No. 17-1483

IN THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

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

v.

ABBOTT LABORATORIES and ABBVIE INC.,
Defendants-Appellees.

On Appeal from the United States District Court
for the Northern District of Illinois
Case No. 13-C-5865
Honorable Sara L. Ellis

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF APPELLEES, URGING AFFIRMANCE

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed.R.App.P. 26.1, Washington Legal Foundation (WLF) states that it is a corporation organized under § 501(c)(3) of the Internal Revenue Code. WLF has no parent corporation, nor has it issued any stock owned by a publicly held company.

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IDENTITY AND INTERESTS OF *AMICUS CURIAE*

Washington Legal Foundation (WLF) is a public-interest law firm and policy center headquartered in Washington, DC, with supporters in all 50 States, including many in Illinois.[1] WLF devotes a substantial portion of its resources to defending free enterprise, individual rights, a limited and accountable government, and the rule of law.

To that end, WLF has appeared before this Court as well as other federal and state courts to argue against overly expansive theories of tort liability and excessive punitive damages. *See, e.g., Flomo v. Firestone Natural Rubber Co.*, 643 F.3d 1013 (7th Cir. 2011). Of particular relevance to this case, WLF has repeatedly appeared in federal courts to argue against an overly expansive interpretation of the Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. § 1961 *et seq.* *See, e.g., GlaxoSmithKline LLC v. Allied Services Division Welfare Fund, Inc., cert. denied*, 136 S. Ct. 2409 (2016); *RJR Nabisco Inc. v. European Community*, 136 S. Ct. 2090 (2016); *Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639 (2008).

WLF is concerned that the reflexive invocation of RICO by civil litigants

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[1] Pursuant to Fed.R.App.P. 29(c)(5), WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief. All parties have consented to the filing of this brief.

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

WLF is particularly concerned by the use of RICO against medical product manufacturers accused of promoting their products for off-label uses, allegedly in violation of the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.* "Off-label" use of drugs and devices (that is, use of a medical product for a purpose other than that for which it has been approved by the Food and Drug Administration (FDA)) is an extremely important part of medical care in this country. To ensure that information about such care is available to doctors and patients nationwide, WLF has regularly litigated in support of First Amendment rights to disseminate and receive truthful information about safe and effective off-

label uses. *See, e.g., United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012); *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015). WLF is concerned that if the plaintiffs' bar is permitted to litigate the accuracy of safety and effectiveness claims in the context of treble-damage RICO lawsuits, valuable and truthful speech will be chilled.

STATEMENT OF THE CASE

Depakote is the brand name for divalproex sodium, a widely prescribed pharmaceutical drug. Depakote first received FDA approval in 1983, for use in treating certain types of epileptic seizures. FDA later approved Depakote as safe and effective for treating a number of other conditions. As is true for a large number of FDA-approved drugs, many doctors have concluded that Depakote is also effective in treating medical conditions for which it has not received FDA approval, and they frequently prescribe it for those off-label uses. A number of those off-label uses have become sufficiently well accepted in the medical community that they are listed in leading medical compendia, such as the American Hospital Formulary Service Drug Information and the DRUGDEX Information System.

Until expiration of its patents in 2008, Appellee Abbott Laboratories held exclusive marketing rights for Depakote. After 2008, other drug companies began

marketing competing generic versions of Depakote, and the market share of Abbott Laboratories (and its successor, Appellee AbbVie Inc.—collectively, "AbbVie") decreased substantially. Brand-name and generic versions of Depakote nonetheless continue to be widely prescribed by doctors for a wide range of on-label and off-label uses.

Appellants Sidney Hillman Health Center of Rochester and Teamsters Health Services and Insurance Plan Local 404 (collectively, the "Funds") are third-party payors (TPPs) that provide medical benefits to union members (and their spouses/beneficiaries) in, respectively, Rochester, New York, and Springfield, Massachusetts. The Funds allege that in 1998 AbbVie initiated a promotional campaign to persuade doctors to prescribe Depakote for off-label uses and that, as a result, nationwide sales of Depakote increased substantially, reaching a peak of $1.5 billion annual sales in 2007. Second Amended Complaint (SAC) ¶8. They allege that, in connection with this promotional effort, AbbVie misrepresented the results of certain medical studies that, according to the Funds, failed to demonstrate the safety and effectiveness of Depakote in treating conditions for which the drug was not labeled. SAC ¶9.

