No. 13-289

In the Supreme Court of the United States

PFIZER INC.; WARNER-LAMBERT CO., LLC,
Petitioners,
v.
KAISER FOUNDATION HEALTH PLAN, INC., *et al.*,
Respondents.

PFIZER INC.; WARNER-LAMBERT CO., LLC,
Petitioners,
v.
HARDEN MANUFACTURING CORP., *et al.*
Respondents,

PFIZER INC.; WARNER-LAMBERT CO., LLC,
Petitioners,
v.
AETNA, INC.,
Respondent.

On Petition for a Writ of Certiorari to the U.S. Court of Appeals for the First Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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QUESTIONS PRESENTED

Amicus curiae addresses both of the Question Presented:

1. Whether RICO's proximate causation requirement may be satisfied by mere foreseeability or instead requires a direct causal relationship.

2. Whether plaintiffs may show fraud causation and damages by aggregate evidence of a correlation between the alleged fraud and doctors' prescribing behavior without any showing of actual individualized causation.

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BRIEF OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

INTERESTS OF *AMICI CURIAE*

The Washington Legal Foundation (WLF) is a non-profit public interest law and policy center with supporters in all 50 states.[1] WLF devotes a substantial portion of its resources to defending free enterprise, individual rights, and a limited and accountable government.

To that end, WLF has appeared before this Court as well as other federal and State courts to argue against overly expansive theories of tort liability and excessive punitive damages. Of particular relevance to this case, WLF has appeared in this Court to argue against an overly expansive interpretation of the Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. § 1961 *et seq.* *See, e.g., Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639 (2008); *Beck v. Prupis*, 529 U.S. 494 (2000); *Rotella v. Wood*, 528 U.S. 549 (2000); *H.J. Inc. v. Northwestern Bell Tel. Co.,* 492 U.S. 229 (1989).

WLF also litigates actively in opposition to

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[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than *amici* and their counsel, made a monetary contribution intended to fund the preparation or submission of this brief. All parties have consented to this filing; letters of consent have been lodged with the Court. More than 10 days prior to the due date, counsel for *amici* provided counsel for Respondents with notice of *amici*'s intent to file.

excessive government interference with health care delivery. In particular, it has opposed efforts by the Food and Drug Administration (FDA) to interfere with the practice of medicine by restricting the rights of doctors to prescribe FDA-approved drugs for off-label uses, and by restricting the flow of truthful information to doctors and patients regarding effective off-label uses of those drugs. As a result of WLF litigation, FDA is subject to a permanent federal court injunction that imposes limits on such speech restrictions. *See Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 73-74 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000).

The Allied Educational Foundation (AEF) is a non-profit charitable foundation based in Englewood, New Jersey. Founded in 1964, AEF is dedicated to promoting education in diverse areas of study, such as law and public policy, and has appeared as *amicus curiae* in this Court on a number of occasions.

Amici are concerned that the reflexive invocation of RICO by civil litigants engaged in otherwise garden-variety commercial disputes does violence to the original purpose of RICO and unnecessarily burdens our federal judicial system. While Congress adopted RICO as a tool to fight organized crime, civil RICO is now all too often invoked in "everyday fraud cases brought against respected and legitimate enterprises." *Sedima, S.P.R.L. v. Imrex Co.,* 473 U.S. 479, 499 (1985). While such use of RICO is at times a reflection of the statute's expansive language, *amici* are concerned that much of the time RICO is invoked inappropriately by opportunistic plaintiffs seeking to force the settlement of doubtful claims by defendants

unable to cope with the threat of treble damages and the unfavorable publicity that arises anytime one is labeled a "racketeer."

Amici applaud the Court for its efforts to impose reasonable limits on civil RICO litigation by requiring plaintiffs to demonstrate that their alleged injuries were proximately caused by the defendant's conduct. *Amici* are concerned that the First Circuit decision, if allowed to stand, will substantially undermine those efforts. *Amici* are also concerned that the First Circuit's acceptance of Respondents' use of aggregate evidence to show fraud causation and damages unfairly handcuffs RICO defendants' ability to defend themselves.

