No. 17-1483

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE SEVENTH CIRCUIT**

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SIDNEY HILLMAN HEALTH CENTER OF ROCHESTER and TEAMSTERS HEALTH SERVICES AND INSURANCE PLAN LOCAL 404,

*Plaintiffs-Appellants*,

v.

ABBOTT LABORATORIES, INC. and ABBVIE INC.,

*Defendants-Appellees*.

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On Appeal from the United States District Court
for the Northern District of Illinois
No. 13 C 5865 (Hon. Sara L. Ellis)

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# BRIEF OF *AMICI CURIAE* THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, THE NATIONAL ASSOCIATION OF MANUFACTURERS, AND THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, IN SUPPORT OF APPELLEES AND URGING AFFIRMANCE

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Robert N. Weiner (Counsel of Record)
Jeffrey L. Handwerker
R. Stanton Jones
Sally L. Pei
ARNOLD & PORTER
KAYE SCHOLER LLP
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
robert.weiner@apks.com
*Counsel for Amici Curiae*

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## STATEMENT OF INTEREST[1]

The Chamber of Commerce of the United States of America (Chamber) is the world's largest business federation. It represents 300,000 direct members and indirectly represents the interests of more than three million businesses and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent its members' interests in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases like this one that raise issues of concern to the nation's business community.

The National Association of Manufacturers (NAM) is the nation's largest manufacturing association, representing small and large manufacturers in every industrial sector and in all 50 states, including pharmaceutical manufacturers. Manufacturing employs nearly 12 million men and women, contributes nearly $2.17 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for three-quarters of private-sector research and development. The NAM is the powerful voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in

[1] Counsel for all parties have consented to this filing. No party's counsel authored this brief in whole or in part; no party or party's counsel contributed money that was intended to fund the preparation or submission of this brief; and no person (other than *amici curiae*, their counsel, or their members) contributed money that was intended to fund the preparation or submission of this brief.

the global economy and create jobs across the United States. The NAM regularly files amicus briefs in cases of importance to the manufacturing community.

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's members research, develop, and manufacture medicines that allow patients to live longer, healthier, and more productive lives. In 2015 alone, PhRMA members invested an estimated $58.8 billion to discover and develop new medicines.[2] PhRMA's mission is to advocate for public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA closely monitors legal issues that affect the pharmaceutical industry and, where the organization can provide a useful perspective or important information in cases that are significant to its members, frequently participates as an *amicus curiae*.

The questions in this case concerning the limits on claims under the Racketeering Influenced and Corrupt Organizations Act ("RICO") are important not only to the fairness of federal civil litigation, but also to the vitality of the marketplace of ideas regarding new prescription drugs. Third-party payors ("TPPs") regularly assert RICO claims against *amici*'s members on the theory that

[2] PhRMA, 2016 PhRMA Annual Membership Survey 5 (2016), http://goo.gl/JmXEpY.

a manufacturer's allegedly wrongful statements to medical professionals about its product caused TPPs to pay or reimburse prescriptions for unapproved uses instead of supposedly safer, more effective, or cheaper available alternatives.

The district court correctly held that the TPPs in this case, who sought treble damages on such a theory, failed to plead proximate causation. The court rejected the TPPs' argument that the proximate-cause analysis should turn on foreseeability and intent, concluding instead that Plaintiffs' purported causal chain between Defendants' representations to physicians and the TPPs' alleged injuries was too attenuated to establish proximate cause.

*Amici* submit this brief in support of Defendants-Appellees to demonstrate the soundness of the result below and to emphasize the need for a rigorous proximate-cause inquiry under RICO. The Supreme Court has decisively rejected the notion that foreseeability and intent govern proximate cause. Instead, Supreme Court precedent compels dismissal of claims where plaintiffs fail to allege a direct relation between their purported injuries and the alleged injurious conduct. A sensible proximate-cause standard is necessary to discourage abusive litigation against pharmaceutical companies, including *amici*'s members. The importance of deterring such lawsuits extends beyond protecting pharmaceutical companies from the burdens of speculative litigation. More broadly, such litigation potentially chills protected speech, deprives physicians and other medical professionals of

truthful, beneficial scientific information, and ultimately denies patients the advantage of informed medical treatment. Particularly in this context, the limitation the Supreme Court imposed on RICO liability is critical. This Court should enforce it.

## INTRODUCTION

This case is part of a continuing wave of RICO suits by TPPs against pharmaceutical manufacturers. In the typical case, TPPs seek treble damages under 18 U.S.C. § 1964(c) for injuries allegedly resulting from a pharmaceutical company's purported misrepresentations about its product. Section 1964(c) permits "[a]ny person injured in his business or property by reason of a violation of" RICO's substantive provisions to sue for treble damages. TPPs usually allege that the pharmaceutical manufacturer's misrepresentations about the safety and efficacy of its drug increased the amount TPPs paid to cover prescriptions written by healthcare providers in the exercise of their independent medical judgment.

This case fits the familiar mold. Plaintiffs claim they suffered injuries under RICO resulting from Defendants' purported misrepresentations about the safety or efficacy of the prescription drug Depakote. The district court correctly dismissed those claims. Multiple intervening factors break any causal link between Defendants' statements and Plaintiffs' alleged injuries, not least physicians' independent judgment in prescribing Depakote and patients' decisions to fill those

prescriptions. The ostensible chain of causation between the alleged misrepresentations and the claimed injury is too attenuated and discontinuous to support Plaintiffs' claim for treble damages.

