No. 14-2318-cv

United States Court of Appeals for the Second Circuit

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

Plaintiffs–Appellants,

STATE OF LOUISIANA, CITIZENS OF THE STATE OF LOUISIANA, LOUISIANA DEPARTMENT OF HEALTH AND HOSPITAL, AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED, CHARLES C. FOTI, JR., IN HIS OFFICIAL CAPACITY AS THE ATTORNEY GENERAL FOR THE STATE OF LOUISIANA AS PARENS PATRIAE ON BEHALF OF,

Plaintiffs,

v.

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

Defendants–Appellees.

On Appeal from the United States District Court
for the Eastern District of New York

BRIEF OF PUBLIC JUSTICE, P.C. AND THE AMERICAN ASSOCIATION FOR JUSTICE AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLANTS

Elizabeth J. Cabraser
Jordan Elias
Lieff Cabraser Heimann & Bernstein, LLP
275 Battery Street, 29th Floor
San Francisco, CA 94111-3339
(415) 956-1000

Matthew W.H. Wessler
Public Justice, P.C.
1825 K Street NW, Suite 200
Washington, DC 20006
(202) 797-8600

Jeffrey R. White
Center for Constitutional Litigation, P.C.
777 Sixth Street NW, Suite 520
Washington, DC 20001
(202) 944-2839

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CORPORATE DISCLOSURE STATEMENT

Public Justice, P.C., is a professional corporation. It does not have any parent companies, and there is no publicly held corporation that owns 10% or more of its stock.

The American Association for Justice is a voluntary national bar association. It does not have any parent companies, and there is no publicly held corporation that owns 10% or more of its stock.

STATEMENT OF THE INTEREST OF *AMICI CURIAE*[1]

Public Justice, P.C. is a national public interest law firm that focuses on precedent-setting and socially significant civil litigation, including by pursuing justice for the victims of intentional misconduct. To further its goals of promoting and defending access to justice for consumers, businesses, employees, and others harmed by such misconduct, Public Justice has initiated projects dedicated to fighting abuses of mandatory arbitration, opposing overly broad assertions of federal preemption, and preserving the integrity of collective and class actions. The experience of Public Justice has been that the collective and class action mechanisms, properly employed, often represent the only meaningful way for American consumers, businesses, and employees to vindicate important legal rights.

The American Association for Justice ("AAJ") is a voluntary national bar association whose members represent small businesses, injured workers, personal injury plaintiffs, and civil rights

[1] Pursuant to Fed. R. App. P. 29(c)(5), *Amici* certify that no party's counsel authored this Brief in whole or in part; no party or party's counsel contributed money intended to fund the preparation or submission of the Brief; and no person other than *Amici* contributed money intended to fund the preparation or submission of the Brief. Both parties have consented to the filing of this Brief.

claimants. AAJ has long worked to preserve access to the courts for those who seek legal recourse for wrongful injury. AAJ strongly believes that by holding wrongdoers (including major pharmaceutical makers) accountable, the civil justice system fulfills its purposes of both compensating those who have been harmed and deterring conduct that endangers others. AAJ is concerned that the decision of the district court below places justice out of reach for injured consumers and third-party payors, and undermines the accountability that fosters safety.

These *Amici* respectfully submit this Brief in support of Appellants urging this Court to reverse the orders below and permit this federal fraud action to proceed.

INTRODUCTION

RICO affords relief to victims of schemes to defraud, while shielding from liability actors whose conduct cannot be shown to have had a direct, substantial, and foreseeable effect on the business or property of the aggrieved party. At issue in this appeal is how proximate cause—a doctrine that universally prioritizes flexibility—works in civil RICO cases that have yet to reach a jury.

When Congress enacted RICO in 1970, it did so against the

backdrop of centuries of common law regulating the relationship between tortfeasors and those injured by their conduct. *See generally Beck v. Prupis*, 529 U.S. 494, 502-04 (2000). The U.S. Supreme Court therefore has consistently directed lower courts to interpret RICO in light of the "common-law principles" that Congress "incorporate[d]" into RICO. *Id.* at 504. In this case, the district court lost sight of that directive. It applied a rigid form of proximate cause that lacks support in the common law and undermines the flexibility that proximate cause embodies.