STATEMENT OF THE CASE

Neurontin is the brand name for gabapentin, a widely prescribed pharmaceutical drug. Neurontin first received FDA approval in 1993, for use in treating epileptic seizures. FDA later approved Neurontin for use in treating a type of neuropathic pain (*i.e.*, pain due to nerve damage). As is also true for a large number of other FDA-approved drugs, many doctors have concluded that Neurontin is also effective in treating medical conditions for which it has not received FDA approval, and they frequently prescribe it for such "off label" uses as treatment of bipolar disorder, unapproved types of neuropathic pain, and migraines.

Neurontin was first developed and patented by a division of Petitioner Warner-Lambert Co., LLC. Warner-Lambert was purchased by Petitioner Pfizer Inc. in 2000. Warner-Lambert and Pfizer (collectively

"Pfizer") heavily promoted sales of Neurontin until its patent expired in late 2004. That promotional activity included the dissemination of medical studies (some of which were funded by Pfizer) that concluded that Neurontin was effective in treating a number of conditions for which it was not labeled.

Respondents—a health maintenance organization (HMO), two insurance companies, a union trust fund, and a self-insured employer—provide health care coverage for their members/customers, including expenditures for prescription drugs. They ultimately concluded that some of the off-label prescriptions written for Neurontin (and for which they had provided cost reimbursement) were medically inappropriate. They further concluded that Pfizer had caused those inappropriate prescriptions to be written by disseminating medical studies containing false information about Neurontin's safety and effectiveness. They filed RICO lawsuits in 2004 and 2005 against Pfizer, alleging that it had engaged in a pattern of "racketeering activity" that led doctors to prescribe, and that in turn led Respondents to pay for, unnecessary off-label uses of Neurontin.

The claims of the HMO and its affiliates (collectively, "Kaiser") went to trial. The trial court granted summary judgment against the other Respondents. A jury determined that the medical studies disseminated by Pfizer were false (*i.e.*, that they included claims regarding Neurontin that were not sufficiently supported by medical data and that omitted other relevant data), and it awarded Kaiser

more than $47 million in damages under RICO.[2]

Although Kaiser questions the propriety of the wide-spread off-label use of Neurontin, many medical professionals disagree with that assessment—as evidenced by the fact that Neurontin and generic gabapentin continue to be widely prescribed for the off-label uses for which Kaiser (and the jury) deemed the drug to be ineffective. For example, in 2011 the Cochrane Group, an international nonprofit organization that compiles scientific evidence concerning the use of drugs, concluded that gabapentin was effective in treating off-label neuropathic pain—a conclusion that the First Circuit acknowledged in its opinion. Pet. App. 55a-56a.

Pfizer appealed from the jury verdict in favor of Kaiser, while the entities against which summary judgment was entered filed two separate appeals ("*Harden*" and "*Aetna*"). The First Circuit consolidated the three appeals for oral argument before a single three-judge panel. The panel issued three separate decisions in April 2013, affirming the judgment for Kaiser, *id.* at 1a-56a, while reversing the grants of summary judgment in *Harden* and *Aetna*. *Id*. at 57a-77a, 78a-94a.

The First Circuit rejected Pfizer's claim that Kaiser failed to demonstrate that Pfizer's "racketeering activity" was the proximate cause of Kaiser's claimed

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[2] The district court trebled those damages to $142 million. Although Pfizer continues to stand by the accuracy of the medical reports in question, it has not challenged the jury's falsity determination on appeal.

injuries. *Id.* at 21a-32a. While conceding that the "foreseeability" of injury to the plaintiff "is needed for, but does not end the inquiry as to, proximate causation," *id.* at 20, it concluded that Kaiser's evidence had gone beyond a mere showing of foreseeability by showing that Kaiser was "a primary and intended victim of Pfizer's scheme to defraud." *Id.* at 26a. Rejecting Pfizer's argument that there were "too many steps in the causal chain between its misrepresentations and Kaiser's alleged injury," the court concluded that "the causal chain in this case is anything but attenuated. Pfizer has always known that, because of the structure of the American health care system, physicians would not be the ones paying for the drugs they prescribed." *Id.* at 28a-30a.