Other courts of appeals have rightly viewed similar claims with skepticism. Allowing TPPs to sue for such indirect injuries would not only defy Supreme Court precedent; it would also amplify existing incentives for burdensome litigation. Given the *in terrorem* effect of treble-damages suits under RICO and the enticement they create for plaintiffs to sue, it is essential that courts enforce appropriate limits on private civil RICO claims. Preventing abusive litigation is all the more important because it can chill lawful speech about beneficial and medically accepted unapproved uses of FDA-approved drugs. This Court should affirm the dismissal of Plaintiffs' claims.

## ARGUMENT

### I. Plaintiffs Failed To Satisfy RICO's Proximate-Cause Requirement

"[C]ivil RICO liability is not unlimited[.] … [P]roximate cause is a means of limiting the potentially limitless liability flowing factually from a person's acts." *Flood v. Waste Mgmt., Inc.*, 986 F.2d 1424, at *4 (7th Cir. 1993) (unpublished opinion) (quotation marks omitted). Courts rigorously enforce this important limitation on plaintiffs' ability to recover treble damages under RICO. Plaintiffs' claims rely on a meandering causal chain—if so fragmentary a sequence can be

called a "chain"—alleging injuries several steps removed from any alleged misrepresentations by Defendants. This attenuated theory of liability fails to establish proximate cause. The district court correctly dismissed Plaintiffs' claims.

### A. Plaintiffs' Injuries Must Bear a Direct Relation to the Allegedly Fraudulent Conduct

"When a court evaluates a RICO claim for proximate causation, the central question … is whether the alleged violation led *directly* to the plaintiffs' injuries." *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 461 (2006) (emphasis added). A plaintiff must demonstrate "some direct relation between the injury asserted and the injurious conduct alleged." *Holmes v. Sec, Inv'r Prot. Corp.*, 503 U.S. 258, 268 (1992); *see Hemi Group, LLC v. City of New York*, 559 U.S. 1, 9-10 (2010); *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 654-55 (2008); *Empress Casino Joliet Corp. v. Johnston*, 763 F.3d 723, 729 (7th Cir. 2014).

In considering whether a direct relation exists, "the general tendency" is "not to go beyond the first step" in the causal chain. *Holmes*, 503 U.S. at 271. Causal theories positing multiple intermediate steps between the alleged violation and the injury are usually insufficient to satisfy proximate cause. *Cf. Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1394 (2014) (in Lanham Act case, finding proximate cause despite an "intervening link" in the causal chain, because the injury followed "more or less automatically").

### 1. Plaintiffs' Claims of Injury Are Too Indirect To Establish Proximate Cause Under RICO.

Plaintiffs' theory of liability entails a winding, disconnected "chain" of events. Plaintiffs contend that Defendants made misleading statements to physicians about the safety and efficacy of Depakote. Those statements allegedly "encourag[ed]" doctors to prescribe Depakote in greater amounts and led patients and caregivers to fill those prescriptions, which, according to Plaintiffs, eventually led to Plaintiffs' paying or reimbursing such prescriptions for ineffective or unsafe uses. *See* Dist. Ct. Dkt. 117 at 13. The district court correctly concluded that this theory was "too attenuated to establish the required proximate causation." *Id.*

Plaintiffs' circuitous theory of liability fails the direct-relation test articulated in *Holmes* and consistently applied in later Supreme Court decisions. Intervening factors, such as "doctors' independent medical decisions to prescribe Depakote over other medications and patients' individual decisions to fill those prescriptions" interrupted the causal chain, making Plaintiffs' alleged injuries too remote to warrant recovery under RICO. *Id.*

In *Holmes*, the Securities Investor Protection Corporation (SIPC) claimed that the defendant's stock-manipulation scheme prevented two broker-dealers from meeting their obligations to customers, and that the broker-dealers' ensuing insolvency triggered the SIPC's duty to reimburse the broker-dealers' customers.

The SIPC contended that its advance of funds to reimburse the customers' claims was a cognizable injury. 503 U.S. at 262-63.

The Supreme Court held that the intervening events—*i.e.*, the broker-dealers' insolvency—severed the causal chain. The link between the SIPC's injury and the stock manipulation was "too remote," because the customers' injuries, which depended on the broker-dealers' insolvency, might have had other causes. *Id.* at 271.

Here, the TPPs' injuries are likewise "too remote": they depend on physicians' exercise of independent medical judgment to prescribe Depakote (and patients' decisions to fill those prescriptions), which might have been influenced by factors other than Defendants' alleged misrepresentations.

The Court rejected another attenuated causal theory in *Anza v. Ideal Steel Supply Corp*. The plaintiff claimed that owners of a competing steel supply business had engaged in a fraudulent tax scheme and used the proceeds to open a new facility that cut into the plaintiff's market share. The Court recognized that the attenuation of the causal chain in *Anza* differed from that in *Holmes*. In *Anza*, "[t]he cause of Ideal's asserted harms … [was] a set of actions (offering lower prices) entirely distinct from the alleged RICO violation (defrauding the State)," as opposed to the single causal strand in *Holmes*. 547 U.S. at 458. Nevertheless , it was "equally clear" that proximate cause was not satisfied given the lack of a

direct relation between the injuries claimed and the allegedly injurious conduct. *Id*. Here, too, the source of Plaintiffs' purported harms (too many patients submitting too many Depakote prescriptions to TPPs for reimbursement) is entirely distinct from the alleged RICO violation (misrepresentations to physicians). It is irrelevant whether the alleged misrepresentations made the harm more likely—*i.e.*, by increasing the likelihood that too many people would submit claims. That was the precise allegation in *Anza*—the tax scheme enabled the defendants to undercut the plaintiffs' business—and the Supreme Court rejected it. *Anza*, 547 U.S. at 460.

