolerable.

B. Unlike the previous petitions raising this issue—all of which presented flawed vehicle choices—this case offers the Court a straightforward opportunity to resolve the conflict in the lower courts and provide needed guidance concerning RICO's causation standards.

The early cases implicating the question were poor vehicles because, at the time, the split over RICO causation was in its infancy. The purchasers' petition in *Zyprexa* did not, for instance, even attempt to demonstrate a conflict in the lower courts. *See* Pet. for Cert., *Sergeants Benevolent Ass'n Health & Welfare Fund v. Eli Lilly* (No. 10-1173). And Pfizer's petition in *Neurontin* flagged only a shallow split between the First Circuit's decision there and the Second Circuit's decision in *Zyprexa*. *See* Pet. for Cert. at 22-23, *Pfizer Inc. v. Kaiser Found. Health Plan, Inc.* (No. 13-289).

But the disagreement has substantially deepened since those decisions. Last year in *Avandia*, the Third Circuit joined the First Circuit's side of the conflict. *See* 804 F.3d at 644. And the decision below has entrenched the Second Circuit's contrary position, sharply diminish-

ing the possibility of any further meaningful percolation. The split is, therefore, ripe for this Court's review.

The only other relevant petition, from the Third Circuit's decision in *Avandia*, offered a far worse vehicle for resolving the question presented. That petition focused largely on an entirely different, antecedent question concerning RICO's *injury* requirement. *See* Pet. for Cert. at i, *GlaxoSmithKline LLC v. Allied Servs. Division Welfare Fund* (No. 15-1078), ("Whether a [third-party purchaser] states a plausible RICO injury by alleging that a manufacturer's failure to disclose risk information inflated the price of a medication."). Unlike the plaintiffs in *Avandia*, the petitioners here *do* allege that "the drug was ineffective [and] injured" their beneficiaries, *id.* at 2, and thus the petition cleanly (indeed only) presents the question concerning RICO causation.

In addition, *Avandia* presented no factual record to speak of; it was an interlocutory appeal from the district court's denial of a motion to dismiss. *See* 804 F.3d at 637. Here, by contrast, the district court decided the case on summary judgment after a full evidentiary hearing at which both sides presented substantial documentary evidence and expert testimony. App. 2a; *see also supra* at 11-12. This case thus provides the Court with the detailed and thorough record necessary to decide the proper causation standard for RICO drug-fraud cases. Given the intractable circuit split and the importance of the question presented to stakeholders from all sides, this Court should grant certiorari here.

III. The Second Circuit's rule—that third-party doctors' intervening prescribing decisions defeat causation—is contrary to this Court's cases and undermines RICO.

Split aside, the Second Circuit's approach to RICO causation is wrong. A rule that the individual decisions of prescribing physicians thwart causation "undercut[s]" RICO's "core" causation principles and contradicts this Court's RICO jurisprudence. *Neurontin*, 712 F.3d at 38. Left to stand, the decision below improperly denies "compensation for those who are directly injured, whose injury was plainly foreseeable and was in fact foreseen, and who were the intended victims of a defendant's wrongful conduct." *Id.*; *see also Sedima v. Imrex Co.*, 473 U.S. 479, 497-98 (1985). Because the fraudulent misrepresentation of Ketek's safety risks caused doctors to prescribe Ketek when, absent the fraud, they would have prescribed a different (and safer) antibiotic, the purchasers have shown causation. The Second Circuit was wrong to conclude otherwise.

A. This Court has already held that the existence of third parties in the chain of causation does not categorically defeat RICO causation. In *Bridge*, this Court emphasized that "a person can be injured 'by reason of' a pattern of . . . fraud even if he has not relied on any misrepresentations" directly. 553 U.S. at 649. That conclusion built on the common law's long recognition "that plaintiffs can recover in a variety of circumstances where, as here, their injuries result directly from the defendant's fraudulent misrepresentations to a third party." *Id.* at 653.