The First Circuit also rejected Pfizer's claim that Kaiser failed to demonstrate but-for causation. Pet. App. 32a-47a. To support but-for causation, Kaiser relied principally on the expert report of Dr. Meredith Rosenthal. Dr. Rosenthal's regression analysis of aggregate statistical evidence concluded:

> [T]he percentages of Neurontin prescriptions that were caused by Pfizer's fraudulent marketing of Neurontin were, by off-label indication, as follows: 99.4% of prescriptions for bipolar disorder; 70% of prescriptions for neuropathic pain; 27.9% of prescriptions for migraine; and 37.5% of prescriptions for doses over 1800 mg/day.

Id. at 12a. Importantly (from Pfizer's perspective), Dr. Rosenthal did not rely on any testimony from individual doctors regarding why they chose to

prescribe Neurontin, deeming such evidence "unreliable." *Id.* at 13a. The First Circuit concluded that Dr. Rosenthal's report was sufficient to survive a summary judgment motion on but-for causation, even though (as Pfizer pointed out) the only testimony at trial from doctors who prescribed Neurontin off-label uses was that their prescribing decisions had *not* been influenced by Pfizer's marketing efforts. *Id.* at 43a-44a. The court held that Kaiser had presented aggregated evidence that it had "suffered the sort of injury that would be the expected consequence of the defendant's wrongful conduct." *Id.* at 43a. Once such a showing is made, the court held, a RICO plaintiff seeking to establish but-for causation need not offer evidence that excludes other possible sources of its injury. Rather, at that point "the burden shifts to the defendant to rebut this causal inference." *Id.*

The First Circuit panel simultaneously issued short opinions reversing the grants of summary judgment in *Harden* and *Aetna*. Noting that the plaintiffs in those two cases also sought to rely on Dr. Rosenthal's expert report, the court referred to its *Kaiser* opinion in holding that the plaintiffs had submitted sufficient evidence on proximate causation and but-for causation to withstand motions for summary judgment. *Id.* at 57a-77a; 78a-94a.

SUMMARY OF ARGUMENT

This case raises issues of exceptional importance to the business community, and to the pharmaceutical industry in particular. As the Petition well documents, Pet. at 3, the lower courts are seeing a boom in RICO suits against pharmaceutical manufacturers for alleged

inaccuracies in their marketing concerning the efficacy of off-label uses of prescription drugs. Given the ever-increasing annual expenditures for health care in general and for prescription drugs in particular, it is unsurprising that health insurers are exploring all options for holding down costs. But if the First Circuit's decisions are upheld, one can reasonably expect that they will turn increasingly to the RICO option: attempting to brand pharmaceutical companies as "racketeers" in an effort to utilize RICO's treble damages provision. The First Circuit has interpreted RICO's causation requirements in a manner that conflicts with existing precedent and will make it much easier for future claimants of all stripes to bring gargantuan damage claims before juries.

Review is warranted to address that conflict. Pfizer discusses at length the conflict between the decisions below and the decisions of other federal appeals courts and district courts regarding the proximate causation requirement in RICO cases. *Amici* write separately to focus on the conflict between the decisions below and this Court's decision. The Court held in *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258 (1992), that 18 U.S.C. § 1964(c)'s "by reason of" language imposes a "proximate cause" requirement on civil RICO claimants. It is not enough for a claimant to demonstrate that the defendant's actions were simply a but-for cause of his injury; there must also be a sufficiently "direct relationship" between the claimant and the defendant. 503 U.S. at 268. The directness of the relationship is a "central element" of proximate causation because "the less direct an injury is, the more difficult it become to ascertain the amount of a plaintiff's damages

attributable to the violation, as distinct from other, independent factors." *Id.* at 269.

The First Circuit appeared to recognize that the requisite direct relationship cannot be established based solely on evidence that injury to the claimant was a "foreseeable" result of the defendant's actions. Pet. App. at 20a. The court concluded, however, that a direct relationship existed here because the evidence showed not only foreseeability but also that Kaiser was a "primary and intended victim of Pfizer's scheme to defraud." *Id.* at 26a. But that conclusion adds nothing to the court's "foreseeability" determination. It was not based on evidence that Pfizer set out purposely to injure Kaiser or that the causal chain here was particularly direct. Rather, it was based on the court's conclusion that increased Neurontin prescriptions among Kaiser's members attributable to Pfizer's off-label marketing would increase Kaiser's costs, and thus that Kaiser's injury was a "foreseeable and natural consequence of Pfizer's scheme." *Id.* Review is warranted to address the conflict between the decisions below and this Court's precedents indicating that foreseeability alone is not enough to establish proximate cause.

