No. 13-289

In The Supreme Court of the United States

PFIZER INC.; WARNER-LAMBERT COMPANY, LLC,

Petitioners,

v.

KAISER FOUNDATION HEALTH PLAN, INC., ET AL.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The First Circuit

BRIEF IN OPPOSITION FOR RESPONDENT AETNA, INC.

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QUESTION PRESENTED

Does the court of appeals' summary judgment decision, which correctly stated the RICO proximate cause standards, applied those standards to respondent's evidence, and reached a fact-bound holding that the evidence sufficiently demonstrated a genuine dispute of material fact, merit review by this Court?

PARTIES

Aetna, Inc. was an appellant below and is the respondent in this Court.

Pfizer Inc. and Warner-Lambert Company, LLC were appellees below, and are petitioners in this Court. Petitioners were also appellants in the related cases, *Kaiser Foundation Health Plan, Inc. v. Pfizer, Inc.*, 712 F.3d 21 (1st Cir. 2013), and appellees in *Harden Manufacturing Corp. v. Pfizer, Inc.*, 712 F.3d 60 (1st Cir. 2013), the two other decisions appealed from in the Petition.

RULE 29.6 STATEMENT

Aetna, Inc. is a publicly traded corporation. No publicly held corporation owns 10% or more of Aetna, Inc.'s stock.

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INTRODUCTION

In 2004, petitioners ("Pfizer") pled guilty to two felonies, and paid fines and damages of $430 million to the United States, for marketing the epilepsy drug Neurontin for other medical conditions for which it was not FDA-approved ("off-label" uses). Pet. App. 120a-121a. Pfizer's secret marketing plan – internally labeling Neurontin as "snake oil for the twentieth century" – targeted health insurers generally, and respondent ("Aetna") specifically, as the victims that would pay for those prescriptions. *Id.* 81a-84a, 115a. Pfizer mass-marketed Neurontin to doctors to persuade them of its efficacy for particular off-label conditions, while suppressing negative results of clinical trials showing its inefficacy. *Id.* 102a.

Aetna, like other health insurers, maintains a "formulary" of FDA-approved drugs it agrees to pay for. Aetna added Neurontin to its formulary after the FDA approved it in 1993 for epilepsy. But prescriptions do not identify patients' illnesses. Doctors wrote millions of such "condition-anonymous" Neurontin prescriptions for insured patients' off-label conditions.

Until Pfizer was caught, the snake oil plan worked. Neurontin sales, which Pfizer projected at $500 million over its patent life, increased to more than $2 billion annually by 2003, almost entirely due to off-label prescriptions. *Id*. 110a. As Pfizer had predicted, Aetna's Neurontin costs spiked commensurately.

In 2005, Aetna sued Pfizer under RICO, 18 U.S.C. § 1962(c), to recover for more than one million

purchases of off-label Neurontin prescriptions resulting from Pfizer's snake oil campaign. Pfizer seeks review of the court of appeals' decision that sustained Aetna's RICO claims against summary judgment.

Straining to make the case appear certiorari-worthy, Pfizer asserts the court of appeals employed an erroneous foreseeability-only standard for RICO proximate cause. Pet. 18. However, the court of appeals correctly articulated and scrupulously applied the standards of *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258 (1992), and subsequent RICO decisions of this Court, requiring the evidence be probative of a direct relation between the injury asserted and the injurious conduct alleged. Pet. App. 20a-24a, 28a-30a. The court of appeals found that standard was met by Aetna's evidence, principally quarter-by-quarter proof of Aetna's payments for insureds' Neurontin prescriptions before and after Pfizer commenced its snake oil campaign, supplemented by expert regression analysis that limited Aetna's claims to off-label prescriptions attributable to the fraud. *See id.* 11a-14a, 85a-86a.

Pfizer's real grievance is not with the causation standard applied by the court of appeals, but rather its determination that Aetna's evidence met the standard. Pfizer is merely seeking review for correction of what it argues was an error in the court of appeals' fact-bound application of settled law to the evidence.

