

AUG 30 2013

IN THE

Supreme Court of the United States

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PFIZER INC.; WARNER-LAMBERT COMPANY, LLC,
Petitioners,

v.

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

PFIZER INC.; WARNER-LAMBERT COMPANY, LLC,
Petitioners,

v.

HARDEN MANUFACTURING CORPORATION, ET AL.,
Respondents.

PFIZER INC.; WARNER-LAMBERT COMPANY, LLC,
Petitioners,

v.

AETNA, INC.,
Respondent.

**On Petition for Writs of Certiorari to the
United States Court of Appeals
for the First Circuit**

PETITION FOR WRITS OF CERTIORARI

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QUESTIONS PRESENTED

The court of appeals held that petitioners could be found liable to respondent health insurers and other third-party payors under the Racketeer Influenced and Corrupt Organizations Act (“RICO”), 18 U.S.C. § 1961 *et seq.*, for marketing the drug Neurontin for “off-label” uses for which it is allegedly ineffective. The court of appeals held that, because it is foreseeable that such marketing would cause third-party payors to pay for off-label prescriptions, RICO’s proximate causation requirement is met even though individual physicians’ prescribing decisions are based on multiple independent factors including clinical experience. The court of appeals also held that causation and damages for fraud could be shown by an economist’s aggregate analysis that off-label Neurontin prescriptions increased in relation to marketing expenditures.

The questions presented are:

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.

PARTIES AND RULE 29.6 STATEMENT

Petitioner Pfizer Inc. has no parent corporation and no entity owns 10% or more of its stock. Petitioner Warner-Lambert Company LLC is the successor to Warner-Lambert Company and is wholly owned by Pfizer Inc.

In *Pfizer Inc. v. Kaiser Foundation Health Plan, Inc.*, the respondents are Kaiser Foundation Health Plan, Inc., Kaiser Foundation Hospitals, Kaiser Foundation Health Plan of Colorado, Kaiser Foundation Health Plan of Georgia, Inc., Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc., Kaiser Foundation Health Plan of the Northwest, and Kaiser Foundation Health Plan of Ohio.

In *Pfizer Inc v. Harden Manufacturing Corp.*, the respondents include Harden Manufacturing Corporation, ASEA/AFSCME Local 52 Health Benefits Trust, and Louisiana Health Service Indemnity Company, d/b/a Blue Cross Blue Shield of Louisiana.

In *Pfizer Inc. v. Aetna, Inc.*, the sole respondent is Aetna, Inc.

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Pursuant to Rule 12.4 of the Rules of this Court, petitioners Pfizer Inc. and Warner-Lambert Company LLC (collectively, "Pfizer") respectfully file this single petition for certiorari from three related decisions issued by the court of appeals on the same day, each arising from the same multidistrict litigation concerning Neurontin, a prescription drug made by Pfizer. In each case, health insurers or other third-party payors alleged that Pfizer had made misleading statements and omissions, in violation of RICO and related state statutes, by marketing Neurontin for "off-label" uses. In one decision, the court of appeals affirmed a \$142 million judgment against Pfizer, and in the other two decisions, the court of appeals reversed summary judgments for Pfizer and remanded to allow respondents' RICO and related state-law actions to proceed. The decisions of the court of appeals warrant review by this Court because they conflict with other precedents and raise important and recurring questions concerning the proper test for proximate causation under RICO and the permissibility of aggregate statistical proof in collective fraud cases.

OPINIONS AND ORDERS BELOW

The opinion of the court of appeals in *Kaiser Foundation Health Plan, Inc. v. Pfizer, Inc.* (Pet. App. 1a-56a) is reported at 712 F.3d 21. The district court's findings of fact and conclusions of law in that case (Pet. App. 95a-221a) are unpublished but available at 2011 WL 3852254. The district court's order partially granting and partially denying Pfizer's motion for amended and additional findings (Pet. App. 222a-237a) is reported at 810 F. Supp. 2d 366, the order denying Pfizer's post-trial motion for judgment as a matter of law (Pet. App. 238a) is unpublished, and the order

denying Pfizer's summary judgment motion (Pet. App. 264a-293a) is reported at 677 F. Supp. 2d 479.

The opinion of the court of appeals in *Harden Manufacturing Corp. v. Pfizer, Inc.* (Pet. App. 57a-77a) is published at 712 F.3d 60. The district court's order granting Pfizer summary judgment in that case (Pet. App. 239a-263a) is published at 754 F. Supp. 2d 293. The district court's order denying the *Harden* respondents' renewed motion for class certification (Pet. App. 294a-336a) is published at 257 F.R.D. 315. The district court's order denying reconsideration regarding the renewed motion for class certification (Pet. App. 337a-347a) is unpublished but available at 2011 WL 1882870.

The court of appeals' opinion in *Aetna, Inc. v. Pfizer, Inc.* (Pet. App. 78a-94a) is published at 712 F.3d 51. The district court's order granting Pfizer's motion for summary judgment in that case (Pet. App. 264a-293a) is published at 677 F. Supp. 2d 479.

JURISDICTION

The court of appeals entered judgments in the *Kaiser*, *Harden*, and *Aetna* cases on April 3, 2013. Pet. App. 1a, 57a-58a, 78a. On June 17, 2013, in each case, Justice Breyer extended the time within which to file a petition for a writ of certiorari to and including August 30, 2013. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Relevant provisions of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.*, are reproduced in the Appendix (Pet.

App. 350a). Relevant state statutes are reproduced in the Appendix (Pet. App. 351a-355a).

STATEMENT

More than \$250 billion is spent on prescription drugs in the United States each year, and between twenty and sixty percent of the prescriptions filled are for off-label uses of those drugs. In light of those staggering numbers and RICO's draconian treble damages provisions, 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. In those suits, third-party payors claim that inaccurate marketing led them to overpay for the ensuing prescriptions. In making those claims, they seek to relax traditional causation requirements by arguing that drug marketing is foreseeably related to eventual third-party payments for increased prescriptions. They also offer aggregate statistical evidence in an attempt to overcome the lack of evidence that any individual doctors' prescribing decisions were influenced by any alleged misrepresentations by drug manufacturers.