Review is also warranted to address the conflict between the decisions below and other federal appellate decisions regarding the use of aggregate evidence to establish but-for fraud causation and damages. *Amici* write separately to focus on the particular unfairness to defendants in permitting but-for causation to be established on the basis of aggregate evidence when, as here, *all* available evidence from doctors indicates that the independent

medical judgment of individual doctors was an intervening cause that broke the causal chain between Pfizer's promotional activity and Kaiser's reimbursement costs.

The First Circuit justified its ruling by asserting that once Kaiser submitted its aggregated evidence, the burden shifted to Pfizer to demonstrate that a causal relationship did not exist. The court cited a Seventh Circuit decision in support of its burden-sifting rule. But that decision is inapposite; indeed, the decision appears to undercut the First Circuit's conclusion that Pfizer properly bore the burden of rebutting Kaiser's aggregated evidence.

As a result of the First Circuit's ruling, defendants will have great difficulty in preventing RICO cases, even when based solely on aggregated evidence, from reaching the jury on the issue of but-for causation. By instructing district judges, when ruling on summary judgment motions, to ignore the absence of evidence that intervening actors actually relied on the defendant's alleged fraud, the First Circuit is undermining defendants' right to defend against each individual fraud claim. Review is warranted to resolve the conflict between the decisions below and the decisions of other federal appeals courts, and to determine whether the decisions below are consistent with this Court's understanding of a defendant's right to defend itself in a civil proceeding.

REASONS FOR GRANTING THE PETITION

I. THE DECISION BELOW CONFLICTS WITH THIS COURT'S DECISIONS REGARDING PROXIMATE CAUSE IN RICO CASES

The First Circuit's conclusion that RICO's proximate cause requirements can be satisfied based on little more than the foreseeability of the plaintiff's injury squarely conflicts with a long line of decisions from this Court. Review is warranted to address that conflict, particularly given the increasing frequency with which proximate cause issues arise in RICO cases raising claims against pharmaceutical companies.

The Court held more than two decades ago in *Holmes* that a civil litigant may not recover damages for a RICO violation in the absence of evidence that his injuries were proximately caused by the violation. The statute creating a private right of action for violations of RICO, 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 . . . and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney's fee.

Holmes relied on §1964(c)'s "by reason of" language in concluding that Congress intended to require proof of proximate cause. While conceding that the language could be read to mean that a plaintiff demonstrates injury, and therefore may recover damages, "simply on showing that the defendant violated § 1962, the

plaintiff was injured, and the defendant's violation was a 'but for' cause of plaintiff's injuries," the Court rejected that "expansive" reading, based largely on "the very unlikelihood that Congress meant to allow all factually injured plaintiffs to recover." *Holmes*, 503 U.S. at 265-66.

The Court stated that "the infinite variety of claims that may arise make it virtually impossible to announce a blackletter rule that will dictate the result in every case" regarding whether an injury was "proximately caused" by the defendant's actions. *Id.* at 272 n.20 (quoting *Associated General Contractors of Cal., Inc. v. Carpenters*, 459 U.S. 519, 536 (1983)). Nonetheless, the Court provided some general guidelines for use in making that determination:

> [A]mong the many shapes this concept took at common law was a demand for some direct relation between the injury asserted and the injurious conduct alleged. . . . Although such directness of relationship is not the sole requirement of Clayton Act causation, it has been one of its central elements, for a variety of reasons. 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.

Id. at 269 (citations omitted).[3]

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[3] *Holmes* went on to conclude that the plaintiff could not demonstrate that its injury was proximately caused by the defendant's alleged racketeering activity (stock manipulation)