When a tort case reaches the summary judgment stage, courts apply a straightforward framework to determine whether proximate cause is satisfied. First, they ask whether the plaintiff has proffered evidence that he suffered "the sort of injury that would be the expected consequence" of the defendant's wrongful act. *BCS Services v. Heartwood 88, LLC*, 637 F.3d 750, 758 (7th Cir. 2011). If so, the burden shifts to the defendant to demonstrate that some "intervening cause" broke the causal chain between the alleged conduct and injury. Absent such proof, the plaintiff will have "done enough to withstand summary judgment on the ground of absence of causation." *Id.*

Here, the lower court disregarded RICO's common-law foundation by eliminating a key proximate-cause consideration—foreseeability—from the analysis. Moreover, the court unraveled the burden-shifting framework that controls the proximate-cause inquiry at summary judgment: the court assumed that for a civil RICO claim to advance to trial, a plaintiff must show that the alleged wrongful act was the "sole determinant" of the injury. JA 1505.[2] To the contrary, under long-settled tort law, a plaintiff need not "offer evidence which positively exclude[s] every other possible cause" to defeat summary judgment. *Carlson v. Chisholm-Moore Hoist Corp.*, 281 F.2d 766, 770 (2d Cir. 1960) (citation omitted). All RICO requires for proximate cause is evidence that the corrupt practices were a direct and substantial factor in bringing about the injury in question.

The district court not only erred in imposing a heightened proximate-cause bar, but its reasoning—if upheld—would create an affirmative (and avoidable) circuit split. The First Circuit issued a trio of decisions in 2013 holding that precisely this type of pharmaceutical fraud claim may proceed, notwithstanding doctors' individual

[2] "JA" denotes the Joint Appendix.

prescription decisions. *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21 (1st Cir. 2013) ("*Neurontin I*"); *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 51 (1st Cir. 2013) ("*Neurontin II*"); *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 60 (1st Cir. 2013) ("*Neurontin III*"), *cert. denied as to all*, 134 S. Ct. 786 (2013). In none of these decisions did the First Circuit perceive any conflict either with the Supreme Court's RICO precedent or with this Court's decision in *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010) ("*Zyprexa*"). This Court can and should follow the First Circuit's sound reasoning on nearly identical facts.

Apart from raising the specter of a circuit split, the district court's dismissal of these claims ignores common sense. Doctors won't prescribe a drug they know is unsafe or ineffective, and the fraud at issue here involves a pharmaceutical company's deliberate falsehoods about the safety and efficacy of a drug—a claim that is readily susceptible to proof through aggregate evidence. Left to stand, the district court's dismissal would remove a critical deterrent to wrongdoing that causes economic damage, exacerbates the high costs of our health care system, and creates the danger of severe physical injury.

ARGUMENT

I. THE DISTRICT COURT'S ORDERS CREATE AN INDEFENSIBLE GULF BETWEEN RICO AND THE COMMON LAW OF TORTS

A. As the Supreme Court Has Repeatedly Held, RICO's Proximate-Cause Standard Is the Common Law's Standard.

RICO's proximate-cause requirement derives from "common-law foundations." *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 457 (2006); *Hemi Group, LLC v. City of New York*, 559 U.S. 1, 9 (2010). At its core, "proximate cause" simply refers to the "judicial tools used to limit a person's responsibility for the consequences of that person's own act." *Holmes v. Securities Inv. Protection Corp.*, 503 U.S. 258, 268 (1992). Over the years, the doctrine has taken "many shapes" in "reflect[ing] 'ideas of what justice demands, or of what is administratively possible and convenient.'" *Id.* (quoting Prosser & Keeton on the Law of Torts § 41, p. 264 (5th ed. 1984)).

Because of the "infinite variety of claims that may arise," proximate cause does not lend itself to exact definition or "a black-letter rule that will dictate the result in every case." *Holmes*, 503 U.S. at 272 n.20. Instead, the Supreme Court has provided a general guidepost: proximate cause for RICO purposes requires "some direct relation

between the injury asserted and the injurious conduct alleged." *Id.* at 268; *see also Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 654 (2008) (stating that proximate cause under RICO is purposely "flexible"). The Court has cautioned that the term "direct" should not be interpreted strictly—it "should merely be understood as a reference to the proximate-cause enquiry" and nothing more. *Holmes*, 503 U.S. at 272 n.20; *see also BCS Services*, 637 F.3d at 757 (reversing grant of summary judgment as to RICO claim where lower court misunderstood and misapplied proximate-cause standard); *Sedima v. Imrex Co.*, 473 U.S. 479, 497-98 (1985) (holding that "RICO is to be read broadly" and "liberally construed to effectuate its remedial purposes," which are "nowhere more evident than in the provision of a private action.").