Until the court of appeals issued the decisions below, the lower courts had overwhelmingly rejected invitations to permit such loose causation requirements and aggregate proof shortcuts, recognizing that individual physicians base their prescribing decisions on innumerable independent factors, including their own clinical experience. For example, in *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010), the Second Circuit addressed substantially similar claims by third-party payors that they had overpaid for prescriptions as a result of the

fraudulent off-label promotion of the drug Zyprexa. The Second Circuit came to two conclusions that conflict with the First Circuit's here. *First*, the court concluded that RICO proximate causation cannot be shown where physicians and pharmacy committees "all play a role in the chain" between drug promotion and payments by third-party payors. *Id.* at 134. *Second*, the court rejected any attempt to cure this problem by "show[ing] proximate cause through generalized proof" of a relationship between marketing and off-label prescriptions, because "[t]he nature of prescriptions . . . means that this theory of causation is interrupted by the independent actions of prescribing physicians." *Id.* at 135.

This petition presents the opportunity to resolve the conflict the decisions below have thus created on the proper test for RICO proximate causation, and to resolve the uncertainty that has arisen in the lower courts from the absence of a controlling opinion on that question in *Hemi Group, LLC v. City of New York*, 559 U.S. 1 (2010). The petition also presents the opportunity to resolve the conflict the decisions below have created on the sufficiency of aggregate proof in the absence of individualized causation. Here, the court of appeals allowed aggregate proof of fraud causation and damages to suffice even where there is no evidence that individual doctors made any individual prescribing decisions based on petitioners' drug marketing. The need for this Court's guidance to the lower courts on both these questions is underscored by the dramatic surge in civil damages actions brought by third-party payors against prescription drug manufacturers for marketing prescription drugs for off-label uses.

A. “Off-Label” Use of Prescription Drugs

Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, new pharmaceutical products may not be sold or otherwise introduced into commerce unless they have been approved by the Food and Drug Administration (the “FDA”). *Id.* § 355(a). To obtain FDA approval, a manufacturer must demonstrate that a drug is both safe and effective for use under the conditions described in the proposed label for the drug. *Id.* § 355(d)(4)-(5). A showing of effectiveness ordinarily requires two double-blind, randomized controlled trials. 21 C.F.R. § 314.126. Manufacturers generally may promote drugs only for uses on labels approved by the FDA. 21 U.S.C. § 352(f); *id.* § 355(b)(1)(F).

By contrast, doctors are free to prescribe drugs for “off-label” uses because the FDA does not regulate the practice of medicine. *Id.* § 396. Off-label use of approved drugs is therefore “widespread in the medical community and often is essential to giving patients optimal medical care.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 351 n.5 (2001) (quotations omitted). As leading medical organizations have noted, off-label use of approved drugs permits physicians to make treatment decisions “in light of all information available and in the best interests of the individual patient.” Am. Medical Ass’n, *Medicare Patient Access*, 18 REPORTS OF BOARD OF TRUSTEES 122, 124 (2004), *available at* www.ama-assn.org/meetings/public/interim04/bot_reports.pdf.

For example, because it is difficult to conduct double-blind, randomized testing for certain illnesses, “[a]n overwhelming majority of cancer, kidney dialysis, and AIDS patients receive treatment for those

conditions with off-label drugs”—and such patients would face “devastating, and perhaps fatal, consequences” if such treatments were not available. Amy E. Todd, *No Need for More Regulation: Payors and Their Role in Balancing the Cost and Safety Considerations of Off-Label Prescriptions*, 37 AM. J.L. & MED. 422, 425 (2011). Similarly, off-label drugs play a crucial role in the treatment of children, who generally cannot be subjected to double-blind, randomized clinical trials; in fact, “80 percent of drugs administered to children are given off-label.” U.S. General Accounting Office, *PRESCRIPTION DRUGS: IMPLICATIONS OF DRUG LABELING AND OFF-LABEL USE*, at 13 n.6 (1996). And off-label uses are often prescribed even to more general patient populations prior to FDA approval; for example, doctors popularized aspirin’s efficacy in reducing the risk of heart attacks decades before the FDA approved that use. See Michael I. Krauss, *Loosening the FDA’s Drug Certification Monopoly: Implications for Tort Law and Consumer Welfare*, 4 GEO. MASON L. REV. 457, 471-72 (1996).

B. Neurontin

Neurontin, known generically as gabapentin, was developed as an anti-epileptic drug in the 1980s and early 1990s by Parke-Davis, an operating division of Warner-Lambert, which was acquired by Pfizer Inc. in 2000. Pet. App. 107a-108a, 112a. In late 1993, the FDA approved Neurontin for use in treating epileptic seizures. Pet. App. 6a. Parke-Davis and later Pfizer filed applications for other uses, and in 2002 the FDA approved Neurontin for treating a type of neuropathic pain (*i.e.*, pain due to nerve damage). Pet. App. 4a n.1, 7a.

Neurontin is widely prescribed for a number of off-label uses, including treatment of bipolar disorder, unapproved types of neuropathic pain, and migraines. Pet. App. 7a. Psychiatrists have long prescribed anti-epileptic drugs such as Neurontin for off-label use in treating bipolar disorder. Pet. App. 242a, 328a. In addition, widely used industry drug compendia recommend Neurontin in some cases for diabetic neuropathy and migraines, *see, e.g.*, DrugDex® Information System, DRUGDEX-EV 1427, at 53, 57 (updated Sept. 2011) (recommending Neurontin), and 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. Pet. App. 55a-56a, 113a n.4.

The record in these cases reflects that Parke-Davis and Pfizer had helped to generate and disseminate information concerning off-label uses of Neurontin by funding studies (Pet. App. 123a-125a, 135a-136a, 148a-149a), publishing articles, case reports, and advertising supplements (Pet. App. 126a-130a, 136a-144a, 147a-148a, 153a-155a), sponsoring continuing medical education events (Pet. App. 131a-133a, 144a-145a, 150a-151a, 154a), and responding to requests from HMOs, third-party researchers, and individual physicians (Pet. App. 133a-134a, 149a, 157a-160a). The district court, relying primarily on the FDA's strict efficacy standards, Pet. App. 170a, found that scientific evidence did not support Neurontin's effectiveness for certain off-label uses, Pet. App. 123a-155a, and that the representations regarding these uses thus were fraudulent.

C. 2004 Penalties For Neurontin Promotion

In 1996, a *qui tam* action was filed alleging that Parke-Davis had promoted Neurontin for off-label uses, Pet. App. 14a-15a, which at the time was treated as a strict-liability offense without regard to the truth of the manufacturer's representations. *But see United States v. Caronia*, 703 F.3d 149, 168 (2d Cir. 2012) (holding the First Amendment precludes "criminalizing the truthful off-label promotion of FDA-approved prescription drugs"). In May 2004, petitioners reached a settlement in which Warner-Lambert agreed to plead guilty to two misdemeanor counts for having marketed Neurontin for off-label purposes in 1995 and 1996 and to pay \$240 million in criminal fines, and Pfizer agreed to pay an additional \$190 million in civil fines. Pet. App. 15a.