Relying on *Holmes*, the Court in *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451 (2006), determined that the plaintiff's RICO action under 18 U.S.C. § 1964(c) failed to adequately allege proximate cause. The plaintiff was an entrepreneur who contended that a business rival violated RICO by failing to properly pay New York sales taxes on some of its sales. The plaintiff alleged that it was injured by the RICO violation because by failing to charge sales tax, the competitor was able to undercut the plaintiff's prices and thereby induce customers to reduce their purchases from the plaintiff. The Court explained that in evaluating a RICO claim for proximate causation, the "central question" a court must ask is whether the alleged violations led "directly" to the plaintiff's injuries. 547 U.S. at 461. The Court did not contest the dissent's contention that the plaintiffs' injuries were an entirely foreseeable result of the defendants' fraudulent scheme. It nonetheless concluded that no "direct" relationship existed between the fraudulent scheme and the plaintiff's injuries, and thus that proximate cause was lacking. *Id.* Among the reasons the Court cited for determining that the relationship was insufficiently direct: "Businesses lose and gain customers for many reasons, and it would require a complex assessment to establish what portion of [the plaintiff's] lost sales were the product of [the defendants'] decreased prices." *Id.* at 459.

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because the link between the stock manipulation and its injury was "too remote"—the harm only arose because the stock manipulation caused harm to third parties who were thereby rendered insolvent and thus unable to meet their obligations to individuals in whose shoes the plaintiff claimed to stand. *Id.* at 271.

In *Hemi Group, LLC v. City of New York,* 559 U.S. 1 (2010), the Court again invoked proximate causation principles to dismiss a civil RICO action. The plaintiff, New York City, sought to recover RICO damages from out-of-state cigarette retailers who allegedly violated New York law by failing to file customer information with New York State. The plaintiff alleged that the failure to file caused it injury (in the form of lost tax revenue) because the failure deprived it of the opportunity to contact cigarette purchasers to demand that they pay city taxes on their purchases. In rejecting a claim that proximate cause was established by allegations that the city's loss of tax revenues was a highly foreseeable result of the defendant's misconduct, the plurality opinion explained that "in the RICO context, the focus [of the proximate cause inquiry] is on the directness of the relationship between the conduct and the harm. Indeed, *Anza* and *Holmes* never even mention the concept of foreseeability." 559 U.S. at 12 (plurality opinion). The plurality concluded that the relationship between the defendants' failure to file reports with a state government and a city government's subsequent loss of tax revenues was "far too indirect" to support proximate causation, regardless whether the loss was a foreseeable result of the defendant's actions. *Id.* at 10.[4]

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[4] *Hemi Group*'s precedential value is somewhat limited by the failure of any single opinion to garner support from a majority of the justices. Four justices joined the plurality opinion; the fifth justice in the majority, Justice Ginsburg, wrote a separate opinion and concurred only in part with the plurality's proximate cause analysis. 559 U.S. at 994-95 (Ginsburg, J., concurring in part and concurring in the judgment). But the Court's inability in *Hemi*

The First Circuit's conclusion that Kaiser, Harden, and Aetna demonstrated proximate cause was based on criteria that conflict with the standards set forth in *Holmes*, *Anza*, and *Hemi Group*. The uncontested evidence at trial demonstrated the existence of multiple links in the causal chain leading from Pfizer's dissemination of off-label information to Kaiser's alleged injury. As Pfizer has explained, the chain involved "at least four steps." Pet. at 14. In particular, causation does not exist unless a doctor—exercising independent judgment—decided to prescribe Neurontin for an off-label use *because* he/she was induced to do so by Pfizer's promotional scheme, and Kaiser agreed to reimburse the costs of the off-label prescription. If the doctors, independent actors who are not parties to this litigation, had some other motivation for prescribing Neurontin, the causal chain is broken. Moreover, as the Second Circuit observed in concluding that causation could not be proven in a case raising a remarkably similar RICO challenge to the promotional practices of another pharmaceutical company (Eli Lilly and Co.), doctors generally based their prescribing decisions on a variety of sources of information:

Group to arrive at a consensus view regarding the relevance of foreseeable to proximate cause does not undercut *Anza*'s prior rejection of a foreseeability standard. As the *Hemi Group* plurality explained, the *Anza* "dissent criticized the majority view for 'permit[ting] a defendant to evade liability for harms that are not only foreseeable, but the *intended* consequences of the defendant's unlawful behavior.' 547 U.S. 470 (Thomas, J., concurring in part and dissenting in part). But the dissent there did not carry the day, and no one has asked us to revisit *Anza*." *Hemi Group*, 559 U.S. at 12 (plurality).