What, then, is meant by "some direct relation," *Holmes*, 503 U.S. at 268, between racketeering activity and injury? On this question RICO—like tort law in general—"follow[s] the Restatement." *Parks v. AlliedSignal, Inc.*, 113 F.3d 1327, 1332 (3d Cir. 1997). Proximate cause will typically be established where a plaintiff shows that he suffered "the sort of injury that would be the expected consequence of the defendant's wrongful conduct." *BCS Services*, 637 F.3d at 758. In other

words, proximate cause is "largely a proxy for foreseeability." *Systems Mgmt., Inc. v. Loiselle*, 303 F.3d 100, 104 (1st Cir. 2002). In a civil RICO case, a plaintiff "need only show that the defendants' wrongful conduct was 'a substantial and foreseeable cause' of the injury and the relationship between the wrongful conduct and the injury is 'logical and not speculative.'" *In re ClassicStar Mare Lease Litig.*, 727 F.3d 473, 487 (6th Cir. 2013) (citation omitted).[3]

B. The District Court's Ruling Imposes an Unjustifiably High Proximate-Cause Standard.

The district court failed to apply these principles, erring in multiple respects. JA 1491-1501. First, relying on the plurality opinion in *Hemi*, the court held that "for[e]seeability is not the focus of the proximate cause determination in RICO cases." JA 1490. That takes a dictum "and builds a castle on it." *Metropolitan Life Ins. Co. v. Glenn*,

[3] If this sounds imprecise, it is—and intentionally so. The common-law "substantial factor" test for legal causation is framed to be tailored to the myriad circumstances in which tort cases may arise. *See, e.g., Roberson v. Counselman*, 686 P.2d 149, 159 (Kan. 1984) (noting that it is neither "possible" nor "desirable" to "reduce the 'substantial factor' test to lower and more concrete terms . . . .") (emphasis and citation omitted). In fact, the test originated to help "resolve situations involving multiple causes to an event," and the word "substantial" is simply "used to express the notion that the defendant's conduct has such an effect in producing the harm as to lead reasonable minds to regard it as a cause." Restatement (Second) of Torts § 431, cmt. a.

554 U.S. 105, 128 (2008) (Scalia, J., dissenting). Foreseeability is, and always has been, a core aspect of proximate cause. *See Bridge*, 553 U.S. at 658 (under the "proximate-cause principles articulated in *Holmes* and *Anza*," the claimed injury to business or property must be a direct, "*foreseeable* and natural consequence" of the racketeering activity) (emphasis added).

Courts that have considered proximate cause in civil RICO cases after *Hemi* have *not* read that decision to eliminate one of the traditional concepts informing the analysis. For example, the Sixth Circuit held that, even post-*Hemi*, RICO's proximate-cause standard incorporates both "directness—whether there exists some direct relation between the injury and the injurious conduct alleged," and "foreseeability—whether the plaintiff's injury was a foreseeable consequence of the conduct alleged." *Wallace v. Midwest Fin. & Mortg. Servs. Inc.*, 714 F.3d 414, 419 (6th Cir. 2013). The First Circuit flatly rejected the notion that *Hemi* changed the law. *See Neurontin I*, 712 F.3d at 38 n.13 (observing that *Hemi* "produced a 4-1-3 decision with no majority on the proximate cause question" and involved a "factual situation" that is "easily distinguished").

The district court also committed a second error of law. Its dismissal order assumes that RICO requires the alleged wrongful conduct to be the "sole determinant" in causing the plaintiff's injuries. JA 1505. That is incorrect. Proximate cause in civil RICO cases "is not . . . the same thing as a sole cause. Instead, a factor is a proximate cause if it is 'a substantial factor in the sequence of responsible causation.'" *Cox v. Administrator U.S. Steel & Carnegie*, 17 F.3d 1386, 1399 (11th Cir. 1994) (citation omitted), *cert. denied*, 513 U.S. 1110 (1995). Under the Supreme Court's RICO precedent, proximate cause looks to whether the alleged wrongful act was a direct, substantial, and foreseeable cause of the injury. *Bridge*, 553 U.S. at 658; *Holmes*, 503 U.S. at 268.[4]

And when it comes to proximate cause, "substantial" does *not* mean "only," or even "most likely"; it means a cause that is more than

[4] The district court compounded its error in multiple other ways. For instance, it failed to mention, let alone analyze, "the societal interest in deterring illegal conduct" which is also part of this flexible inquiry. *Neurontin I*, 712 F.3d at 36 (citing *Holmes*, 503 U.S. at 269-70). And the court stressed reliance even though "the Supreme Court *rejected* the claim that reliance was a necessary element to establish proximate cause for RICO claims predicated upon federal fraud allegations." D. Smith & T. Reed, Civil RICO ¶ 6.04[3] (Matthew Bender 2014) (emphasis added) (citing *Bridge*, 553 U.S. at 659); *compare, e.g.*, JA 1498.