D. The District Court Proceedings

Respondents—a health maintenance organization, two insurance companies, a union trust fund, and a self-insured employer—brought these actions against Pfizer in 2004 and 2005, alleging that Pfizer had exaggerated Neurontin's efficacy in publications, continuing medical education seminars, and communications with physicians. In each case, respondents alleged that such inaccurate marketing had led physicians to prescribe, and in turn respondents to pay for, unnecessary off-label uses of the drug.

1. Kaiser

Kaiser Foundation Health Plan, Inc., its six regional health plans and the Kaiser Foundation Hospitals (collectively "Kaiser") operate one of the nation's largest health maintenance organizations.

Kaiser takes an active approach to prescription management and filters information about prescription drugs through several steps. *First*, Kaiser Foundation Hospitals operates a Drug Information Service (“DIS”), which researches and disseminates information about prescription drugs. Pet. App. 104a-105a. *Second*, committees at each of the Permanente Medical Groups (“PMGs”) associated with each Kaiser regional health plan establish each group’s “formulary,” a list of drugs approved for reimbursement. Pet. App. 105a-106a. *Third*, physicians at each PMG associated with a regional health plan issue prescriptions. *Id.*

With respect to Neurontin, DIS prepared monographs in order to assist PMG formulary decisions. Pet. App. 105a-106a, 156a-159a. Two PMG committees added Neurontin to their formularies without restrictions in 1994, before any asserted misrepresentations concerning off-label uses of the drug. Pet. App. 106a. Others added Neurontin to their formularies without restrictions in 1995, 1996, and 2000. Pet. App. 106a-107a. And still others added Neurontin to their formularies in 1994 but restricted its use to neurologists. Pet. App. 106a. Based in part on information that the DIS obtained from Parke-Davis, one of these committees later authorized Neurontin to treat a pain syndrome in 1997 and then removed all restrictions on Neurontin in 1999. Pet. App. 107a. Neurontin remained on all PMG committees’ formularies until at least 2010—as did favorable information about Neurontin’s use for neuropathic pain on Kaiser’s website. Pet. App. 161a.

In February 2005, Kaiser sued Pfizer in the United States District Court for the District of Massachusetts under RICO and California’s Unfair Competition Law

“UCL”), alleging that Pfizer had engaged in a pattern of mail and wire fraud by misrepresenting Neurontin’s efficacy for certain off-label uses. Pet. App. 101a. Kaiser’s claims were part of a multidistrict litigation concerning Neurontin in the District of Massachusetts. In late March 2010, Kaiser’s claims went to trial in that district, and a jury found Pfizer liable for violating RICO and awarded Kaiser \$47,363,092 in damages, which was trebled to \$142,089,276. *Id.* The district court also awarded Kaiser \$95 million on the UCL claims, Pet. App. 220a, but because that amount was encompassed by the jury’s award, entered judgment against Pfizer for amount of the jury award, \$142,089,276, Pet. App. 348a-349a.

The district court found that petitioners had engaged in mail and wire fraud by publishing studies supporting Neurontin’s efficacy for off-label uses while not disclosing negative results, and by making similar claims in continuing medical education seminars and advice to Kaiser’s DIS and individual doctors. Pet. App. 123a-155a. The district court recognized that plaintiffs faced a “difficult challenge” in establishing that this conduct caused issuance of prescriptions for which the plans overpaid “because the prescribing decisions of physicians are influenced by a wide range of factors, including their own clinical experience and the clinical experience of their colleagues.” Pet. App. 163a-164a.

All the prescribing doctors who testified at trial—including Kaiser’s experts—denied relying on any misrepresentations by Pfizer. Pet. App. 164a. And the district court repeatedly acknowledged that no physician in the multidistrict litigation has ever stated that he or she prescribed Neurontin for off-label use based on the alleged misrepresentations. *See, e.g.*, Pet.

App. 259a, 285a, 327a-328a, 345a. Nonetheless, the district court found that Kaiser had established proximate causation by presenting evidence that Pfizer's promotional activities had "affected decisions about Neurontin's placement on formulary without restrictions" and that "Kaiser has a 95% compliance rate with its formulary." Pet. App. 160a-161a.

In awarding damages, the district court relied upon a statistical analysis by Dr. Meredith Rosenthal, a health economist. Pet. App. 164a-168a. Dr. Rosenthal examined the impact of all Pfizer promotional activities upon Neurontin sales. Pet. App. 164a-165a & n.19. Dr. Rosenthal did not disaggregate expenditures on off-label marketing that was fraudulent, but simply assumed that such marketing had the same effect as Pfizer's overall expenditures, and concluded that those expenditures caused approximately 99% of Neurontin prescriptions for bipolar disorder, 70% for neuropathic pain, 28% for migraines, and 38% for enlarged dosages, Pet. App. 166a.

2. Harden

The *Harden* respondents—an insurance company, a union trust fund, and a self-insured employer, all of which act as third-party payors providing medical and prescription drug coverage to their members—sued Pfizer in May 2004 on behalf of a putative nationwide class of third-party payors. Pet. App. 60a-61a. The *Harden* plaintiffs claimed that, in violation of RICO, the New Jersey Consumer Fraud Act, N.J. Stat. Ann. §§ 56:8-1 to 56:8-195, and state common law, Pfizer had engaged in a pattern of mail and wire fraud by misrepresenting Neurontin's efficacy for bipolar

disorder. Pet. App. 59a; *see also* Pet. App. 343a (dropping claims respecting other off-label uses).

The *Harden* case was transferred to the Neurontin multidistrict litigation in the District of Massachusetts, where the *Harden* plaintiffs asserted that Pfizer had misrepresented Neurontin's efficacy in publications, seminars, and communications directly to doctors, Pet. App. 296a-298a, causing non-party physicians to write unwarranted Neurontin prescriptions for off-label uses for which respondents had overpaid, Pet. App. 64a. The *Harden* plaintiffs sought to rely upon the same aggregate analysis Dr. Rosenthal presented in *Kaiser* in order to establish causation and damages. Pet. App. 261a, 322a-325a.