> Lilly was not, however, the *only* source of information on which doctors based prescribing decisions. An individual patient's diagnosis, past and current medications being taken by the patient, the physician's own experience with prescribing Zyprexa, and the physicians's knowledge regarding the side effects of Zyprexa are all considerations that would have been taken into account in addition to the alleged misrepresentations distributed by Lilly.

UFCW Local 1776 v. Eli Lilly and Co., 620 F.3d 121, 135 (2d Cir. 2010). Accordingly, there is substantial reason for concluding that many doctors wrote off-label Neurontin prescriptions for reasons unrelated to Pfizer's promotional activity.

The standards established by *Holmes, Anza*, and *Hemi Group* strongly suggest that Kaiser cannot establish proximate cause. Those decisions explained that the "central question" in determining proximate cause "is whether the alleged violations led 'directly' to the plaintiff's injuries." *Anza*, 547 U.S. at 461; *Hemi Group*, 559 U.S. at 12 (plurality opinion); *Holmes*, 503 U.S. at 269. The "directness of the relationship" is key because "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." *Id.* When, as here, causation requires Kaiser to prove that independent actors (*e.g.*, the prescribing doctors) responded in a manner that did not break the causal chain, ascertaining the amount of damages (if any) suffered by Kaiser becomes exceedingly difficult. The proximate cause requirement is designed in substantial part to

ensure that courts are not required to entangle themselves in complex damage allocation proceedings of this sort.

Indeed, Kaiser concedes that Pfizer's marketing scheme was not responsible for many of the off-label Neurontin prescriptions for which it provided reimbursement. Dr. Rosenthal conceded for example, that no causal relationship existed between Pfizer's marketing scheme and more than 72% of the Neurontin prescriptions written to treat migraine (an off-label use). That concession is a recognition that in many instances the causal chain has indeed been broken, and that determining the precise number of instances will require courts to evaluate competing, complex economic models. Other complex factors that must be evaluated when, as here, the causal chain includes multiple links include the extent of the plaintiff's economic loss. For example, if (in the hypothetical absence of a marketing scheme) Neurontin had not been prescribed to a Kaiser member suffering from bipolar disorder, then presumable his doctors would have prescribed an alternative medication to treat the disorder. Under those circumstances, computing Kaiser's damages requires determining the cost of the alternative medication and deducting that cost from the cost of the Neurontin prescription. *Holmes* and *Anza* explained that a principal purpose of proximate cause requirements is to permit courts to avoid entanglement in complex disputes of this sort.

In contrast, the First Circuit deemed the proximate cause requirement to have been met based on little more than evidence that Kaiser's injury was

foreseeable. Pet. App. 26a. The First Circuit contended that Kaiser was an "intended victim" of Pfizer's scheme, *id*, but that contention was based solely on its finding that Kaiser's injury was a "foreseeable and natural consequence" of the scheme. Moreover, the *Hemi Group* plurality explicitly stated that proximate cause cannot be established when the relationship of the violation to the injuries is insufficiently "direct," even when the injuries were "the intended consequences of the defendant's unlawful behavior." 559 U.S. at 12.

The First Circuit asserted that its "foreseeable and natural consequence" standard for proximate cause was supported by the Court's decision in *Bridge*. Pet. App. at 26a. That assertion is without merit. *Bridge* focused solely on reliance; it held that a plaintiff asserting a RICO claim based on mail fraud need not prove that it personally relied on the defendant's alleged misrepresentation. *Bridge*, 553 U.S. at 642. *Bridge* did not purport to address the general standards for demonstrating proximate causation in a RICO case. Moreover, the Court recognized that there existed a "direct" relationship between the alleged wrongdoing and the defendant's injury: if the allegations of the complaint were true, then the plaintiffs "clearly were injured by [the defendants'] scheme. *Id.* at 649. In other words, there was no plausible argument (as there is here) that the acts of third parties could break the causal chain.