The Supreme Court's most recent case on proximate cause under RICO, *Hemi Group*, reconfirmed the need for a direct causal relation between the alleged violation and the injury. There, the City of New York alleged that out-of-state cigarette vendors' failure to report cigarette sales to state tobacco tax administrators violated RICO. The City claimed that the failure to report those sales prevented the City from seeking back taxes, and thus the vendors' actions deprived the City of cigarette excise tax revenue. 559 U.S. at 4-6.

A plurality of the Court held that the City's causal theory was "far more attenuated than the one [the Court] rejected in *Holmes*," *id.* at 9, resting "not just on separate *actions*, but separate actions carried out by separate *parties*," *id.* at 11, specifically, "the independent actions of third and even fourth parties," *id.* at 15. If there was no proximate cause in *Anza*, where the same party performed different

actions, *a fortiori* there was none in *Hemi Group*, where different parties committed the fraud and caused the harm. So too here. Plaintiffs' causal theory depends on independent actions of "third and even fourth parties"—at a minimum, physicians' decisions to prescribe Depakote and patients' decisions to fill those prescriptions—to connect the alleged misrepresentations to Plaintiffs' injuries.

Indeed, in the closely related context of the federal antitrust laws, it is well established that indirect purchasers may not assert antitrust claims. *Motorola Mobility LLC v. AU Optronics Corp.*, 775 F.3d 816, 820-22 (7th Cir. 2015). Permitting such claims would burden litigation with "massive evidence and complicated theories" attempting to trace harms through the distribution chain. *Illinois Brick v. Illinois*, 431 U.S. 720, 741 (1977). These considerations underpin the logic of RICO's proximate-cause requirement. *See Holmes*, 503 U.S. at 266-67 & n.10. A violation "may be expected to cause ripples of harm to flow through the Nation's economy; but … there is a point beyond which the wrongdoer should not be held liable." *Blue Shield of Va. v. McCready*, 457 U.S. 465, 476-77 (1982) (quotation marks omitted).

### 2. Other Courts of Appeals Have Rejected Similar Claims for Lack of Proximate Cause.

The Second, Ninth, and Eleventh Circuits have all rejected claims broadly similar to Plaintiffs' for failure to satisfy RICO's proximate-cause requirement. This Court should not chart a different course.

In *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010), the TPP plaintiffs claimed that Eli Lilly's alleged misleading marketing of Zyprexa resulted in the TPPs' reimbursing excessive Zyprexa prescriptions and overpaying for those prescriptions. *Id.* at 131. The district court denied summary judgment on the overpricing claim but did not reach the excess-prescription theory. The Second Circuit reversed, explaining, "After *Hemi Group*, it is clear that plaintiffs' overpricing theory is too attenuated to meet RICO's requirement of a direct causal connection between the predicate offense and the alleged harm." *Id.* at 136 (quotation marks omitted). "Plaintiffs' 'theory of liability rest[ed] on the independent actions of third and even fourth parties,' as physicians, PBMs [pharmacy benefit managers], and PBM Pharmacy and Therapeutics Committees all play a role in the chain between Lilly and TPPs." *Id.* at 134; *see Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 90-91 (2d Cir. 2015) (applying *Eli Lilly* and denying class certification because plaintiffs could not establish RICO causation through generalized proof).

The Ninth Circuit similarly affirmed the dismissal of a TPP complaint for failure to plead proximate cause under RICO. *United Food & Commercial Workers Central Pa. & Reg'l Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255, 257-58 (9th Cir. 2010). The TPP plaintiffs alleged economic injury from Amgen's allegedly unlawful marketing of Aranesp and Epogen. Citing *Hemi Group*, the court determined that the TPPs' claim against Amgen "involved at least four independent links," and thus was "too attenuated to satisfy the Supreme Court's proximate causation requirement in the RICO context." *Id.* at 257.

Consistent with the Second and Ninth Circuits, the Eleventh Circuit in *Southeast Laborers Health & Welfare Fund v. Bayer Corp.*, 444 F. App'x 401 (11th Cir. 2011), affirmed the dismissal of a TPP's RICO claim for failure to plead proximate cause. *Id.* at 410. The Eleventh Circuit concluded that "the first *Holmes* factor"— the difficulty in ascertaining the damages attributable to the RICO violation as opposed to other independent, superseding causes—"weighed heavily against a finding of proximate causation." *Id.*[3]

[3] The Eleventh Circuit also found that its holding in *Bayer Corp.* was consistent with its prior decision in *Ironworkers Local Union 68 v. AstraZeneca Pharmaceuticals LP*, 634 F.3d 1352 (11th Cir. 2011). *Bayer Corp.*, 444 F. App'x at 410 n.5. In *Ironworkers*, TPPs alleged that fraudulent statements by AstraZeneca induced TPPs to "unnecessarily pay for the more expensive Seroquel off-label prescriptions." 634 F.3d at 1356-57 (brackets omitted). The district court dismissed the claims for failure to plead proximate cause. The Eleventh Circuit affirmed, holding that the TPPs had not plausibly alleged any injury, because they failed to allege that they had not priced the risk of misrepresentations by drug manufacturers into the premiums they charged enrollees. *Id.* at 1359-60, 1364.