In May 2009, the district court denied the *Harden* plaintiffs' requests to certify a class of third-party payors. *See* Pet. App. 330a-336a. In December 2010, after the *Kaiser* jury trial and based in part on the record and findings from that trial, the district court granted Pfizer summary judgment in *Harden* on the ground that the *Harden* plaintiffs "cannot establish causation" because they "have not directly relied on misrepresentations by defendants" and failed to show "how many or which physicians who prescribed Neurontin to their members relied on fraud." Pet. App. 262a-263a.

In so holding, the district court rejected the plaintiffs' attempted reliance upon Dr. Rosenthal's regression analysis, reasoning that it "does not suffice to demonstrate the extent of harm caused by the fraud, as opposed to run-of-the-mill off-label detailing." Pet. App. 261a; *see also* Pet. App. 328a (noting that the Rosenthal study "d[id] not take into account any other factors that may have led doctors to prescribe

Neurontin for off-label indications”). Citing numerous decisions in similar cases throughout the nation, the court held that the Rosenthal opinion was the type of “aggregate proof” that “[m]ost courts have rejected” as incapable of proving class-wide reliance in cases such as this one. Pet. App. 261a-262a.

3. *Aetna*

Respondent Aetna, Inc., an insurance company that provides medical and prescription drug coverage to its members, sued Pfizer in May 2004 for violating RICO and Pennsylvania law. Like Kaiser and the *Harden* plaintiffs, Aetna claimed that Pfizer had engaged in a pattern of mail and wire fraud by misrepresenting Neurontin’s efficacy for various off-label uses, Pet. App. 264a-265a, and sought to rely on Dr. Rosenthal’s aggregate analysis to establish causation as well as damages, Pet. App. 282a-287a. In January 2010, before the *Kaiser* trial, the district court granted Pfizer’s motion for summary judgment in *Aetna* for much the same reasons it later did so in *Harden*. Pet. App. 289a-290a. Specifically, the district court noted that, “despite over a decade of Neurontin-related litigation, which I have presided over as the multi-district litigation judge, no evidence has been presented of any doctor who states that she relied on a misrepresentation or omission in prescribing Neurontin for an off-label indication.” Pet. App. 285a. Finding Dr. Rosenthal’s aggregate analysis “legally insufficient to effectively segregate damages caused by Defendants’ misrepresentations from damages caused by other sources,” Pet. App. 289a-290a; *see also id.* at 284a-285a (noting other decisions holding that “a plaintiff TPP or class must prove through individualized evidence that the misrepresentation caused specific physicians, TPPs, or consumers to rely

on the fraud, and cannot rely on aggregate or statistical proof”), the district court held that Aetna could not survive summary judgment on causation.

E. The Court of Appeals Decisions

Pfizer appealed the district court’s judgment in *Kaiser*, and the *Harden* and *Aetna* respondents appealed the summary judgments against them. Although the appeals were briefed separately, they were assigned to the same panel, which heard argument in all three cases on the same day and issued simultaneous decisions.

In *Kaiser*, the court of appeals affirmed the \$142 million damages judgment against Pfizer. The court rejected Pfizer’s argument that the chain of events between Pfizer’s misrepresentations and Kaiser’s alleged injury was too attenuated to satisfy RICO’s “proximate cause ‘direct relation’ requirement.” Pet. App. 28a. It did so even though that chain involved “at least four steps: Pfizer communicating tainted information about Neurontin to Kaiser’s DIS; the DIS producing monographs that rely on the misrepresentations; those monographs influencing the PMGs in their formulary decisions; and the prescribing physicians (who exercise independent medical judgment) acting within the formulary to issue the prescriptions.” *Id.* Instead, the court of appeals held, “the causal chain in this case is anything but attenuated” because “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.” Pet. App. 29a-30a. The court of appeals dismissed “[t]he fact that some physicians may have considered factors other than Pfizer’s detailing materials in making their prescribing

decisions” as merely “a damages question” rather than a matter of causation. Pet. App. 31a.

To the contrary, in the court of appeals’ view, RICO proximate causation requires only a showing that an “injury was plainly foreseeable and was in fact foreseen,” Pet. App. 28a; *see id.* at 31a (citing *BCS Servs., Inc. v. Heartwood 88, LLC*, 637 F.3d 750, 754 (7th Cir. 2011) (stating that proximate cause “does its work” where “defendant couldn’t have foreseen the effect of his wrongdoing”)). And in the court of appeals’ view, that lenient foreseeability test was satisfied here by general knowledge about the “structure of the American health care system.” Pet. App. 29a-30a.¹

The court of appeals further held in *Kaiser* that Dr. Rosenthal’s aggregate statistical evidence was legally sufficient proof of but-for causation. Pet. App. 35a-47a. The only testimony by prescribing doctors was that “their decisions to prescribe Neurontin were *not* influenced by Pfizer’s fraudulent marketing.” Pet. App. 43a-44a (emphasis added). The court of appeals nonetheless held that it was not Kaiser’s burden to show that doctors were so influenced but rather Pfizer’s burden to show that they were not. Pet. App. 43a (holding that “the burden shifts to the defendant” once a plaintiff shows the “sort of injury” that was foreseeable).

The court of appeals also reversed the summary judgments entered on the RICO claims in the *Harden* and *Aetna* cases. *See* Pet. App. 77a (also vacating

¹ The court of appeals noted the parties’ assumption that proximate causation under the UCL is the same as under RICO. Pet. App. 20a n.8.

dismissal of state law claims and denial of class certification); Pet. App. 94a (also vacating dismissal of state law claims).

In *Harden*, relying explicitly upon its decision in *Kaiser*, the court of appeals held that evidence that the plaintiffs there were “the primary and intended victims of [Pfizer’s] scheme to defraud” and that their injury was “a foreseeable and natural consequence’ of Pfizer’s scheme” was sufficient for the plaintiffs to survive summary judgment on proximate causation. Pet. App. 70a (alteration in original) (citation omitted). The court of appeals likewise found, again relying on the *Kaiser* opinion, that Dr. Rosenthal’s aggregate statistical evidence (plus similar anecdotal evidence) was sufficient to overcome summary judgment, despite the testimony from individual physicians that “they prescribed Neurontin for off-label uses without relying on Pfizer’s misrepresentations.” Pet. App. 73a.

In *Aetna*, the court of appeals similarly relied upon its decision in *Kaiser* and held that Aetna had presented evidence sufficient to satisfy RICO’s proximate causation requirement because “[a] jury could have found that Aetna, like Kaiser, was the primary and intended victim of the scheme to defraud, and that the injury suffered was a foreseeable and natural consequence of the fraudulent scheme.” Pet. App. 91a (quotation omitted). In addition, the court of appeals held Dr. Rosenthal’s aggregate statistical evidence (plus similar anecdotal evidence) sufficient to defeat summary judgment on but-for causation. Pet. App. 89a-90a.