Nor does the court of appeals' decision conflict with a decision of another circuit on any important federal question. Pfizer tries to manufacture the appearance of a conflict by reference to two other circuits' decisions in prescription drug marketing cases. Pet. 22-24. One court found the evidence before it insufficient to permit a third party payer *class* to prosecute claims they overpaid for prescription drugs, but expressly disclaimed its ruling's applicability to non-class RICO claims of an individual health insurer (like Aetna). The other, an unpublished and non-precedential decision affirming a motion to dismiss, cited the plaintiff's concession that there were no concealed study results that involved the drugs and uses the defendant was alleged to have promoted. Neither decision conflicts with the court of appeals' articulation or application of the correct RICO proximate cause standard in this case. They merely reached different outcomes after applying the same law to different pleadings and evidence and in different procedural postures.

Lacking legal basis for a writ of certiorari, Pfizer and its supporting *amici curiae* raise and exaggerate baseless fears that, if Pfizer is liable for damages to Aetna, whom Pfizer's admittedly *illegal* actions specifically and successfully targeted, doctors might stop *legally* prescribing other drugs for off-label uses for patients for whom they might be effective. *See* Pet. 5-6; PhRMA Br. 9-13. Pfizer couples this with a "Chicken Little" argument that affirming the court of appeals' decisions will expose drug manufacturers

who illegally market their products to "massive potential damages." Pet. 25. Yet viewed objectively, Pfizer's liquidated liabilities to date, $430 million to the United States and $142 million to Kaiser Foundation Health Plan ("Kaiser"), plus its potential exposure to Aetna and a class, collectively, would represent only a small fraction of the billions of dollars Pfizer made, and has retained for more than 10 years, from illegal off-label Neurontin sales.

The decision of the court of appeals does not merit review by this Court. The Petition should be denied.

STATEMENT OF THE CASE

Pfizer's consolidated Petition also seeks review of two companion decisions, *Kaiser* (Pet. App. 1a-56a) and *Harden* (*id*. 57a-77a). The court of appeals' decisions describe in detail the facts and procedural history of the three cases. Those discussions, found at Pet. App. 2a-19a, 60a-68a, and 82a-86a, are incorporated herein.[1]

[1] Respondents in those cases have submitted briefs in opposition to the Petition, containing exhaustive recitations of the record concerning Pfizer's illegal marketing of Neurontin for off-label uses, its sales and profits therefrom, and Neurontin's inefficacy for such off-label uses, which Aetna also adopts by reference.

In 2005, Aetna and Kaiser jointly filed a RICO complaint against Pfizer. Aetna and Kaiser opposed summary judgment jointly, principally with evidence of each's quarterly Neurontin purchases before and after Pfizer's fraud commenced, and an expert's regression analysis of that data and other factors that determined the portions of their respective off-label Neurontin purchases attributable to Pfizer's marketing fraud. CA 1 A1289-1313 (Rosenthal Report); A1411-23, A1470, A1472 (Hartman Report).

The district court rendered a split decision over the issue of RICO causation, allowing Kaiser's claims to proceed to trial, but dismissing Aetna's claims. Pet. App. 264a. The district court cited anecdotal evidence that a few doctors Kaiser employed had been exposed to Pfizer's fraudulent marketing pitches, and found that, unlike Kaiser, "[t]here is no evidence in the record that . . . Aetna at any point directly relied on Pfizer's 'half truths,'" *id*. 289a, thereby conflating direct reliance with *Holmes*' "direct relation" test.

However, at Kaiser's subsequent trial, "no individual physician testified in this case (or in the MDL litigation as a whole) that he or she prescribed Neurontin as a result of fraudulent off-label promotion." *Id*. 164a. Instead, Kaiser relied upon the same evidence the district court had ruled was inadequate for Aetna at summary judgment to prove Pfizer's fraud caused its injury and to prove its damages. *See id.* 164a-166a. The district court concluded the aggregate statistical evidence and explanatory expert testimony captured the "many variables that affect

an individual physician's prescriptions." *Id*. 218a. Kaiser won a RICO judgment for over $47 million (trebled to over $142 million). *Id.* 101a.