The First Circuit suggested that proximate cause should be deemed to exist because failing to do so might mean that "no viable plaintiffs would remain" to vindicate the law." Pet. App. 29a n.12. But this Court

has never indicated that exceptions to the "direct relationship" requirement ought to be recognized in order to ensure that a viable plaintiff will always be available to seek civil redress for RICO violations. To the contrary, the Court has routinely declined to allow policy considerations to color its efforts to effectuate congressional purpose with respect to RICO. *Holmes* concluded, based on Congress's decision to model RICO after the antitrust laws, that Congress intended to incorporate the antitrust law's strict adherence to proximate cause requirements. *See* 503 U.S. at 271-72 (quoting *Associated Gen. Contractors* to the effect that "[t]he general tendency of the law, in regard to damages at least, is not to go beyond the first step"); *Hemi Group*, 559 U.S. at 10 ("Our cases confirm that the 'general tendency' applies with full force to proximate cause inquiries under RICO.").

The First Circuit also asserted that "the causal chain in this case is anything but attenuated" because "the structure of the American health care system" is such that "physicians would not be the ones paying for the drugs they prescribed." Pet. App. 29a-30a. That assertion is a non sequitur. The importance of the role of doctors as independent actors in the causal chain is not whether they will bear the costs of prescriptions they write, but whether their prescription practices were influenced by Pfizer's marketing scheme. Because doctors enjoy largely unfettered discretion to write prescriptions in accordance with their own professional judgments, the causal chain in this case can only be described as attenuated.

In sum, review is warranted to resolve the substantial conflict between the First Circuit's

decisions and this Court's decisions regarding proximate cause in RICO cases.

II. THE DECISION BELOW CONFLICTS WITH OTHER FEDERAL APPELLATE DECISIONS REGARDING THE USE OF AGGREGATED EVIDENCE TO ESTABLISH BUT-FOR CAUSATION IN RICO CASES

Review is also warranted to resolve the sharp conflict between the First Circuit and numerous other federal court decisions regarding the use of aggregate evidence to establish but-for causation in the absence of any showing of actual individualized causation. Indeed, the First Circuit recognized the conflict and stated that "we disagree" with those decisions. Pet. App. 47a n.18.

While conceding a conflict with district court decisions, the First Circuit sought to distinguish federal appeals court decisions on which Pfizer has relied to support its position on but-for causation. Its effort to distinguish those decisions is unconvincing. It conceded that the Second Circuit in *UFCW Local 1776* (a RICO challenge to a drug company's promotional activities) concluded that the plaintiffs failed to establish but-for causation, but it asserted that the Second Circuit's analysis was limited to a different damages theory. Pet. App. 45a.[5] Not so. The Second

[5] The plaintiffs asserted two theories: (1) "excess price" (*i.e.,* the defendants' activities caused them to pay more for the defendants' drugs than they would have in the absence of improper promotion); and (2) "excess quantity" or "quantity effect" (*i.e.,* the defendants' activities caused them to pay for a larger number of

Circuit's discussion of the "quantity effect theory"—the same theory being asserted by Kaiser—stated explicitly:

> The nature of prescriptions, however, means that this theory of causation is interrupted by the independent actions of prescribing physicians. . . . Furthermore, additional variables interfere further with the plaintiffs' theory of causation. As the district court noted, the evidence showed that at least some doctors were not misled by Lilly's alleged misrepresentations, and thus would not have written "excess" prescriptions as identified by the plaintiffs. *This makes general proof of but-for causation impossible.*

IFCW Local 1776, 620 F.3d at 135 (emphasis added).[6] *See also Ironworkers Local Union 68 v. AstraZeneca Pharms., LP*, 634 F.3d 1352, 1363 (11th Cir. 2011) (third-party payer cannot establish economic injury from an improper promotional campaign in the absence of evidence that a patient's doctor would not have prescribed the drug "had he known all the true information about the drug").

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the defendants' drugs). Kaiser raises only the latter type of claim.

[6] The quoted language appears in a section of the opinion that rejected efforts to certify a plaintiff class for the "quantity effect" claim, and does not explicitly address whether that claim could survive a summary judgment motion. Nonetheless, the language is unequivocal in its rejection of assertions that aggregated evidence—unsupported by evidence showing individualized causation—can establish but-for causation.

The First Circuit dispensed with any requirement that Kaiser provide individualized evidence regarding how its doctors would have reacted had they not been subjected to improper promotion from Pfizer. Rather, it held that Kaiser could establish a *prima facie* case of but-for causation based solely on the aggregated evidence gathered by Dr. Rosenthal in her expert report, and that thereafter the burden fell on Pfizer to rebut the inference of causation. Pet. App. 43a. Review of that holding is warranted, not only because it directly conflicts with other appeals court holdings, but also because it unfairly deprives defendants of the ability to defend themselves against individual fraud claims.