REASONS FOR GRANTING THE WRIT

I. THE COURT OF APPEALS' RULINGS ON RICO PROXIMATE CAUSATION CONFLICT WITH THE DECISIONS OF OTHER CIRCUITS AND RAISE AN IMPORTANT AND RECURRING QUESTION LEFT OPEN BY *HEMI GROUP*

RICO permits private individuals to sue for treble damages and attorney's fees if they are "injured in [their] business or property by reason of" certain statutory violations. 18 U.S.C. § 1964(c). RICO was enacted "to provide new weapons of unprecedented scope for an assault upon organized crime and its economic roots," *Russello v. United States*, 464 U.S. 16, 26 (1983), but civil RICO claims have taken the statute far afield from its roots, with more than 7,500 civil RICO cases filed in the past decade alone.² And "there is no such thing as prosecutorial discretion to limit the use of civil RICO by plaintiffs' attorneys." William H. Rehnquist, *Remarks of the Chief Justice*, 21 ST. MARY'S L.J. 5, 10 (1989).

In light of this sweeping potential for limitless civil RICO litigation against a wide array of business practices far afield from organized crime, and the

² See Administrative Office of the United States Courts, Office of Judges Programs, Statistics Division, *Statistical Tables For The Federal Judiciary*, Table C-2 (2003-2012), available at <http://www.uscourts.gov/Statistics/StatisticalTablesfortheFederalJudiciary.aspx>; Lee Coppola & Nicolas DeMarco, *Civil RICO: How Ambiguity Allowed the Racketeer Influenced and Corrupt Organizations Act to Expand Beyond Its Intended Purpose*, 38 NEW ENG. J. ON CRIM. & CIV. CONFINEMENT 241, 254 (2012).

specter of treble damages, this Court has repeatedly interpreted civil RICO claims as limited by a meaningful proximate causation requirement. In *Holmes v. Securities Investor Protection Corporation*, 503 U.S. 258 (1992), this Court held that RICO’s requirement that a private individual suing under the statute be injured “by reason of” a statutory violation requirement is a “demand for some direct relation between the injury asserted and the injurious conduct alleged.” *Id.* at 268. The Court reaffirmed this “direct relation” test for RICO proximate causation in *Anza v. Ideal Steel Corporation*, 547 U.S. 451, 461 (2006) (describing the proper inquiry as “whether the alleged violation led directly to the plaintiff’s injuries”).

The failure of any opinion to command a majority in *Hemi Group, LLC v. City of New York*, 559 U.S. 1 (2010), however, has led to uncertainty on the proper test for RICO causation. Compare *id.* at 12 (plurality opinion) (basing RICO proximate causation “on the directness of the relationship between the conduct and the harm”), with *id.* at 18-19 (Ginsburg, J., concurring in part and concurring in the judgment), and *id.* at 22-29 (Breyer, J., dissenting). While many lower courts have continued to take guidance from the “direct relation” test set forth in *Holmes* and *Anza* and embraced in the plurality opinion in *Hemi Group*, the decisions below instead adopt a foreseeability test akin to the one articulated in the *Hemi Group* dissent. See *id.* (Breyer, J., dissenting). The proximate causation issue warrants this Court’s review to resolve the uncertainty created by the divided opinions in *Hemi Group* and to give much-needed guidance to the lower courts, which are now in conflict on this issue.

A. The Court Of Appeals' Proximate Cause Decisions Conflict With The Direct-Relation Test Set Forth In *Holmes* And *Anza*

In each of the decisions below, the court of appeals held that RICO proximate causation is satisfied by a showing of intent and foreseeability without regard to the directness of the causal chain. These rulings conflict with the “direct relation” test set forth in *Holmes* and *Anza*, adopting instead a test of mere foreseeability. While embraced by the *Hemi Group* dissent, such a foreseeability test was rejected in *Anza*. In *Anza*, the plaintiff alleged that a competitor had fraudulently failed to pay sales tax as part of a scheme to lower its costs so that it could undercut the plaintiff's prices, and argued that its injury was the intended and foreseeable consequence of the competitor's unlawful behavior. 547 U.S. at 454-55. This Court disagreed, holding that “[a] RICO plaintiff cannot circumvent the proximate cause requirement simply by claiming that the defendant's aim was to increase market share at [the plaintiff's] expense.” *Id.* at 460.

The court of appeals below, in contrast, held that the “core proximate causation principle” under RICO is compensating the intended or foreseeable victims of a defendant's wrongful conduct. Specifically, according to the court of appeals, RICO's “core proximate causation principle” is “allowing compensation for those who are directly injured” in the sense that their “injury was plainly *foreseeable* and was in fact *foreseen*, and who were the *intended* victims of a defendant's wrongful conduct.” Pet. App. 28a (emphases added). The court of appeals found that principle satisfied so long as respondents' injury was a “foreseeable and

natural consequence” of the scheme. Pet. App. 70a. Moreover, the court adopted a lenient view of such foreseeability, finding it capable of proof simply by reference to the general “structure of the American health care system,” in which it is generally known that insurers, not physicians, pay for the drugs that physicians prescribe. Pet. App. 29a-30a.

The decisions below mention *Anza* and *Hemi Group* only in passing. Pet. App. 69a. *Kaiser* devotes only two sentences to *Anza*, Pet. App. 23a, and its footnote discussing *Hemi Group* fails to mention the plurality’s treatment of foreseeability, Pet. App. 28a-29a n.12. While the court of appeals mentions *Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639 (2008), decided between *Anza* and *Hemi Group*, see Pet. App. 24a-27a, 30a, *Bridge* cannot reconcile the decisions below with the *Holmes-Anza* direct-relation test. *Bridge* considered an issue that *Anza* did not reach, namely, whether RICO requires mail and wire fraud claims to be based on direct reliance. *Bridge*, 553 U.S. at 646 n.4. *Bridge* states that the plaintiffs there were the “primary and intended victims of the scheme to defraud,” *id.* at 650, and that the plaintiffs’ injury in that case was “a foreseeable and natural consequence,” *id.* at 658. But *Bridge* did not reconsider *Anza* or hold contrary to *Anza* that intent and foreseeability are enough to establish RICO proximate causation.