On appeal, Aetna argued it should have been given the same opportunity as Kaiser to try its RICO claims to a jury. CA 1 Br. 3, 25-26, 35-38. The court of appeals agreed, finding their claims and proof materially indistinguishable.

> While the trial record in *Kaiser* was somewhat larger than the record here, the record on summary judgment in this case was very similar and included much of the same expert and other evidence as to causation.

Pet. App. 79a.

Regarding the sufficiency of Aetna's aggregate statistical evidence and expert regression analysis, the court of appeals held:

> For the reasons stated in *Kaiser*, that evidence could be found by a reasonable factfinder to show that Pfizer's marketing of Neurontin for off-label indications caused a sharp increase in the number of prescriptions that Aetna paid for or reimbursed.

Id. 86a.

Correctly applying the standards of the Court's unanimous holding in *Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 341 (2008), the court of appeals held Aetna's evidence "demonstrated a causal relationship between Pfizer's alleged fraudulent

marketing to doctors and Aetna's payment for off-label prescriptions of Neurontin. Aetna did not have to show direct reliance to establish proximate or but-for causation." Pet. App. 91a.

REASONS FOR DENYING THE WRIT

I. THE COURT OF APPEALS CORRECTLY STATED AND PROPERLY APPLIED RICO'S PROXIMATE CAUSE STANDARDS

Pfizer argues the court of appeals misstated RICO's proximate cause test and claims the court "held that RICO proximate causation is satisfied by a showing of intent and foreseeability without regard to the directness of the causal chain." Pet. 19.

Pfizer completely mischaracterizes the decision. The court of appeals held proximate cause could *not* be satisfied that way:

> Here, the harm to [Aetna][2] plainly was foreseeable, and foreseeability is needed for, but does not end the inquiry as to, proximate causation. The proximate causation question in this appeal concerns whether the chain of

[2] We replace references to "Kaiser" in the *Kaiser* decision with "Aetna" for clarity. The court of appeals concluded that the same RICO proximate causation rationale it used in the *Kaiser* decision applied to its *Aetna* decision. Pet. App. 90a.

> events between Pfizer's misrepresentations and [Aetna]'s payment for the prescriptions is so attenuated that, for legal and policy reasons, [Aetna]'s claim for recovery should be denied.

Pet. App. 20a-21a.

The court of appeals faithfully applied this Court's articulation of RICO's proximate causation standards to both Kaiser's and Aetna's claims, *id*. 21a-32a, 90a, finding it "clear" that both "directness" and the other "functional" factors discussed in *Holmes* "are part of the proximate cause inquiry." Pet. App. 21a-24a. Because the court of appeals "properly stated [the] rule of law," SUP. CT. R. 10, the Petition presents nothing more than a claim of fact-bound misapplication of correctly-stated law. The Petition should be denied as unworthy of review for this reason alone.[3]

Petitioners' effort to create the illusion of a circuit split fares no better. The first-cited court of appeals decision (Pet. 22-23) – *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010) – a class action case claiming overpayment for a drug, disclaimed its holding's applicability to an individual (non-class) claim by a health insurer that it paid for more prescriptions than it would have absent the defendant's

[3] While the Petition does not present a question concerning but-for causation, the court of appeals specifically addressed the issue and found Aetna's evidence sufficient. *See* Pet. App. 89a-90a.

fraud, which it termed an "excess quantity" theory. *Id.* at 136. The court of appeals recognized that "[Aetna's] case, of course, is just such an individual claim by a [health insurer]." Pet. App. 46a.

Petitioners next cite (Pet. 23-24) the not-for-publication decision in *United Food & Commercial Workers Central Pennsylvania & Regional Health & Welfare Fund v. Amgen, Inc.,* 400 F. App'x 255 (9th Cir. 2010). Putting aside the distinguishing features of that case (including plaintiff's admission that there were no concealed study results involving the subject drugs, 400 F. App'x at 257), not even the Ninth Circuit considers the decision precedent. *Id.* at footnote "*."