"trivial" or "incidental." *Mittal Steel Point Lisas Ltd. v. United States*, 542 F.3d 867, 879 (Fed. Cir. 2008). It means "something that makes a difference in the result," i.e., a factor that "tend[s] along with other factors to produce" the injury. *O'Connor v. Raymark Indus., Inc.*, 518 N.E.2d 510, 592 (Mass. 1988). Thus, where plaintiffs show "some reasonable connection" between the alleged conduct and injury—as did these Appellants—the proximate-cause element is met. *Kilburn v. Socialist People's Libyan Arab Jamahiriya*, 376 F.3d 1123, 1128 (D.C. Cir. 2004) (citing Prosser & Keeton § 41, p. 263).

C. The Causal Chain in This Case Is Sufficiently Direct.

The district court's confusion over proximate cause led it astray. It dismissed Appellants' RICO claims on the grounds that the chain of causation was fatally interrupted by "the independent actions of prescribing physicians." JA 1505. The court thought proximate cause foundered on the multivariable "prescribing decisions of physicians," which supposedly "def[ied]" any effort to connect Aventis' alleged fraud to the asserted harm. JA 1505; JA 1499. But a RICO plaintiff need only show that the alleged injurious conduct was a substantial cause.

Proximate cause calls for a pragmatic inquiry, particularly at

summary judgment. In RICO cases (as in other tort cases), summary judgment based on the absence of proximate cause is *not* justified where the "plaintiff presents evidence that he suffered the sort of injury that would be the expected consequence of the defendant's wrongful conduct." *BCS Services*, 637 F.3d at 758; *see also Neurontin III*, 712 F.3d at 68. Once the plaintiff does this, "he has done enough to withstand summary judgment on the ground of absence of causation." *BCS Services*, 637 F.3d at 758; *accord In re Publ'n Paper Antitrust Litig.*, 690 F.3d 51, 66 (2d Cir. 2012) (holding that "if an act is deemed wrongful because it is believed significantly to increase the risk of a particular injury, we are entitled—in the tort context at least—to presume that such an injury, if it occurred, was caused by the act.").

Although it is the *defendant's* burden to prove that an intervening event broke the causal chain, the district court below reasoned that "safety considerations . . . are *not necessarily determinative* of a doctor's decision regarding what to prescribe." JA 1505 (emphasis added). Yet the mere possibility that other factors contributed to the harm in certain instances—e.g., one doctor's decision to prescribe Ketek because of a patient's allergy to another antibiotic—does not "snap[] the causal

chain," or "wip[e] out the defendant's liability that connects the wrongful act to the defendant's injury," as a matter of law. *BCS Services*, 637 F.3d at 757. Otherwise defrauded plaintiffs would be forced to "prove a series of negatives" and "offer evidence which positively excludes every other possible cause of the accident"—an impossible burden that no court has ever embraced. *Id.* (citing *Carlson*, 281 F.2d at 770). For these reasons, the First Circuit properly held:

> [T]he fact that some physicians may have considered factors other than Pfizer's detailing materials does not add such attenuation to the causal chain as to eliminate proximate cause. Rather, this argument presents a question of proof, to be resolved at trial, regarding the total number of prescriptions (if any) that were attributable to Pfizer's actions.

Neurontin III, 712 F.3d at 67. The same goes for Aventis' actions here.

D. An Affirmance Here Would Create an Unnecessary Circuit Split.

The district court acknowledged, but did not meaningfully address, its evident disagreement with the *Neurontin* decisions involving materially indistinguishable facts. JA 1507. If this Court were to affirm, a conflict between circuits would emerge—a result that can and should be avoided. *See United States v. Philip Morris USA, Inc.*, 396 F.3d 1190, 1201 (D.C. Cir. 2005) (Courts of Appeals should "avoid

creating circuit splits when possible").

The district court declined to apply *Neurontin* because it read *Zyprexa* as requiring dismissal. *See* JA 1507-08. Not true. In *Zyprexa*, the plaintiffs claimed that Eli Lilly's fraudulent marketing of Zyprexa caused them to pay an inflated price for prescriptions that would not otherwise have been written. 620 F.3d at 123. Their RICO theory was that Lilly made misrepresentations to justify price increases, and that doctors saw the inflated prices, thought the drug was better, and consequently prescribed more of it. *Id.* at 131, 133 (discussing fraud-on-the-market theory of price inflation). This theory of causation, however, had a major flaw: "[P]rescribing doctors do not generally consider the price of a medication when deciding what to prescribe for an individual patient." *Id.* at 133.