The choice of RICO proximate causation test is crucial in third-party payor cases like those below, for the chain of causation asserted by respondents and accepted by the court of appeals, even if somehow foreseeable, was far too attenuated to be direct. It involves at least three steps: (i) petitioners’ communication to the medical community of various allegedly misleading statements, which (ii) influenced

physicians to prescribe Neurontin, which (iii) caused respondents, who chose not to restrict insurance coverage for off-label Neurontin use, to pay for those prescriptions. (In *Kaiser*, the chain involved yet a fourth step, which took place when the PMG groups either placed Neurontin on their formularies without restriction or removed existing restrictions; the court ignored this step by suggesting that all the distinct Kaiser entities could be treated as “a single entity,” Pet. App. 30a n.13.) Because this chain of causation is indirect and attenuated, and necessarily depends on non-party physicians’ innumerable discretionary and multi-factored prescribing decisions, it falls well short of proximate causation as this Court’s direct-relation requirement has defined it. *Anza*, 547 U.S. at 460.

The indirectness of the causal relationship here is underscored by several aspects of the decisions below. *First*, the RICO claims the court of appeals permitted or upheld were based on alleged misrepresentations with no direct connection to respondents’ injury. For example, respondents claim that petitioners “detailed” sales representatives to visit doctors’ offices to make allegedly misleading presentations, but presented “no evidence as to what the detailers said to any of the doctors.” Pet. App. 260a. Likewise, respondents claim that petitioners sponsored various misleading publications, but presented “no evidence as to . . . what [publications] any of the doctors read.” *Id.*; see Pet. App. 285a-286a.

Second, undisputed evidence in all three cases shows that “the prescribing decisions of physicians are influenced by a wide range of factors, including their own clinical experience and the clinical experience of their colleagues.” Pet. App. 164a; see Pet. App. 328a.

Third, there is no evidence in any of the three cases (or the multidistrict litigation as a whole) that even a single individual physician relied upon any alleged misrepresentations in prescribing Neurontin. As the district court noted, “no individual physician testified in [the *Kaiser*] case (or in the MDL litigation as a whole) that he or she prescribed Neurontin as a result of fraudulent off-label promotion.” Pet. App. 164a. Instead, “treating physicians . . . testified repeatedly that they relied on their own clinical experience or the clinical experience of trusted colleagues, rather than Pfizer’s misleading advertising.” Pet. App. 345a.

Accordingly, whether respondents in each of the cases below can satisfy the RICO proximate causation requirement depends pivotally upon whether the causal connection between Pfizer’s marketing and respondents’ alleged injuries must be merely foreseeable or instead must be direct. In holding that petitioners’ focus on the number of steps involved “misconstrues” this Court’s direct relation test, Pet. App. 28a, the court of appeals’ decisions show the need for this Court’s guidance as to which RICO proximate causation test now governs—directness or foreseeability—especially in light of the fact that neither test commanded a majority in *Hemi Group*.

B. The Court Of Appeals’ Proximate Cause Decisions Conflict With Decisions Of Other Circuits

The decisions below also conflict with decisions of other circuits concerning RICO’s proximate cause requirement. As noted above, *see supra* pp. 3-4, the Second Circuit held in *Lilly*, 620 F.3d 121, that economic injuries claimed by third-party payors based on the allegedly fraudulent off-label promotion of the

prescription drug Zyprexa failed to establish proximate cause, even if the plaintiffs' injuries were "the foreseeable and natural consequence of petitioners' scheme." *Id.* at 129.³ *Lilly* emphasized that the chain of causation was "interrupted by the independent actions of prescribing physicians," *id.* at 135, and that there were numerous potential independent factors influencing those actions, including "[a]n individual patient's diagnosis, past and current medication being taken by the patient, the physician's own experience with prescribing Zyprexa, and the physician's knowledge regarding the side effects of Zyprexa," *id.*

Similarly, in *United Food & Commercial Workers Central Pennsylvania & Regional Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255 (9th Cir. 2010), an employee health and welfare fund and others that, like respondents, pay for prescription drugs, sued a drug manufacturer under RICO for allegedly fraudulent promotion of prescription drugs for off-label uses. Much as in the cases here, the connection between this alleged misconduct and the plaintiffs' alleged injury—overpayment for prescriptions—involved multiple "independent links," including "doctors' decisions to prescribe [the drug off-label]." *Id.* at 257. The plaintiffs argued that RICO's proximate causation requirement was satisfied because the injury they suffered from paying for prescriptions for off-label uses was the "direct, natural, and foreseeable result" of

³ Brief for Plaintiffs-Appellees, *UFCW Local 1776 v. Eli Lilly & Co.*, No. 09-0222-cv, at 36 (2d Cir. June 19, 2009) (arguing that RICO's proximate cause requirement was satisfied because their injury was "the foreseeable and natural consequence of petitioners' scheme") (quotation omitted).

the manufacturer's fraudulent scheme.⁴ The Ninth Circuit rejected that argument, citing the plurality opinion in *Hemi Group* and holding that "[t]his causal theory is too attenuated to satisfy the Supreme Court's proximate causation requirement in the RICO context." *Id.*⁵

At least four other circuits similarly have recognized that RICO's direct-relation test for proximate causation is not satisfied by mere foreseeability. See *Green Leaf Nursery v. E.I. DuPont De Nemours & Co.*, 341 F.3d 1292, 1307 (11th Cir. 2003) (affirming dismissal of RICO claims despite allegations of direct targeting "because the directness inquiry is not a question of specific intent"); *Perry v. American Tobacco Co.*, 324 F.3d 845, 850 (6th Cir. 2003) ("foreseeability . . . is distinct from the requirement of a direct injury"); *Serv. Employees Int'l Union Health & Welfare Fund v. Philip Morris Inc.*, 249 F.3d 1068, 1076 (D.C. Cir. 2001) ("Foreseeability and direct injury . . . are distinct concepts, both of which generally must be established by a plaintiff.")

⁴ Brief of Appellants, *United Food & Commercial Workers Cent. Pa. & Reg'l Health & Welfare Fund v. Da-Vita, Inc.*, No. 09-56118, at 34 (9th Cir. Jan. 4, 2010).

⁵ District courts in other circuits have likewise held the RICO proximate cause requirement unsatisfied where the connection between pharmaceutical company promotions and prescribing decisions is indirect and interrupted by the independent actions of prescribing physicians. See, e.g., *Ironworkers Local Union No. 68 v. AstraZeneca Pharms. LP*, 585 F. Supp. 2d 1339, 1344 (M.D. Fla. 2008), *aff'd on other grounds*, 634 F.3d 1352 (11th Cir. 2011); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, MDL No. 2100, 2010 WL 3119499, at *6-7 (S.D. Ill. Aug. 5, 2010).