Plaintiffs' cursory treatment of these authorities does not distinguish them from this case. *See* Br. 20-21 n.9. Plaintiffs assert that their claims, unlike in *Eli Lilly*, are based on "unnecessary prescriptions, *not* inflated prices." *Id.* Plaintiffs' characterization of their claims is questionable, *see* Dist. Ct. Dkt. 103 at 7-8, 10-11, but in any event that distinction is irrelevant. Injuries arising from excessive prescriptions or inflated prices are both contingent on the actions of "third and even fourth parties." *Hemi Group*, 559 U.S. at 15. Here, the TPPs' injuries depend on not just the manufacturer's alleged misrepresentation to a physician, but also the physician's exercise of independent judgment to prescribe the product, the patient's decision to fill the prescription, the submission of a claim to the TPP, and the TPP's payment of the claim. There is no reason to "go beyond the first step" in the chain. *Holmes*, 503 U.S. at 271.

As for the Ninth Circuit's opinion in *Amgen*, Plaintiffs make the unsubstantiated assertion that "the causal chain in that case contained many more links than that at bar," and that the decision does not articulate a bright-line rule that "doctors' decisions break the causal chain." Br. 21 n.9. But the salient point in *Amgen*—as here—is that causal theories involving multiple independent steps fail to satisfy RICO proximate cause. 400 F. App'x at 257. Proximate cause requires a direct relation between the alleged harmful conduct and the injury.

Circuitous theories of causation involving different actions by multiple different parties do not satisfy that requirement.

### B. Foreseeability and Intent Do Not Create a Direct Relation Between Defendants' Conduct and Plaintiffs' Alleged Injuries.

Plaintiffs nevertheless claim that Defendants' statements proximately caused their injuries because the harms were foreseeable and Plaintiffs were the intended victims of Defendants' alleged scheme. This argument runs headlong into Supreme Court precedent emphasizing that "the focus is on the directness of the relationship between the conduct and the harm," not on "foreseeability." *Hemi Group*, 559 U.S. at 12. "Foreseeability and direct injury (or remoteness) are distinct concepts, both of which must generally be established by a plaintiff." *Laborers Local 17 Health & Benefit Fund v. Philip Morris, Inc.*, 191 F.3d 229, 236 (2d Cir. 1999).

Plaintiffs rely principally on *Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639. But *Bridge* does not allow Plaintiffs to conflate foreseeability and direct injury. In *Bridge*, the plaintiffs alleged that they lost property auctions because of the defendants' fraudulent bidding practices. This Court had held that the plaintiffs' failure to claim direct reliance on any false statements by the defendants did not foreclose recovery under RICO. The Supreme Court affirmed, holding that first-party reliance, while relevant to directness, is not a required element of a

RICO claim, either as a matter of statutory interpretation or as a component of proximate cause. *Id.* at 657-59. The plaintiffs' lack of reliance on the defendants' misrepresentations did not automatically defeat the claims.

But the Court in *Bridge* did not deviate from the *Holmes/Anza* direct-relation test. First-party reliance was separate from the broader question whether the plaintiffs had satisfied proximate cause. First-party reliance was not "necessary to ensure that there is a sufficiently direct relationship between the defendant's wrongful conduct and the plaintiff's injury to satisfy the proximate-cause principles articulated in *Holmes* and *Anza*." 553 U.S. at 657-58. To be sure, in determining whether there was a "sufficiently direct relationship," the Court observed that the plaintiffs' injuries were "a foreseeable and natural consequence" of the defendants' scheme. *Id*. But that was not the end of the analysis. Critically, "unlike in *Holmes* and *Anza*, there [were] no independent factors that account[ed] for [plaintiffs'] injury." *Id*. at 658. The lack of any superseding action or event in the causal chain clearly distinguished *Bridge* from the Court's prior cases on proximate cause under RICO.

This Court's analysis at a later stage of the *Bridge* litigation confirms this reading. In *BCS Services Inc. v. Heartwood 88, LLC*, 637 F.3d 750 (7th Cir. 2011), this Court made clear that the causal chain was sufficiently direct to satisfy RICO's proximate-cause requirement. No intervening elements severed the chain

between the fraudulent bidding scheme and plaintiffs' losses at the auction. "The only intermediate cause and effect pair" was the automatic bidding and selection of the winning bid—which "[did]n't weaken the inference that by having more hands in the air the defendants stole tax liens from the other bidders." *Id.* at 757.

Even if *Bridge* had left doubts, subsequent Supreme Court decisions reaffirm that directness, not foreseeability, is the test for proximate cause under RICO. The *Hemi Group* plurality criticized the dissent for relying on foreseeability. "Indeed," the plurality observed, "*Anza* and *Holmes* never even mention the concept of foreseeability." 559 U.S. at 12.

Cases in related contexts confirm this analysis. The Supreme Court in *Lexmark*, for example, analyzed the plaintiffs' claims for a direct relation between the injury and the alleged Lanham Act violation. The Court made no mention of foreseeability in finding that the plaintiffs had adequately pleaded proximate cause. 134 S. Ct. at 1394-95.

