No. 15-1525

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

PETITIONERS' REPLY BRIEF

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PETITIONERS' REPLY

In its brief opposing certiorari, the respondents offer one—and only one—reason why this Court should deny review: the Second Circuit, they say, "did not address or decide" the "question set out in the petition." BIO 17, 19. According to respondents, there is no "rule" in the Second Circuit that "doctors always break the chain of causation" and hence no split over RICO's causation standard. BIO 14. As a result, they say, the decision below will "ha[ve] no effect beyond its unique facts." BIO 19.

Respondents are mistaken. As explained in the petition, the Second Circuit has embraced precisely such a rule—and it did so in *this* case. The purchasers' RICO claims were dispatched here because, in the Second Circuit, "proof of causation [i]s impossible" where it turns on "the intervening actions of prescribing physicians." App. 47a. That has been the rule in the Second Circuit ever since *Zyprexa*, where the court likewise held that the "theory of causation" for these sorts of RICO claims "is interrupted by the independent actions of prescribing physicians." *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 135 (2d Cir. 2010).

Petitioners are far from alone in this view. To the contrary, the pharmaceutical industry's leading trade group recently told this Court that, in the Second Circuit, causation "is too attenuated to support a RICO claim" because "the causal chain involves several intervening events, including physicians' exercise of their independent medical judgment." PhRMA Amicus Br. Supporting Petr. at 4, *GlaxoSmithKline LLC v. Allied Servs. Division Welfare Fund* (No. 15-1078). Exactly so.

The respondents' blind denialism also infects their view of the split among the circuits. They simply repeat

their claim that the Second Circuit "did *not* hold that the presence of doctors breaks the causal chain" and so is "not at odds with any other circuit court." BIO 17, 15. But that view runs headlong into the Second Circuit's actual decision in this case and in *Zyprexa*. And again, the respondents' own allies disagree: The First and Third Circuits "broke" with the Second Circuit, PhRMA has explained, leaving the lower courts "intractably divided" on "how to evaluate" causation. PhRMA Amicus Br. at 19. On one side, the existence of third-party doctors in the chain of causation does not preclude a finding of causation under RICO; on the other side it does.

Aside from their lone theory against review, the respondents speculate about the impact of the Second Circuit's decision. They argue that the decision below is uniquely "fact-bound" and unlikely to have any lasting effect. BIO 14. But already, lower courts have cited the decision to dismiss drug-fraud claims. And that trend will only continue.

In *Bridge v. Phoenix Bond & Indemnity Co.*, this Court made clear that RICO provides a remedy for plaintiffs who have been harmed by the foreseeable actions of others. 553 U.S. 639 (2008). The circuits, however, have split over *Bridge*'s significance in cases involving health-care fraud—disagreeing as to whether the predictable actions of doctors snap the causal chain. All stakeholders have repeatedly asked for this Court's guidance. This Court should step in now.

I. The Second Circuit decided the question presented.

The bulk of the respondents' opposition presses a single argument for why review is unwarranted: "the Second Circuit did not address or decide the issue" presented by the petition. BIO 16–17. But what exactly do

respondents think the Second Circuit didn't decide? They do not say.

The question that the petition asks this Court to resolve is whether the presence of "doctors break[s] the causal chain" in RICO cases that allege that "a manufacturer misrepresented a drug's safety to prescribing doctors to increase sales." Pet i. The Second Circuit held that it does. It ruled that the plaintiffs' "theory of injury"—that third-party doctors relied on a misrepresentation to over-prescribe Ketek—was "foreclose[d]" 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 alleged fraud. App. 34a. Doctors' prescribing decisions, in other words, are an "intervening action" that makes proof of causation "impossible." App. 47a (explaining that the conclusion that "generalized proof of causation was impossible because of the intervening actions of prescribing physicians" was "sound").

The Second Circuit applied this rule because an earlier decision in the same circuit, *Zyprexa*, required it. *See* App. 34a ("*Zyprexa* controls this case."). Respondents suggest that *Zyprexa* applied only because the evidence was "insufficient" to establish "but-for causation." BIO 10. But that is not what the Second Circuit said. *Zyprexa* applied because there is a rule in the Second Circuit that "physicians' prescribing decisions are too independent to allow proof of causation." App. 24a (affirming the district court's "causation holding [based] on *Zyprexa*'s statements"). *Zyprexa*, the Second Circuit explained in the decision below, held that "the multifaceted and individualized nature of physicians' prescribing decisions" thwarted RICO causation. App. 36a. And, contra the respondents, the court explained that "[t]he same is true here." *Id.*

II. The circuits are fundamentally split over the governing causation standards in RICO drug-fraud cases.

Nevertheless, to avoid a split, the respondents offer essentially the same argument. They say that, because the "court ruled that in '*this* case'" the evidence failed to establish causation, the Second Circuit "is not at odds with any other circuit court." BIO 14–15. In other words, respondents insist that the Second Circuit's decision should be "viewed" in a "limited" way—as nothing more than a garden-variety "sufficiency of the evidence" case. BIO 14. That is wrong.