(quotation omitted); *Allegheny Gen. Hosp. v. Philip Morris, Inc.*, 228 F.3d 429, 441 (3d Cir. 2000) (“specific intent to harm does not magically . . . cause alleged antitrust [and RICO] injuries to be direct”); *see also Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 927 (3d Cir. 1999) (“Although [some of] the alleged *wrongdoing* was more directly aimed at the Funds, the *injury* itself certainly was no more direct than the indirect injury that arose from the defendants’ actions toward smokers.”).

The decisions below cannot be reconciled with these decisions. Like the plaintiffs in *Lilly* and *Amgen*, respondents allege that they were forced to overpay for prescriptions as a result of misleading off-label promotion, but the court of appeals held that this chain satisfied RICO’s proximate cause requirement merely because respondents’ prescription payments were intended and foreseeable. This conflict among the courts of appeals warrants the Court’s review.

C. The Proximate Cause Question Raised By The Decisions Below Is Important and Recurring

The question presented by the decisions below concerning the touchstone of RICO’s proximate cause requirement—directness or foreseeability—further warrants review by this Court because it affects a large number of cases, involving massive potential damages, in which the lower courts are in need of this Court’s guidance. More than 7,500 civil RICO suits have been filed in the past decade alone. The vast amounts—approximately \$250 billion—spent each year on prescription drugs, and the relative ease with which RICO claims may be based on mail or wire fraud, has led to a growing number of RICO claims

seeking treble damages based on alleged fraudulent off-label promotion by pharmaceutical companies. While the lower courts have for the most part rejected such claims on various grounds,⁶ the First Circuit's rulings below are an open invitation to forum shopping that will likely result in a dramatic escalation in such claims. See Thomas M. Greene, *A New Weapon in Pharma Cases*, 47 TRIAL 40, 44 (Nov. 2011) (authored by respondents' counsel in *Harden*) (predicting increased RICO litigation against pharmaceutical companies because "RICO's powerful remedies make it an attractive tool" for civil litigants in such cases). If left unreviewed, the decisions below threaten to upend the ability of the lower courts to deal with such cases with certainty and expedition.

⁶ See, e.g., *Lilly*, 620 F.3d at 135-36; *Amgen, Inc.*, 400 F. App'x at 257; *Ironworkers Local Union No. 68 v. AstraZeneca Pharms., LP*, 634 F.3d 1352, 1360 (11th Cir. 2011); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 248 (3d Cir. 2012); *Se. Laborers Health & Welfare Fund v. Bayer Corp.*, 444 F. App'x 401, 410 (11th Cir. 2011); *Health Care Serv. Corp. v. Pharmacia & Upjohn, Inc. (In re Bextra and Celebrex Mktg. Sales Practices and Prods. Liab. Litig.)*, No. 11-CV-00310, 2012 WL 3154957, at *5-7 (N.D. Cal. Aug. 2, 2012); *Health Care Serv. Corp. v. Pfizer, Inc.*, 2:10-CV-221, 2012 WL 2505555 (E.D. Tex. Apr. 23, 2012), *report and recommendation adopted*, 2012 WL 2504884 (E.D. Tex. June 28, 2012); *Health Care Serv. Corp. v. Olivares*, No. 2:10-CV-221-TJW-CE, 2011 WL 4591913, at *6-7 (E.D. Tex. Sept. 2, 2011), *report and recommendation adopted*, 2011 WL 4591915 (E.D. Tex. Sept. 30, 2011); *Dist. 1199P Health & Welfare Plan v. Janssen*, 784 F. Supp. 2d 508, 523-25 (D.N.J. 2011); *In re Yasmin & Yaz*, 2010 WL 3119499, at *5-8; *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037, 1049-53 (N.D. Cal. 2009), *aff'd*, 464 F. App'x 651 (9th Cir. 2011); *S. Ill. Laborers' & Employers Health & Welfare Fund v. Pfizer Inc.*, No. 08cv5175, 2009 WL 3151807, at *5-7 (S.D.N.Y. Sept. 30, 2009).

II. THE COURT OF APPEALS' DECISIONS CONFLICT WITH OTHER DECISIONS ON THE IMPORTANT AND RECURRING QUESTION OF THE SUFFICIENCY OF AGGREGATE STATISTICAL PROOF

This Court has expressed concern in other contexts with a “Trial by Formula” approach to litigation that relies on aggregate models in place of individualized inquiries into the transactions or occurrences that purportedly caused a plaintiff’s injury. *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541, 2560-61 (2011) (holding that the defendant in an employment discrimination case “is entitled to individualized determinations of each employee’s eligibility for backpay”); *see also, e.g., Philip Morris USA v. Williams*, 549 U.S. 346, 353 (2007) (holding that Due Process requires that the defendant be afforded “an opportunity to present every available defense” (citation omitted)); *cf. Comcast Corp. v. Behrend*, 133 S. Ct. 1426, 1433 (2013) (holding that “any [statistical] model supporting a ‘plaintiff’s damages case must be consistent with its liability case”).

The court of appeals’ decisions trigger similar problems insofar as they rely upon Dr. Rosenthal’s aggregate analysis as the core proof of causation and damages in all three decisions. Despite Dr. Rosenthal’s admitted failure to measure the impact of the alleged misrepresentations actually at issue, or to account for the numerous independent factors that influence individual physicians’ prescribing decisions, the decisions below held that her mathematical analysis was sufficient to establish causation and damages and shifted the burden to Pfizer to demonstrate alternative causes. If allowed to stand,

these decisions will invite the widespread use of such procedures in RICO and other fraud actions.

A. The Court Of Appeals' Decisions Conflict With Decisions Of Other Lower Courts Concerning The Use Of Aggregate Evidence To Prove Fraud Causation And Damages

The court of appeals' decisions create a conflict with the decisions of the Second Circuit and other lower courts as to the use of aggregate proof to show collective fraud.

For example, in denying certification of a class of third party payors, the Second Circuit held in *Lilly* that plaintiffs could not establish causation and damages through "generalized proof" of the impact of marketing on prescriptions. 620 F.3d at 134-35. The court there reasoned that this is so because prescribing decisions are based on multiple considerations, many of which were independent of any fraudulent promotion by Lilly. *Id.*; *see also id.* at 136 (noting that plaintiffs "cannot use generalized proof when individual physicians prescribing Zyprexa may have relied on Lilly's alleged misrepresentations to different degrees, or not at all"). Indeed, the Second Circuit went so far as to hold that "evidence show[ing] that at least some doctors were not misled by Lilly's alleged misrepresentations . . . makes general proof of but-for causation impossible." *Id.* at 135.