The remaining circuit court decisions cited by Pfizer merely "recognized that RICO's direct-relation test for proximate causation is not satisfied by mere foreseeability." Pet. at 24-25. The court of appeals here did the same. Pet. App. 20a ("foreseeability is needed for, but does not end the inquiry as to, proximate causation").

The courts of appeals are in accord, not conflict, concerning RICO proximate cause standards. That courts have reached different outcomes when applying those standards to the varying facts in the cases before them is unremarkable. Pfizer's petition reflects nothing more than a disappointed litigant's request for correction of what it perceives as an error in a court's application of settled law to case-specific evidence.

II. THE COURT OF APPEALS' DECISION DOES NOT CONFLICT WITH THE DECISIONS OF THIS COURT OR OTHER COURTS OF APPEALS CONCERNING THE USE OF STATISTICAL EVIDENCE TO PROVE CAUSATION OR DAMAGES

Petitioners rely on class certification decisions interpreting FED. R. CIV. P. 23 to argue that Aetna cannot use "aggregate statistical proof" to prove proximate cause. Pet. 27 (citing, *inter alia*, *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541 (2011); *Comcast Corp. v. Behrend*, 133 S. Ct. 1426 (2013)). To make these decisions appear relevant, Pfizer calls Aetna's and Kaiser's cases "structural class action[s]" (whatever that means). *Id*. 30. Such class actions decisions (the *Lilly* case included – it was a class action) are inapposite. Aetna's evidence showed, quarter-by-quarter, how many Neurontin prescriptions *it* paid for, before and after Pfizer began marketing Neurontin illegally. CA 1 A1470. In the class action cases, aggregate statistical evidence of what all *other* class members paid or did in the aggregate was offered as proof, for class certification purposes, that every class member was injured and injured in the same way.

Reliance on aggregated evidence is a necessary consequence of the vast nature and effects of Pfizer's crime, which it committed nationwide via widespread mail and wire fraud.[4] The court of appeals correctly

[4] Aetna supplemented its statistical and expert evidence with evidence that Pfizer targeted Aetna as the "number four

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noted this Court has long recognized the utility and necessity of statistical evidence as proof of causation and damages in complex civil cases. Pet. App. 36a-38a. Cases like this, dealing with widespread frauds that are intended to, and do, cause widespread economic damage resulting from millions of individual transactions, can be proven only through such evidence together with expert testimony. Moreover, as the court of appeals acknowledged, such evidence is certainly more reliable than the evidence Pfizer cynically argued was necessary, *i.e.*, thousands of doctors' anecdotal recollections of hundreds of thousands of years-old prescribing decisions, one-by-one. *Id*. 90a ("relying on physicians' individual recollections as to their prescribing decisions might have been an unreliable approach"); *id*. 44a (noting "the scientific invalidity of looking to physician-by-physician accounts of their prescribing decisions").

The court of appeals applied the correct proximate cause standard when it rejected Pfizer's argument, noting "Aetna's failure to present the form of but-for causation evidence that defendants would have favored does not mean that the evidence Aetna

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managed care plan" for listing of Neurontin on its prescription drug formulary shortly after its 1993 FDA approval for epilepsy; with evidence of how Pfizer targeted Aetna and exploited Neurontin's listing on Aetna's formulary "so share building programs can be carried out unrestricted" to get Aetna to pay for excess off-label prescriptions; and causation-related testimony of its pharmacy executive, Michael Brodeur. Pet. App. 83a, 85a, 88a n.1.

did present was insufficient for a jury to conclude that Aetna showed the needed causation." *Id*. 90a n.3 (emphasis in original). The court of appeals properly held "[i]t should have been left to a jury to weigh the aggregate and circumstantial evidence of causation presented by Aetna against any failure to present individualized testimony from doctors." *Id*. 89a-90a.

CONCLUSION

The Court should deny the Petition.

Dated: November 4, 2013
White Plains, New York

Respectfully submitted,

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