The Second Circuit did not apply some uniformly accepted RICO causation standard to a particular set of facts. Nor could it. As explained in the petition, this Court has itself struggled to define the appropriate causation standard in third-party reliance cases. Just six years ago, it failed to reach consensus over whether, and when, the "intervening voluntary acts of third parties" "cut[] the causal chain" under RICO. *Hemi Group v. City of New York*, 559 U.S. 1, 25 (2010) (Breyer, J., dissenting). The source of disagreement there turned on how this Court's earlier decision in *Bridge* should apply to third-party reliance cases. *Compare id.* at 14 (distinguishing *Bridge*) *with id.* at 28 (finding *Bridge* "closely analogous") (Breyer, J., dissenting).

Not surprisingly, then, the lower courts have split too. Though respondents say nothing about it—opting not even to cite *Bridge* or *Hemi*—both the First and Third Circuit have expressly held that "*Bridge* forecloses th[e] argument" that, where misrepresentations are funneled through "prescribing doctors," the "causal link" is "broken." *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 37 (1st Cir. 2016); *In re Avandia*

Mktg., Sales Practices & Prod. Liab. Litig., 804 F.3d 633, 645 (3d Cir. 2015) ("*Bridge* precludes that argument.").

For these courts, doctors who "exercise independent medical judgment in making decisions about prescriptions" are not "independent intervening causes" that defeat the chain of causation. *Neurontin*, 712 F.3d at 39. Why? Because the "scheme" in these drug-fraud cases "relie[s] on the expectation that physicians would base their prescribing decisions *in part* on [the] fraudulent marketing." *Id.* (emphasis added). But a plaintiff need not prove that *every* doctor based *every* prescribing decision on the fraudulent marketing to reach a jury. *See id.* ("The 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."). How many doctors relied on the misrepresentations, and to what extent, "is a damages question." *Id.* To satisfy RICO's causation standard, it is enough in the First and Third Circuits that the fraudulent marketing had "significant"—but not exclusive—influence. *Id.* at 45.[1]

In the Second Circuit, by contrast, it is not. Unlike in the First and Third Circuits, to establish causation in the Second Circuit a RICO plaintiff must show that the misrepresentation was "so significant that it would dic-

[1] Although the respondents at one point suggest that the Third Circuit is not implicated in the split because "it did not decide whether and to what extent aggregate evidence can establish class-wide or individual but-for causation," they later concede that the Third Circuit "actually addressed the issue" presented here—(in their words) "whether doctors' prescribing decision break the chain of causation." BIO 15 & n.6.

tate every physician's decisionmaking"—a standard that can only be met by proving that "*all* pre-disclosure [drug] prescriptions were written in reliance on [a defendant's] alleged fraud." App. 36a (emphasis added). Under the Second Circuit's reading of *Bridge*, because prescribing decisions are "multifaceted" and call "for individualized determinations," App. 34a, doctors may "have acted in the same way regardless of the misrepresentation" and so "the misrepresentation cannot be a but-for, much less proximate, cause of the plaintiffs' injury." App. 27a–28a.[2]

In response, the respondents simply double down on their original "sufficiency of the evidence" theory: The purchasers (they say) offered a "robust regression analysis" in *Neurontin* but only "'simplistic' correlation evidence" here. BIO 15. But this disagreement turns on doctrine, not evidence. As explained in the petition, the same expert testified in both cases and concluded that the causation relationship was stronger—by far—in this case than in *Neurontin*. Ketek's sales declined so "rapidly and completely" "in response to safety information" that a regression was statistically unwarranted. CA2 JA 1130–31, 1134–35, 1161. As a matter of logic, it is easy to see why: In a crowded field of equally effective drugs,

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[2] Despite all this, the respondents nonetheless insist that the Second Circuit did "not even address proximate causation, much less declare an all-encompassing rule that doctors always break the chain of causation." BIO 14. That is wrong—as the plain language just quoted makes clear—but it also misses the point. The Second Circuit's conclusion here flowed from—and was mandated by—its earlier decision in *Zyprexa*. And there, the court definitively ruled that "the independent actions of prescribing physicians" "thwart[ed] any attempt to show proximate cause." 620 F.3d at 135. That rule applies with full force here.

safety data is crucial to prescribing decisions. When all else is equal, doctors will pick the safer drug—as this case demonstrates. After the respondents' fraud came to light, Ketek's sales dropped to virtually zero. JA 1153.