Most recently, in *Bank of America Corp. v. City of Miami*, 137 S. Ct. 1296 (2017), the court of appeals had held that foreseeability established proximate cause under the Fair Housing Act. The Supreme Court reversed, citing *Holmes*, *Anza*, *Hemi Group*, and *Lexmark* and explaining that "proximate cause … requires 'some direct relation between the injury asserted and the injurious conduct alleged.'" *Id.* at 1306. As the Court emphasized, "[f]oreseeability alone does not

ensure the close connection that proximate cause requires." *Id.* at 1306; *accord id.* ("We conclude that the Eleventh Circuit erred in holding that foreseeability is sufficient to establish proximate cause under the FHA."); *id.* at 1305 ("We conclude that foreseeability alone is not sufficient to establish proximate cause under the FHA … .").

Nor does the concept of intent or the intended victim provide the necessary direct relation, as Plaintiffs contend. Br. 24. As numerous courts have recognized, "the existence of specific intent does not answer the question of whether the injury is specifically direct." *Pillsbury, Madison & Sutro v. Lerner*, 31 F.3d 924, 929 (9th Cir. 1994); *see Anza*, 547 U.S. at 460; *Laborers Local 17 Health & Benefit Fund*, 191 F.3d at 243; *see also Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 545 (1983) (finding "insufficient as a matter of law" allegations of indirect injury, "though buttressed by an allegation of intent to harm the plaintiff"). "[S]pecific intent to harm does not magically … cause … injuries to be direct." *Allegheny General Hosp. v. Philip Morris, Inc.*, 228 F.3d 429, 441 (3d Cir. 2000).

### C. This Court Should Follow the Second, Ninth, and Eleventh Circuits, Not the First and Third Circuits.

Plaintiffs urge this Court to follow the First and Third Circuits' conclusions that TPPs pleaded proximate cause in bringing RICO claims similar to Plaintiffs'

in this litigation. But the principles discussed above—in particular, the Supreme Court's continued rejection of foreseeability as the test for proximate cause—cast significant doubt on those circuits' reasoning. There is no reason to deviate from the *Holmes/Anza* direct-relation approach applied by the Second, Ninth, and Eleventh Circuits.

In *In re Neurontin Marketing and Sales Practices Litigation*, 712 F.3d 21 (1st Cir. 2013), TPPs claimed that the defendant's fraudulent promotion of Neurontin caused them to spend more in covering Neurontin than they would have for alternative medications. Relying heavily on *Bridge*, the court held that the TPP met the test for proximate cause. *Id.* at 38. The court recognized that "foreseeability is needed for, but does not end the inquiry as to, proximate causation." *Id.* at 34. But the court did not follow through on that observation, ultimately relying on foreseeability in concluding that the plaintiffs had established proximate cause. The court stated that "Kaiser was both the natural and foreseeable victim of the fraud and the intended victim of the fraud." *Id.* at 37 (citing *Bridge*, 553 U.S. at 658). "[T]he effect of [the defendant's] wrongful conduct was clear in foresight, not in hindsight." *Id.* at 39. Adopting the defendants' contrary position would deny redress to victims whose injuries were foreseeable and intended. *Id.* at 38.

The Third Circuit followed suit in *In re Avandia Marketing, Sales Practices and Product Liability Litigation*, 804 F.3d 633 (3d Cir. 2015). Relying on *Bridge* and *Neurontin*, the court held that TPP plaintiffs had satisfied the proximate cause requirement. *Id.* at 645. The court described *Bridge* as holding that the plaintiffs' injury was "the direct result of petitioners' fraud *because* … it was a foreseeable and natural consequence of petitioners' scheme to [defraud]." *Id.* at 643 (brackets and quotation marks omitted; emphasis added). Importing that misunderstanding of *Bridge*, the court held that plaintiffs likewise had pleaded proximate cause because they were "the 'primary and intended victims of the scheme to defraud' and their injury was a 'foreseeable and natural consequence of [the] scheme,' regardless of whether they relied on the misrepresentations" of GSK regarding the safety of a group of diabetes drugs. *Id.* at 645.

As previously discussed, however, *Bridge* did not hold that foreseeable and intended injuries are directly related to the RICO violation. Instead, *Bridge* held that the *Holmes-Anza* direct-relation requirement was satisfied because no superseding causes severed the causal chain. And since *Bridge*, the Supreme Court has reconfirmed that directness, not foreseeability or intent to injure, controls the proximate-cause analysis. *See supra* pp. 16-17.

## II. Plaintiffs' Lax Approach to RICO's Proximate-Cause Requirement Could Chill Truthful, Beneficial Speech About Medically Accepted Unapproved Uses of FDA-Approved Drugs

The proper test for proximate cause under RICO has critical importance, particularly for the pharmaceutical industry, which faces a rising tide of RICO suits by TPPs. Plaintiffs argue that their foreseeability-and-intent theory of causation will "deter[] wrongful conduct" because "the effect of that wrongful conduct was clear in foresight, not in hindsight." Br. 24 (citing *Neurontin*, 712 F.3d at 39). But deterrence is not so easily cabined. An overly permissive proximate-cause standard will encourage burdensome litigation, which in turn can chill pharmaceutical companies from lawfully disseminating truthful information about beneficial unapproved uses of FDA-approved drugs. These important First Amendment concerns should guide this Court's approach to the proximate-cause inquiry under RICO.