The Court recently addressed such unfairness concerns in the context of class-wide treatment of employment discrimination claims. *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541 (2011). The Ninth Circuit had certified a plaintiff class under Fed.R.Civ.P. 23(b)(2) even though the plaintiffs were asserting a claim for monetary relief. The Court reversed the Ninth Circuit's conclusion that backpay awards could be fashioned without the need for individualized consideration of each class member's discrimination claims, rejecting assertions that "it was possible to replace [individualized] proceedings with Trial by Formula." *Id.* at 2560-61. The Court said that under Rule 23, "a class cannot be certified on the premise that Wal-Mart will not be entitled to litigate its statutory defenses to individual claims," because doing so would "abridge" Wal-Mart's "substantive right[s]." *Id*. at 2561.

Allowing Kaiser to establish but-for causation

without providing *any* showing of actual individualized causation would work a similar unfairness on Pfizer. Kaiser does not contest that thousands of doctors continue to prescribe Neurontin for the off-label uses that Kaiser asserts are medically unwarranted, and that the decision of an individual doctor to prescribe Neurontin based on his/her own clinical experience breaks the causal chain between Pfizer's marketing scheme and any injury to Kaiser. Yet, no matter how much additional evidence from treating physicians Pfizer might have introduced, the First Circuit held that Kaiser would nonetheless be permitted to submit its but-for causation claim to the jury based on aggregated evidence alone. Pet. App. 43a.[7]

The First Circuit repeatedly cited to a Seventh Circuit decision in support of its view of but-for causation and the propriety of shifting the burden of proof to Pfizer of rebutting but-for causation. The First Circuit has badly misconstrued that decision. *BCS Services, Inc. v. Heartwood 88, LLC*, 637 F.3d 750 (7th Cir. 2011), was a follow-on decision that arose in connection with the same litigation at issue in *Bridge*.

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[7] The First Circuit noted Dr. Rosenthal's testimony that the statements of individual doctors regarding their motivation for prescribing a drug is deemed "unreliab[le] in the field of healthcare economics." *Id.* at 13a. However, that generally has *not* been the view of courts when a doctor seeks to testify in a failure-to-warn product liability action that he would still have prescribed a drug even if he had been provided the warning the plaintiff deems adequate. *See Garside v. Osco Drug, Inc.*, 976 F.2d 77, 82 (1st Cir. 1992)(in failure-to-warn cases, courts regularly grant summary judgment when "the physician's testimony shows unequivocally that s/he knew at the relevant time all the information which would have been included in a proper warning") (collecting cases).

To support its but-for causation ruling, the First Circuit attributed the following statement to *BCS*: "'Once a plaintiff presents evidence that he suffered the sort of injury that would be the expected consequence of the defendant's wrongful conduct,' the burden shifts to the defendant to rebut this causal inference." Pet. App. at 43a (quoting *BCS*, 637 F.3d at 758).[8] But the First Circuit misses an essential feature of the Seventh Circuit's statement: the burden remains at all times on the plaintiff to establish that he has "suffered [an] injury." Given the extremely direct relationship between the wrongdoing and the economic loss in *Bridge*/*BCS*, the Seventh Circuit concluded that it was at least "probable" that the plaintiff's economic loss was directly attributable to the defendant's wrongdoing, and that "probability" was sufficient to place but-for causation before the jury. *Id.* at 758. In contrast, whether Kaiser's expenditures are an "injury" attributable to Pfizer's wrongdoing, or merely the result of doctors' independent decisions that their patients' needs are best met by an off-label Neurontin prescription, is very much in dispute. Review is warranted to determine whether such a RICO plaintiff can establish but-for causation without introducing evidence that any individual doctor was influenced by the defendant's wrongdoing.

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[8] The First Circuit doctored the quote. *BCS* said nothing about shifting the burden of proof on causation; rather, it said that the requisite showing "would be enough to withstand summary judgment on the ground of absence of causation." 637 F. 3d at 758.

CONCLUSION

Amici respectfully request that the Court grant the Petition.

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