And the split is absolutely outcome determinative. To see why, consider how the claims in *Neurontin* would have fared had they been brought in New York. Recall that the allegations in *Neurontin* centered on Pfizer's misrepresentation of the efficacy—not the safety—of its blockbuster drug in an effort to increase the number of off-label prescriptions. 712 F.3d at 28. To prove this, the purchasers' "primary evidence" consisted of a statistical econometric analysis showing that "three out of ten" prescriptions for migraines "would not have been written or filled but for the alleged misconduct" and that nearly all (more than nine out of ten) prescriptions written by psychiatrists "would not have been written had there been no fraud." *Id.* at 29–30. A jury agreed and awarded more than $140 million in damages.

But in New York, that case would have never even come close to a jury. For one, the Second Circuit has expressly ruled that where the evidence shows, as it did in *Neurontin*, that "at least some doctors were not misled" by the misrepresentation "and thus would not have written 'excess' prescriptions," proof of causation is "impossible." *Zyprexa*, 620 F.3d at 135. For another, the court has also said that, if the misrepresentations were not "the *only* source of information on which doctors based prescribing decisions," the "theory of causation is interrupted by the independent actions of prescribing physicians." *Id.* And finally, misrepresentations about a drug's efficacy are, in the Second Circuit, a nonstarter. The only way—even hypothetically—that a particular case could overcome the rule that the "individualized

nature of physicians' prescribing decisions" defeats causation is to show that "the dangerousness of the drug would speak for itself." App. 36a, 38a.

III. The Court should step in now.

This is the fourth time within the past ten years that litigants and industry groups alike have asked this Court to weigh in on this important causation question. Given the doctrinal uncertainty and outcome-determinative nature of the divergent standards, leaving the split in place harms all stakeholders. Pet. 24. The respondents offer no argument in response.

Nor do the respondents defend the legal basis for the Second Circuit's extreme causation standard, instead falling back on their recycled "sufficiency of the evidence" claim to argue that this case is not a "viable vehicle." BIO 16–17. Even on its own terms, respondents' portrait of the record is flawed. For instance, the respondents claim that the key causation economist—the same one who successfully testified in *Neurontin*—presented nothing more than a "chart" in this case and failed to attribute the cause of Ketek's shocking sales drop to the fraudulent safety statements. BIO 8. But the expert testified in open court that the "*only* plausible explanation for this decline in sales" was "the new information that was allegedly suppressed by the defendant." JA 1131 (emphasis added). And the respondents' claim (at 7) that not even one medical doctor could testify "that he was misled" by the fraud is contradicted again by the record. *See* JA 2043 (testifying that "*[a]ny* physician who wrote a prescription was misled"). That point was hammered home by the respondents' own medical expert, who stopped prescribing Ketek in 2007. *See* JA 1251, 1253, 1257.

Left to stand, the Second Circuit's rule deals a fatal blow to claims that RICO was designed to promote, and, in turn, denies relief to "those who are directly injured, whose injury was plainly foreseeable and was in fact foreseen, and who were the intended victims of a defendants' wrongful conduct." *Neurontin*, 712 F.3d at 38; *see also Sedima S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 497–98 (1985). Indeed, it has already begun to have that effect. *See Sidney Hillman Health Ctr. of Rochester v. Abbott Labs. and Abbvie Inc.*, —F. Supp. 3d—, 2016 WL 3538808 at *6 (N.D. Ill. June 29, 2016) (citing the decision below to dismiss RICO drug-fraud claims).

When a case reveals that doctors—almost overnight—stop prescribing a drug after discovering that the company concealed serious, life-threatening liver risks, a jury should be permitted to decide whether RICO provides a remedy for the company's fraud. The Second Circuit's rule thwarts this outcome. The Court should grant the petition and reverse.

CONCLUSION

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

September 6, 2016 Respectfully submitted,

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