As the decision below acknowledged, Pet. App. 74a, numerous district courts in other circuits have also held that third-party payors asserting fraudulent drug

promotion claims cannot prove causation or damages through aggregate evidence.⁷

The decisions below cannot be reconciled with such rulings. Here, as in *Lilly*, it was undisputed that individual physicians base their prescribing decisions upon numerous considerations. Pet. App. 164a, 328a, 345a. Also as in *Lilly*, respondents sought to establish causation through aggregate statistical analysis showing that promotional spending increases prescriptions in general. Pet. App. 35a-47a, 71a-74a, 89a-90a. Unlike in *Lilly*, however, the decisions below held that such generalized evidence could be sufficient to prove but-for causation, even if not a single prescribing physician testified that pharmaceutical marketing fraud influenced any prescribing decisions. *Id.*

The *Harden* decision attempted to distinguish *Lilly* on the ground that the plaintiffs in that case “allege a ‘quantity effect’ rather than an ‘excess price’ theory.” Pet. App. 74a. But, while the *Lilly* plaintiffs advanced excess-price as well as quantity-effect theories, see 620

⁷ See, e.g., *Ironworkers Local Union No. 68*, 585 F. Supp. 2d at 1344; *Pa. Emps. Benefit Trust Fund v. AstraZeneca Pharms., LP*, No. 6:09-cv-5003-Or1-22DAB, 2009 WL 2231686, at *5-6 (M.D. Fla. July 20, 2009); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, Master File No. 2:06-cv-5774 (SRC), 2009 WL 2043604, at *24-26 (D.N.J. July 10, 2009); *Se. Laborers Health & Welfare Fund v. Bayer Corp.*, 655 F. Supp. 2d 1270, 1280-83 (S.D. Fla. 2009); *Dist. 1199P Health & Welfare Plan*, 784 F. Supp. 2d at 524-25; *Pa. Emps. Benefit Trust Fund v. Eli Lilly & Co.*, No. 2970, 2009 WL 4768195, at *1-2 (Pa. Ct. C.P. Dec. 10, 2009); *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d at 1052-54; *Health Care Serv. v. Pfizer*, 2012 WL 2505555, at *3-4; *Health Care Serv. v. Olivares*, 2011 WL 4591913, at *6-7.

F.3d at 133-36, the Second Circuit held that *neither* theory was susceptible to generalized proof, *see id.* at 133 (holding that the “excess price theory [was] not susceptible to generalized proof”); *id.* at 136 (holding that plaintiffs “cannot use generalized proof” to establish their quantity-effect theory). Similarly, contrary to *Kaiser’s* suggestion, Pet. App. 46a, while *Lilly’s* ruling concerning aggregate proof came up in connection with class certification, it was not limited to that context. In any event, the distinction fails because respondents’ claims here that they overpaid for prescriptions as a result of the alleged misrepresentations are “in the nature of a structural class action.” *Hood ex rel. Mississippi v. Eli Lilly & Co.*, 671 F. Supp. 2d 397, 433 (E.D.N.Y. 2009).

Accordingly, the court of appeals’ rulings on aggregate proof conflict with *Lilly* and similar district court decisions. Unlike *Lilly*, the decisions below also depart from the well-established principle that fraud claims are unsuitable for generalized proof—and, thus, class treatment—“[i]f there is any material variation in the representations made, or in the degrees of reliance thereon.” Joseph M. McLaughlin, *McLAUGHLIN ON CLASS ACTIONS* § 5:54 (9th ed. 2012); *accord* Fed. R. Civ. P. 23(b)(3) advisory committee’s note (“a fraud cause may be unsuited for treatment as a class action if there was material variation in the representations made or in the kinds or degrees of reliance by the persons to whom they were addressed”). In each case below, there were material variations in both the asserted misrepresentations and individual doctors’ supposed reliance on those misrepresentations. The Rosenthal statistical analysis ignored these variations by correlating increases in prescriptions over time with overall increased

spending on detailing, advertisements, and distribution of retail samples. Pet. App. 11a & n.4.

The court of appeals held that such variations in injury and reliance do not matter because, once a tort plaintiff has presented evidence of causation, “he doesn’t have to offer evidence which positively excludes every other possible cause” of an event. Pet. App. 43a, 73a (quotation omitted). Thus, the court of appeals, in allowing the aggregate analysis, in effect shifted the burden to Pfizer to prove that the alleged misrepresentations were *not* the cause of those decisions, instead of requiring respondents to prove that they were—provided merely that respondents suggested that they had “suffered the sort of injury that would be the expected consequence of the defendant’s wrongful conduct,” Pet. App. 43a, 73a (quotation omitted). The court of appeals thus imposed upon Pfizer the burden of disaggregating the various bases of the numerous, individualized decisions of physicians who prescribe prescription drugs for off-label use. Nothing in RICO or any other fraud law contemplates such a restructuring of burdens of proof through the use of aggregate evidence.

B. The Question Of The Sufficiency Of Aggregate Statistical Proof Is Also Important And Recurring

The court of appeals’ liberal approach to allowing aggregate proof of fraud causation and damages to substitute for individualized proof further warrants this Court’s review because it threatens to invite similar trial by formula in other drug promotion cases. The question of aggregate proof frequently arises where, as here, third-party payors sue pharmaceutical

manufacturers for fraudulent promotion under RICO and seek to prove causation and damages through generalized proof. *See supra* p. 29 n.7. The question also frequently arises in other contexts—for example, in fraud class actions in which plaintiffs seeking to certify a class must show that causation or reliance is susceptible to generalized proof in order to satisfy Rule 23(b)(3)’s commonality and superiority requirements. *See supra* p. 30.

Until the decisions below, other lower courts had overwhelmingly rejected such liberal use of aggregate evidence to eliminate the requirement of individualized proof. *See supra* p. 29 n. 7. By allowing plaintiffs to prove causation and damages simply by pointing to promotional spending by manufacturers concerning off-label usage, without showing that prescribing physicians relied upon any misrepresentations, the decisions below now invite an unlimited escalation in RICO and related cases against pharmaceutical companies for off-label promotion using the shortcut of aggregate proof. Whether aggregate statistical evidence can suffice to show RICO causation in the absence of individualized proof thus is a question of recurring importance warranting this Court’s review.

CONCLUSION

The Court should grant this petition for a writ of certiorari.

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Respectfully submitted,

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