Neurontin does nothing to undermine *Zyprexa*'s reasoning. *See Neurontin I*, 712 F.3d at 46 (First Circuit stated it was not creating a "split in authority"). Like Aventis here, the defendant in *Neurontin* (Pfizer) "lean[ed] heavily" on the *Zyprexa* opinion to contend that RICO's proximate-cause standard can never be satisfied in "pharmaceutical marketing RICO fraud cases." *Neurontin I*, 712 F.3d at

46. The First Circuit rejected that categorical view, distinguishing claims (like those in *Zyprexa*) that rely on a fraud-on-the-market presumption in which prescription decisions break the causal chain "because doctors do not generally consider the price of a drug when they make prescribing decisions." *Neurontin I*, 712 F.3d at 46. Conversely, a pharmaceutical RICO fraud case backed by sufficient evidence may proceed if the claim is that the harm-producing violation concerns a drug's efficacy (or safety) itself, because doctors "certainly consider information about the efficacy of a drug when deciding whether to prescribe it for their patients." *Id.* at 46. There is nothing "bizarre," *Kilburn*, 376 F.3d at 1128, or "speculative," *ClassicStar Mare Lease*, 727 F.3d at 487, about this basis for fraud causation.

The causal chain in this case directly parallels that in *Neurontin*. Appellants' RICO claims arise from Aventis' fraudulent statements regarding Ketek's "safety and efficacy." JA 1473. The chain of causation does not include any doctor reliance on pricing. Appellants allege that, despite knowing that Ketek was "neither more efficacious nor as safe as widely available alternatives," Aventis deceived the FDA about Ketek's safety and efficacy by commissioning a bogus study that led to FDA

approval, and then used that approval to market Ketek to doctors and third-party payors as a safer and more effective antibiotic, resulting in overcharges. JA 1473. Likewise, the plaintiffs in *Neurontin* alleged that Pfizer "suppress[ed] negative information about Neurontin while publishing articles in medical journals that reported positive information about Neurontin's off-label effectiveness," and then used those articles to "misrepresent[] Neurontin's effectiveness" to doctors and the payors who were bilked. *Neurontin I*, 712 F.3d at 28.

Similar evidence, too, supports these parallel allegations. In *Neurontin*, as here, "[t]he primary evidence was the expert testimony of Dr. Meredith Rosenthal," who "use[d] aggregate data and statistical approaches to link patterns in promotional spending to patterns in prescribing for the drug." *Neurontin I*, 712 F.3d at 29. In both this case and *Neurontin*, Dr. Rosenthal found "a causal connection between the fraudulent marketing and the quantity of prescriptions written[.]" *Neurontin I*, 712 F.3d at 30; *compare* JA 1363-67. The First Circuit concluded such evidence showed that "Pfizer's misinformation had a significant influence on thousands of other prescribing decisions," raising "an inference of causation" that made dismissal inappropriate.

Neurontin III, 712 F.3d at 68-69.

So why, if this case and *Neurontin* are nearly identical, did the district court here come out the other way? It failed to appreciate the meaningful distinctions between this case and *Zyprexa*. *See* JA 1504 (agreeing that *Zyprexa* is "distinguishable," but disputing that *Zyprexa* is distinguishable in a "material" way). As an initial matter, the district court failed to contrast the robust record of evidence submitted by Appellants here—including evidence of the dramatic drop in Ketek prescriptions once Aventis' lies were exposed—against the bare-bones expert report in *Zyprexa*.

Further, as discussed above, the district court erroneously reasoned that even if safety concerns play a "central" role in doctors' prescribing decisions, the mere possibility of other factors, such as a patient's medical history or a doctor's experience with other drugs, necessarily interrupted the causal chain "for the same reasons" as in *Zyprexa*. JA 1505. That is wrong. In *Neurontin*, the First Circuit explained that a pharmaceutical case alleging fraudulent *price-setting* fails because no evidence suggests doctors use pricing information when prescribing drugs—an absence of proof that interrupts the causal chain

under that theory.

There is no such absence here. Aventis cannot avoid the fact that a manufacturer's assurances that a drug is safe, and the FDA's related approval of it, *make a difference* in doctors' decisions to prescribe it, and, in turn, to its sales.[5] Moreover, to break the causal chain at the summary judgment stage, the defendant must do more than identify "potential superseding causes." *BCS Services*, 637 F.3d at 757. Given the evidence in this record that doctors do consider safety and efficacy when prescribing antibiotics, "that some physicians may have considered [other] factors" does not "add such attenuation to the causal chain as to eliminate proximate cause." *Neurontin III*, 712 F.3d at 67.