### A. Unapproved Uses of FDA-Approved Medications Are a Legal, Ethical, and Vital Part of Physicians' Treatment of Patients

That the use of a medication or medical device is "off-label" or "unapproved" does *not* mean the use is *dis*approved or "medically inappropriate." *See* James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 83-85 (1998). These terms merely describe the regulatory status of how an FDA-

approved medication or medical device is used in a particular instance. *See id.* at 83. The FDA typically has made no qualitative judgment at all regarding an "off-label" or "unapproved" use.

Congress explicitly limited FDA's regulatory authority regarding uses of prescription drugs. FDA may regulate the manufacture and marketing of drugs, but *not* the practice of medicine. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, does not limit physicians' ability to prescribe FDA-approved drugs to any patient to treat any condition or disease, including unapproved uses. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) ("'[O]ff-label' usage … is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine."). "A physician may prescribe a legal drug to serve any purpose that he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA." *Wash. Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000).

FDA itself has stated that "[o]nce a drug or medical device has been approved or cleared by FDA, generally, healthcare professionals may lawfully use or prescribe that product for uses or treatment regimens that are not included in the product's approved labeling." FDA, *Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical*

*Devices* (Jan. 2009), https://goo.gl/niRhwQ (hereinafter "FDA Good Reprint Practices").

Unapproved uses of FDA-approved drugs are not only lawful, but also integral to the practice of medicine in the United States. As the American Medical Association has recognized, "[t]he prevalence and clinical importance of prescribing drugs for unlabeled uses are substantial." Joseph W. Cranston et al., *Report of the Council on Scientific Affairs: Unlabeled Indications of Food and Drug Administration-Approved Drugs*, 32 Drug Info. J. 1049, 1050 (1998); *see also* Dep't of Defense, TRICARE; Off-Label Uses of Devices; Partial List of Examples of Unproven Drugs, Devices, Medical Treatments, or Procedures, 77 Fed. Reg. 38,177, 38,177 (June 27, 2012) ("[G]ood medical practice and the best interests of the patient require that physicians use legally available drugs, biologics, and devices … according to their best knowledge and judgment.").

Unapproved uses in furtherance of patient health and safety have long been pervasive. One study of prescribing patterns found that approximately 150 million prescriptions—21% of all prescriptions—were written for unapproved uses. David C. Radley et al., *Off-label Prescribing Among Office-Based Physicians*, 166 Archives Internal Med. 1021, 1021 (2006). In some medical specialties, the majority of prescriptions are written for unapproved uses. U.S. Gen. Accounting Office, GAO/T-HEHS-96-212, *Prescription Drugs: Implications of Drug Labeling*

*and Off-Label Use* 3 n.6 (1996) ("[Eighty] percent of drugs administered to children are given off-label."); Paolo G. Casali, Editorial, *The Off-Label Use of Drugs in Oncology*, 18 Annals Oncology 1923, 1923 (2007) ("The off-label use of drugs in oncology has been estimated to reach 50%, or even more.").

Unapproved uses often are necessary for healthcare professionals to meet the accepted standard of care. That standard can require doctors to prescribe a drug for an unapproved use where, as commonly occurs (often because the regulatory machinery lags behind scientific progress), FDA has not approved any drug to treat a disease or condition. FDA Good Reprint Practices, *supra* ("[O]ff-label uses or treatment regimens … may even constitute a medically recognized standard of care."); Nat'l Cancer Inst., *Off-Label Drug Use in Cancer Treatment* (Jan. 1, 20014), https://www.cancer.gov/about-cancer/treatments/drugs/off-label (hereinafter "Nat'l Cancer Inst.") ("Often, usual care for a specific type or stage of cancer includes the off-label use of one or more drugs.").

Reflecting that unapproved uses are often clinically effective and medically necessary, federal law authorizes—and sometimes requires—the government to provide reimbursement for such uses. The Medicaid Act, for example, authorizes the Secretary of Health and Human Services to reimburse states, healthcare professionals, hospitals, and patients for any unapproved use that is "medically accepted." 42 U.S.C. § 1396r-8(d)(1)(B)(i). "Medically accepted" means either

that FDA has approved the drug for the prescribed use, or that the use is cited in one or more of three specified drug compendia. *Id.* § 1396r-8(k)(6). The Medicaid Act also expressly requires states to establish coverage for a drug based on its broader medical acceptance, in contrast to simply FDA approval. *See id.* § 1396r-8(d)(4)(C). Likewise, the Medicare Part D prescription-drug benefit program covers unapproved uses that might not be either FDA-approved *or* compendia-listed. *Id.* § 1395w-102(e); *see also Layzer v. Leavitt*, 770 F. Supp. 2d 579, 583-84 (S.D.N.Y. 2011) (agency unlawfully refused to provide Part D coverage for uses that were not FDA-approved or compendia-listed).

### B. Doctors Should Have Access to the Best Available Information About Unapproved Uses To Inform Their Practice

Given the widespread, medically accepted, and government-subsidized unapproved uses of numerous FDA-approved prescription medicines, healthcare professionals must have access to comprehensive and current information concerning such uses.