And, although some reliance is necessary "to prove causation," a plaintiff need not establish that *every* third-party intermediary relied on the fraudulent representa-

tions. *Id.* at 659; *see also Hemi Group*, 599 U.S. at 23 (Breyer, J. dissenting) (explaining that "no one denies that [the seller's] misrepresentation was a 'but-for' cause of New York City's loss" even though every third-party taxpayer might not have paid taxes even in the absence of the defendant's misconduct). The point, as both the First and Third Circuits recognized, is that *Bridge* "forecloses" a drug company's argument that the chain of causation is necessarily broken because its misrepresentations went to doctors—*some* of whom might not have relied on the misrepresentations in prescribing the drug. *Neurontin*, 712 F.3d at 37; *Avandia*, 804 F.3d at 645. Instead, this type of "scheme to defraud" requires only that a plaintiff satisfy the typical "but-for" and proximate-cause criteria. *Bridge*, 553 U.S. at 647, 661.

B. The purchasers' evidence here easily met those familiar standards. As the purchasers established, many doctors relied on Aventis's safety claims in prescribing Ketek over other equally effective antibiotics within a crowded field; once Ketek's safety risks were "made known to the market," "nearly all" those "prescriptions stopped." JA 1362. That chain of events led the only healthcare-market expert to remark that she had "had never seen" a drug's prescription sales "drop[] so precipitously in response to safety information." JA 1134-35. That should have been enough to establish the basic "but for" premise that, had doctors known the real safety risks, they would not have prescribed Ketek in such volume because—regardless of any other individualized factors—Ketek was not worth the safety risk.

Yet the Second Circuit rejected this presentation, for two equally unpersuasive reasons. *First*, the court concluded that, even if Aventis's misrepresentations of Ketek's safety played a significant role in boosting pre-

scriptions, RICO requires proof that "every physician's" prescribing decision was based "*entirely* on safety," and hence was made in reliance on a drug company's misrepresentations regarding a drug's safety risks. App. 40a-41a (emphasis added). Because this could not be shown, the court ruled that the purchasers' theory "simply does not hold up." App. 41a.

But it is the Second Circuit's causation analysis that "does not hold up." Its requirement that RICO's causation standard may only be satisfied if "no physician would *ever* prescribe it," App. 37a, confuses the concepts of damages and causation. Even assuming that some doctors did not rely on the misrepresentations, or would have prescribed Ketek despite knowing its safety risks (*e.g.*, if a patient was allergic to other antibiotics), those facts bear on the question of how much damage the fraud caused; they do not defeat causation altogether. *See Neurontin*, 712 F.3d at 39; *BCS Servs.*, 637 F.3d at 759 (explaining distinction between the "probability of a harm attributable to defendant's wrongful act" required for causation and "the amount of damages to be awarded to the plaintiff"); *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 466 (2006) (Thomas, J., dissenting) (observing that causation and "certainty of damages . . . are distinct requirements for recovery in tort").

Second, the court ignored the role of safety data in doctors' prescribing decisions, claiming that Ketek was only "marginally" more dangerous than other antibiotics and suggesting that "something other than" the alleged misrepresentations—like a generic entrant or seasonal change—"was at least partly responsible for the decline in sales." App. 41a. But the court's effort to downplay Ketek's safety problems completely misses the point. In a crowded field of equally effective drugs, safety data is

paramount in making prescribing decisions. Exaggerating safety data—even a little—will lead doctors to prescribe one drug over another when they would not have if they had known that the drug actually posed grave risks to patients. The Second Circuit—substituting its own opinion for that of doctors—may have deemed the risk of liver failure and death associated with Ketek "marginal," but, even so, when all else is equal, doctors will pick the safest drug. A causation standard that allows courts to supply unsupported alternative causation explanations or rely on sheer speculation erects an impossible causation bar; it should not be allowed to stand.

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Absent this Court's intervention, the sharp conflict in the lower courts will continue to generate uncertainty over RICO's causation standard in the third-party context, critically undermining Congress's intent that the law "be liberally construed to effectuate its remedial purposes." Pub. L. No. 91–452, § 904(a), 84 Stat. 947; *see Sedima*, 473 U.S. at 498. And, just as important, permitting the uncertainty to linger will have enormously negative consequences for all players in the healthcare system, needlessly forcing drug purchasers and manufacturers alike to incur substantial costs—and, like here, potentially exposing thousands of Americans to serious safety risks. The time is ripe for this Court's review.

CONCLUSION

For the foregoing reasons, this petition for a writ of certiorari should be granted.

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Respectfully submitted,

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