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[5] The medical community hasn't been silent about how Aventis duped the FDA and prescribing physicians. An article published in the New England Journal of Medicine expressed outrage:

> Ketek has been linked to dozens of cases of severe liver injury, been the subject of a series of increasingly urgent safety warnings, and sparked two Congressional investigations of the FDA's acceptance of fraudulent safety data and inappropriate trial methods . . . . In addition to the use of fraudulent data, the substitution of uncontrolled postmarket safety reports for controlled clinical trial data, and the acceptance of trials that could not show efficacy, there was also overt internal pressure brought to bear on FDA reviewers to alter their conclusions.

David B. Ross, M.D., Ph.D., *The FDA and the Case of Ketek*, New England Journal of Medicine, vol. 356, pp. 1601-04 (Apr. 19, 2007), *available at*: http://www.nejm.org/doi/full/10.1056/NEJMp078032.

Rather, it "presents a question of proof to be resolved at trial." *Id.*; *see also Neurontin II*, 712 F.3d at 58 ("It should have been left to a jury to weigh the aggregate and circumstantial evidence of causation . . . against any failure to present individualized testimony from doctors.").

The upshot: if this Court affirms, there will be two competing standards for RICO claims based on pharmaceutical fraud. In the First Circuit, cases arising from intentional misrepresentations about the safety or efficacy of a drug may reach a jury if they are supported by sufficient evidence. In the Second Circuit, those same claims, based on the same allegations and evidence, will die on the vine.

II. THESE CLAIMS ARE SUBJECT TO GENERALIZED PROOF AND, BARRING CLASS TREATMENT, WILL HAVE TO BE RELITIGATED MANY TIMES OVER

Disagreement over a doctor's ability to cut off the causal chain isn't the only point of conflict between the decision below and other cases. For example, the lower court indicated that "RICO causation cannot be established through generalized proof" in *any* pharmaceutical fraud case. JA 1507. That is wrong, and also bad policy; if accepted it would create harmful incentives and open the gates to unfettered wrongdoing of this nature.

To begin, consider again *Neurontin*, in which the First Circuit recognized that generalized proof *can* establish causation in RICO pharmaceutical fraud cases, "especially where the plaintiffs allege a 'quantity effect' rather than an 'excess price' theory." *Neurontin III*, 712 F.3d at 69. The court found that the aggregate evidence (Dr. Rosenthal's analysis connecting the sharp decline in the drug's sales to public revelations of its dangerous side effects), together with evidence of Pfizer's "marketing strategy specifically aimed to increase Neurontin's market share," was "capable of providing proof of but-for causation" and sufficient "to overcome summary judgment." *Id*. at 67-68 (this evidence showed that the alleged injury "was a 'foreseeable and natural consequence' of Pfizer's scheme.") (quoting *Bridge*, 553 U.S. at 658).

In reaching this conclusion, the First Circuit understood what the district court here did not: an aggregate damages model is capable of accounting for alternative marketplace behavior in a "but-for" world. Indeed, it is well established that the "but-for analysis for fraud may adopt the premise that the plaintiff would have entered into a valuable relationship with an entity other than the defendant." Federal Judicial Center, *Reference Manual on Scientific Evidence*, at 436 (3d ed. 2011).

Damages in complex litigation are often determined by comparing historical market conditions to conditions in an alternative world free from illegal activity. *See, e.g.*, *Versata Software, Inc. v. SAP Am., Inc.*, 717 F.3d 1255, 1265 (Fed. Cir. 2013), *cert. denied*, 134 S. Ct. 1013 (2014); *LePage's, Inc. v. 3M*, 324 F.3d 141, 165 (3d Cir. 2003) (en banc), *cert. denied*, 542 U.S. 953 (2004).[6]

This reasoning is not foreclosed by the fact-specific conclusions in *Zyprexa*. There, this Court rejected the use of generalized proof *not* because it is categorically inappropriate, but because the record disclosed that prescription decision making was not uniform. Of particular significance was evidence showing "that at least some doctors were not misled by Lilly's alleged misrepresentations." 620 F.3d at 135.