"[T]he very latest information that can be of value to physicians, pharmacists, and patients must be made available as soon as possible. Frequently, unlabeled use information is extremely important." Stuart L. Nightingale, then-FDA Associate Commissioner for Health Affairs, *Unlabeled Uses of Approved Drugs*, 26 Drug Info. J. 141, 145 (1992). FDA thus "recognize[s] … the important

public health and policy justification supporting dissemination of truthful and non-misleading medical journal articles and medical or scientific reference publications on unapproved uses of approved drugs and approved or cleared medical devices to healthcare professionals and healthcare entities." FDA Good Reprint Practices, *supra*. "[P]ublic health may be advanced by healthcare professionals' receipt of medical journal articles and medical or scientific reference publications on unapproved new uses of approved or cleared medical products that are truthful and not misleading." *Id.*

The manufacturer—having researched and developed a given product and tracked the medical literature—is one of many important sources of information regarding the product. Based on their own assessments of the literature and their professional judgment and medical expertise, doctors may adopt new uses for a particular approved drug. Those new uses "may become an accepted and widely-used treatment for a different [condition], even if the FDA has not approved the drug for that use." Nat'l Cancer Inst., *supra*.

Imposing RICO liability on manufacturers for purported harms suffered by TPPs, based on the manufacturers' dissemination of information to medical professionals, ignores the independent expertise of those medical professionals. Plaintiffs' theory assumes that physicians will unthinkingly accept information, and therefore manufacturers should bear the liability of paying the TPPs—three

times over—for the cost of the physicians' prescriptions. Such a theory is paternalistic, presuming that the TPPs know better than doctors what is best for their patients. The theory is also detrimental to the practice of medicine. Physicians' independent judgment is valuable because it is informed. Without access to cutting-edge scientific literature, physicians may overlook useful treatments for their patients or fail to optimize the benefits of the drugs they prescribe.

### C. Proximate-Cause Limitations on RICO Claims Protect Truthful, Beneficial Speech by Not Encouraging Abusive Litigation

Casting the net too wide in evaluating proximate cause under RICO could discourage protected speech that advances the interests of healthcare professionals and patients. "Speech in aid of pharmaceutical marketing … is a form of expression protected by the Free Speech Clause of the First Amendment." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 557 (2011). The First Amendment is critical "in the fields of medicine and public health, where information can save lives." *Id.* at 566; *see also Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371-77 (2002) (invalidating on First Amendment grounds a statutory ban on promoting unapproved "compounded" drugs); *Buckman*, 531 U.S. at 351 ("[O]ff-label use is generally accepted.").

The Supreme Court also has recognized that where "speakers may self-censor rather than risk the perils of trial," "[t]here is a potential for extraordinary harm and a serious chill upon protected speech." *Ashcroft v. Am. Civil Liberties Union*, 542 U.S. 656, 670-71 (2000); *see also Elrod v. Burns*, 427 U.S. 347, 373 (1976) (plurality opinion) ("The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury.").

That potential plainly exists here. By lowering the bar for establishing causation, the elastic foreseeability-and-intent standard that Plaintiffs advocate encourages speculative litigation. Just as the prospect of winning treble damages incentivizes TPPs to sue, the prospect of paying those damages discourages pharmaceutical manufacturers from providing physicians truthful information about unapproved uses of medicines. That is particularly so because liability will hinge on artificial inquiries into the truth or falsity of communications regarding the safety or efficacy of a product, conducted by a trial judge or jury members who lack regulatory expertise or medical training.

The threat of burdensome, unpredictable litigation is not hypothetical. RICO already encourages plaintiffs to sue by offering a treble damages remedy. "The object of civil RICO is … not merely to compensate victims but to turn them into prosecutors, 'private attorneys general,' dedicated to eliminating racketeering activity." *Rotella v. Wood*, 528 U.S. 549, 557 (2000). The proximate-cause

requirement is an important counterweight to this strong incentive to sue. *See Holmes*, 503 U.S. at 266-68 (the "very unlikelihood that Congress meant to allow all factually injured plaintiffs to recover" under § 1964(c) favors a proximate-cause requirement). "Allowing [RICO] suits by those injured only indirectly would open the door to massive and complex damages litigation, which would not only burden the courts, but would also undermine the effectiveness of treble-damages suits." *Id.* at 274 (brackets and quotation marks omitted).

The relaxed proximate-cause standard that Plaintiffs propose would remove this important bulwark against burdensome litigation and amplify the stimulus that treble damages already provide. *See Jennings v. Auto Meter Prods., Inc.*, 495 F.3d 466, 472-73 (7th Cir. 2007). Validating Plaintiffs' RICO claims for indirect injury may tempt TPPs to range further into dubious theories of liability and to misread or mischaracterize the FDA's administrative actions, potentially spawning additional abusive lawsuits.

The federal government regularly issues warning letters to pharmaceutical companies or conducts investigations regarding particular statements in the companies' product labeling or promotional material. In the past three years, the FDA Office of Prescription Drug Promotion has issued 21 such letters. *Warning Letters and Notice of Violation Letters to Pharmaceutical Companies*, U.S. Food & Drug Admin., https://goo.gl/bbbxm4. These letters are a routine interaction

between the regulator and the regulated party. Nonetheless, federal enforcement actions have historically proven a potent—if inappropriate—stimulus for private lawsuits, and often serve as a "blueprint" for subsequent TPP claims. Lise T. Spacapan & Jill M. Hutchinson, *Prosecutions of Pharmaceutical Companies for Off-Label Marketing*, 22 Annals Health L. 407, 436-38 (2013). This litigation illustrates the point. Plaintiffs filed their RICO claims on the heels of a settlement agreement resolving the government's claims that Defendants' marketing of Depakote resulted in inappropriate charges to the federal government.[4] Plaintiffs' complaint copied in substantial part the *qui tam* complaints that precipitated the enforcement actions.