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[6] Even so, it is not necessary for the trier of fact to consider what these Plans would have paid (or paid for) absent the fraud, because the "general rule of fraud damages is that the defrauded plaintiff may recover out-of-pocket losses caused by the fraud." *First Nationwide Bank v. Gelt Funding Corp.*, 27 F.3d 763, 768-69 (2d Cir. 1994). This rule focuses on the actual fraudulent transactions and the associated loss without regard to alternative scenarios. *See, e.g.*, *Lama Holding Co. v. Smith Barney Inc.*, 668 N.E.2d 1370, 1373 (N.Y. 1996) (holding "[t]he true measure of damage is indemnity for the actual pecuniary loss sustained") (citation omitted); Prosser & Keeton § 110, p. 767 (explaining that the "out-of-pocket" rule "looks to the loss which the plaintiff has suffered in the transaction, and gives him the difference between the value of what he has parted with and the value of what he has received.").

And the plaintiffs' expert in *Zyprexa* failed to resolve the "uncertainty about what the alternatives to an 'excess' prescription would have been, and how they would have been distributed amongst the plaintiffs." *Id.*

Those unique limitations on the suitability of aggregate proof do not exist in this case. Dr. Rosenthal assessed the historical effects of Aventis' alleged misconduct on all market participants, in an analysis that applies equally to all members of the proposed class. The record discloses that safety and efficacy influenced *every* doctor's decisions to prescribe Ketek, and there is no evidence that some doctors were *not* misled by the misrepresentations. Yet the district court, in evaluating whether these and other common issues predominated over individual issues, seems to have overlooked that "[p]redominance is a question of efficiency." *Butler v. Sears, Roebuck & Co.*, 702 F.3d 359, 362 (7th Cir. 2012) (citations omitted), *vacated*, 133 S. Ct. 2768 (2013), *reinstated, Butler v. Sears, Roebuck & Co.*, 727 F.3d 796 (7th Cir. 2013), *cert. denied*, 134 S. Ct. 1277 (2014). It asks: "Is it more efficient, in terms both of economy of judicial resources and of the expense of litigation to the parties, to decide [1] some issues on a class basis or [2] all issues in separate trials?" *Id.* Here the first is true.

Where, as here, the consequences of individual trials include the added institutional burdens of repetitious litigation and, perhaps worse, the inability of many of the defrauded persons to seek recovery at all, a class action is not simply the fairest and most cost-effective form of litigation; it is also the only means of fulfilling civil RICO's deterrence objective. *See, e.g.*, *Klay v. Humana, Inc.*, 382 F.3d 1241, 1270-76 (11th Cir. 2004) (concluding "[i]t would be unjust to allow corporations to engage in rampant and systematic wrongdoing, and then allow them to avoid a class action"); *Vasquez v. Super. Ct.*, 484 P.2d 964, 968-69 (Cal. 1971) (noting that class actions for consumer fraud "produce[] several salutary by-products, including a therapeutic effect upon those sellers who indulge in fraudulent practices, aid to legitimate business enterprises by curtailing illegitimate competition, and avoidance to the judicial process of the burden of multiple litigation involving identical claims.").

Hence, Rule 23(b)(3) does not demand that individual litigation be impossible or that the class mechanism be perfectly suited to the case. The rule requires only relative superiority, as compared with "other available methods for fairly and effectively adjudicating the

controversy." Fed. R. Civ. P. 23(b)(3). Rule 23 implements the promise and directive of Rule 1 that *all* of the Federal Rules "secure the just, speedy, and inexpensive determination of every action and proceeding." The concerns of Rule 1 (justice, speed, and economy), which combine to define due process, are present here to the highest degree given pharmaceutical companies' near-absolute control in setting, increasing, and maintaining prices.

Prescription drug prices are sticky, not fluid. No one—not insurance companies, HMOs, governmental entities, employee benefit plans, or individual patients—can choose to pay less for a drug. Payor and patient alike are stuck, for long periods, with the harmful economic (and sometimes physical and emotional) consequences of prescribers' misinformed choices. Only collective action in court can return ill-gotten profits on any scale adequate to repair loss and deter repeat performances. The district court below ignored this reality and made no mention of the class action mechanism being a plainly superior vehicle for resolving this controversy.

Another central factor in the Rule 23 analysis, manageability, *see* Fed. R. Civ. P. 23(b)(3)(D), is also satisfied with a trial focusing on the

common evidence of Aventis' violations and their market effects. Recent civil RICO trials have gone smoothly. For instance, after the Seventh Circuit reversed the grant of summary judgment on causation grounds in *BCS Services*, "the case was tried to a jury that at the end of a four-week trial found in favor of the plaintiffs and awarded damages against the two remaining groups totaling . . . some $7 million, to which the judge added some $13 million in plaintiffs attorneys' fees and related expenses." *BCS Services v. BG Invs., Inc.*, 728 F.3d 633, 638 (7th Cir. 2013) (affirming verdict).

RICO was modeled on the Clayton Act, an enforcement statute that similarly provides for a private right of action, treble damages, and shifting of attorneys' fees. The Supreme Court interprets the two statutes *in pari materia*, "honoring an analogy that Congress itself accepted and relied upon, and one that promotes the objectives of civil RICO as readily as it furthers the objects of the Clayton Act." *Rotella v. Wood*, 528 U.S. 549, 557 (2000).

> Both statutes share a common congressional objective of encouraging civil litigation to supplement Government efforts to deter and penalize the respectively prohibited practices. The object of civil RICO is thus not merely to compensate victims but to turn them into prosecutors, "private attorneys general," dedicated to eliminating

racketeering activity.

Id. (citations omitted).

In a 2014 decision affirming a jury verdict under the Clayton Act, the Tenth Circuit rejected a challenge to class certification even though "prices were individually negotiated" and "some of the plaintiffs may have successfully avoided damages." *In re Urethane Antitrust Litig.*, __ F.3d __, 2014 U.S. App. LEXIS 18553, at *8, 15 (10th Cir. Sept. 29, 2014). The court explained that the shared evidence of the antitrust conspiracy and its market effects bound together the class and drove the litigation, and that "[t]he presence of individualized damages issues would not change this result. Class-wide proof is not required for all issues." *Id.* at *18. These holdings spotlight the fundamental error below of prioritizing a single issue of proof—the degree to which the fraud induced doctors to prescribe Ketek—over the overwhelmingly common class-wide evidence of Aventis' racketeering conduct and the widespread effects of those violations in the market for its product.

CONCLUSION

Health care costs and health care fraud are of pressing public concern. As a result of Aventis' intentional misrepresentations about the safety and efficacy of Ketek, health care dollars were diverted from

legitimate purchases. RICO was designed with just this sort of fraud in mind, and its proximate-cause standard is flexible enough to capture the direct causal chain.

There is ample evidence that the proposed class of Plans "suffered the sort of injury that would be the expected consequence" of Aventis' scheme to defraud. *Neurontin III*, 712 F.3d at 67 (quoting *BCS Services*, 637 F.3d at 758). A scheme to sell more pills by making false representations of safety directly injures those who pay for the pills. Notably, the immediate decline in Ketek prescriptions when the truth about the side effects began to be known—followed by the complete bottoming-out of sales once the liver toxicity information saturated the medical community—strongly supports a finding that Aventis' deceit was a substantial factor in causing these injuries, and that, but for Aventis' misconduct, the Plans would not have been injured because no doctor worth his salt would have prescribed Ketek.

The Plans were the foreseeable victims of the well-documented fraud and their payment for worthless prescriptions satisfies proximate cause because such payment was its natural consequence. Indeed, the fraud was only complete when the Plans paid for Ketek. The Plans have

presented more than enough evidence to defeat summary judgment as to causation, and to establish that predominantly common issues will drive a trial of this action. *Amici* therefore respectfully ask this Court to reverse the orders on appeal.

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Respectfully submitted,

/s/ *Matthew W. H. Wessler*

Public Justice, P.C.
1825 K Street NW, Suite 200
Washington, DC 20006
Telephone: (202) 797-8600
Facsimile: (202) 232-7203
mwessler@publicjustice.net

Amicus Curiae

Elizabeth J. Cabraser
Jordan Elias
Lieff Cabraser Heimann & Bernstein, LLP
275 Battery Street, 29th Floor
San Francisco, CA 94111-3339
Telephone: (415) 956-1000
Facsimile: (415) 956-1008
ecabraser@lchb.com
jelias@lchb.com

Counsel for *Amicus Curiae* Public Justice, P.C.

Jeffrey R. White
Center for Constitutional Litigation, P.C.
777 Sixth Street NW, Suite 520
Washington, DC 20001
Telephone: (202) 944-2839
Facsimile: (202) 965-0920
jeffrey.white@cclfirm.com

Counsel for *Amicus Curiae* The American Association for Justice

CERTIFICATE OF COMPLIANCE

This Brief of Public Justice, P.C. and the American Association for Justice as *Amici Curiae* in Support of Plaintiffs-Appellees complies with the type-volume limitation of Fed. R. App. P. 29(d) and 32(a)(7)(B) because it contains 5,671 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2007 in 14-point Century Schoolbook font.

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Respectfully submitted,

/s/ *Matthew W. H. Wessler*

Counsel for *Amicus Curiae*
Public Justice, P.C.