Moreover, thousands of product-liability cases involving challenges to the labeling or promotion of pharmaceutical products are pending in courts nationwide. *See, e.g.*, *In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, No. 2:14-md-2592 (E.D. La.) (16,285 pending actions); *In re Benicar (Olmesartan) Prods. Liab. Litig.*, No. 1:15-md-2606 (D.N.J.) (1,865 pending actions). Under Plaintiffs' proposed rule, with the enticement of treble damages, product-liability cases could

[4] The *qui tam* relators in the government enforcement actions, represented by the same counsel as the TPPs in this case, received $84 million as their share of the recovery. *See Abbott Labs to Pay $1.5 Billion to Resolve Criminal & Civil Investigations of Off-label Promotion of Depakote*, Dep't of Justice (May 7, 2012), https://www.justice.gov/opa/pr/abbott-labs-pay-15-billion-resolve-criminal-civil-investigations-label-promotion-depakote.

become a new breeding ground for TPP RICO claims, resulting in enormous burdens on courts and *amici*'s members.

Numerous TPP RICO claims related to product-liability cases have already been percolating through courts in this Circuit and elsewhere. The *In re Testosterone Replacement Products Liability Litigation* in the Northern District of Illinois, for example, comprises 6,786 pending actions. No. 1:14-cv-1748 (N.D. Ill.). Nearly all the plaintiffs are individuals alleging personal injury resulting from their use of testosterone replacement therapies. But the litigation also includes claims by TPPs purporting to have paid or reimbursed for some portion of the prescriptions, based on alleged fraudulent marketing of the drugs at issue. *See* Class Action Complaint of Allied Services Division Welfare Fund, *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 1:15-cv-9525 (N.D. Ill. Oct. 26, 2015); Class Action Complaint of Medical Mutual of Ohio, *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 1:14-cv-8857 (N.D. Ill. Nov. 5, 2014).

Similar TPP RICO claims have arisen in mass litigation in numerous other courts.[5] Courts have dismissed many of these cases, but a few have ended with

[5] *See, e.g.*, *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 65. F. Supp. 3d 283, 294 (D. Mass. 2014) (dismissing TPPs' RICO claims as time-barred); *Ind./Ky./Ohio Reg'l Council of Carpenters Welfare Fund v. Cephalon, Inc.*, No. CIV:A. 13-7167, 2014 WL 2115498, at *6 (E.D. Pa. May 21, 2014) (dismissing TPPs' RICO claims for failure to identify a "scheme to defraud"); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, No.

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large payments by the pharmaceutical companies to settle these burdensome claims. In 2009, for instance, Merck agreed to pay $80 million to settle some 190 TPP claims in federal RICO and state-law consumer protection suits. *Merck to Pay $80 mln to Settle Some Vioxx Cases*, Reuters (Aug. 3, 2009), https://goo.gl/ZU37cS; *In re Vioxx Prods. Liab. Litig.*, No. 2:05-md-1657 (E.D. La.).

A proximate-causation test that permitted claims for economic injury under § 1964(c) to proceed even where the claim depended on numerous intervening events in the causal chain would create an irresistible incentive for insurance providers to bring spurious RICO claims against manufacturers of products, ranging well beyond pharmaceuticals, that would burden the courts for years to come. Entertaining such claims could chill defendants from settling cases involving marketing of pharmaceuticals for fear of tag-along RICO claims by TPPs following the settlement. More fundamentally, the flip-side of the incentive to sue that the prospect of treble damages provides is the disincentive to engage in the conduct that risks incurring such damages. For pharmaceutical companies, that conduct includes disseminating information about unapproved uses of their

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3:09-CV-20071-DRH, 2010 WL 3119499, at *5-8 (S.D. Ill. Aug. 10, 2010) (dismissing TPPs' RICO claims for failure to plead proximate cause); *Ironworkers Local Union No. 68 v. AstraZeneca Pharms. LP*, 585 F. Supp. 2d 1339, 1345 (M.D. Fla. 2008) (same); *see also, e.g.*, Amended Complaint, *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co.*, No. 6:14-cv-02359 (W.D. La. Sept. 9, 2014) (alleging RICO overpricing claims).

products in the first place. An overbroad approach to proximate causation in RICO cases burdens pharmaceutical companies' First Amendment rights and threatens to deprive medical professionals and patients alike of essential scientific information. The district court properly limited plaintiffs' RICO claims. This Court should affirm.

## CONCLUSION

For the foregoing reasons, the district court's decision dismissing the complaint for failure to plead proximate cause should be affirmed.

Dated: June 12, 2017

Respectfully submitted,

/s/ Robert N. Weiner
Robert N. Weiner
Jeffrey L. Handwerker
R. Stanton Jones
Sally L. Pei
ARNOLD & PORTER
KAYE SCHOLER LLP
601 Massachusetts Ave., NW
Washington, DC 20001
(202) 942-5000
robert.weiner@apks.com

*Counsel for Amici Curiae*

## CERTIFICATE OF COMPLIANCE

1. The foregoing Brief of Amicus Curiae complies with the type-volume limitations of Seventh Circuit Rule 29 because the brief contains 6,997 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

2. The brief also 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 this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman 14-point font.

Dated: June 12, 2017

/s/ Robert N. Weiner
Robert N. Weiner

## CERTIFICATE OF SERVICE

I hereby certify that on June 12, 2017, I electronically filed the foregoing document with the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: June 12, 2017

/s/ Robert N. Weiner
Robert N. Weiner