The Funds further allege that in reliance on those misrepresentations, unspecified treating physicians for some of the Funds' beneficiaries prescribed

Depakote for the off-label uses allegedly promoted by AbbVie; that the beneficiaries elected to fill those prescriptions; that they submitted some or all of the costs of the Depakote prescriptions to the Funds for payment; and that the Funds paid those costs to the pharmacy (or other entity) that supplied the drug. SAC ¶¶213-220.

The Funds do not point to any specific beneficiary whose health was adversely affected by an off-label Depakote prescription, or who failed to receive Depakote's supposedly promised beneficial effects. Instead, they allege that they were injured by AbbVie's off-label marketing because the marketing initiated a chain of events that led them to "pay for Depakote prescriptions when there were [unspecified] alternative medications that were cheaper, more effective, or had fewer side effects than Depakote," SAC ¶223; and that "[a]bsent Abbott's improper conduct," they would not have paid for the off-label prescriptions. SAC ¶222.

The Funds allege that AbbVie, by promoting Depakote for off-label uses, "conducted the affairs of an enterprise through a pattern of racketeering activity," in violation of RICO. SAC ¶¶240-259. They allege that the "pattern of racketeering activity" included acts of mail fraud and wire fraud. SAC ¶247. They seek an award of treble damages, plus costs and attorneys' fees, under 18 U.S.C.

§ 1964(c) for themselves and a nationwide class of similarly situated TPPs. SAC ¶258. They also allege a conspiracy to violate RICO and several state-law claims. SAC ¶¶260-301.

On June 29, 2016, the district court granted AbbVie's Rule 12(b)(6) motion to dismiss the complaint. Short Appendix (SA) 5-20. The court concluded that the Funds had inadequately pleaded proximate causation because their "allegations fail[ed] to establish a direct relationship between AbbVie's misrepresentations and their alleged injury." SA19. The court noted that the Funds did not allege that "Abbott made direct misrepresentations to them so as to cause them to place Depakote on their formularies or pay for Depakote when prescribed" but rather made "representations concerning Depakote's safety and efficacy for off-label uses to doctors, patients, and caregivers." SA17. The court concluded that "[t]hese additional intervening events between the alleged misrepresentations and the Funds' alleged overpayments for Depakote—doctors' independent medical decisions to prescribe Depakote over other medications and patients' decisions to fill those prescriptions, for example—make the causal chain too attenuated to establish the required proximate cause." *Ibid.*

The court rejected the Funds' assertion that the proximate-cause analysis should turn solely on whether their injuries were foreseeable. SA14. Instead, the

court held, "in the RICO context, the focus [of the proximate-cause analysis] is on the directness of the relationship between the conduct and the harm." SA15 (quoting *Hemi Group, LLC v. City of New York*, 559 U.S. 1, 12 (2010) (plurality)). The court concluded that the relationship alleged by the Funds between AbbVie's conduct and their injuries was insufficiently direct to establish proximate cause, regardless whether the injuries were foreseeable. SA14-19.

On August 1, 2016, the Funds responded by filing their Second Amended Complaint, a pleading that was largely identical to the previous complaint. On February 6, 2017, the district court granted AbbVie's renewed motion to dismiss. SA2-4. The court "dismisse[d] the RICO claims with prejudice and the state law claims without prejudice subject to refiling in state court." SA2. It concluded that the new complaint failed to include any new "allegations to cure the identified defects in the chain of causation" and that the Funds "essentially ... concede[d]" that they could not plead facts sufficient to meet the proximate-cause standard set forth in the court's June 29, 2016 order. SA3-4. This appeal followed.

SUMMARY OF ARGUMENT

The Supreme Court held more than 25 years ago in *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258 (1992), that RICO's "by reason of "

language imposes a "proximate cause" requirement on civil RICO claimants.[2] It is not enough for a claimant to demonstrate that the RICO defendant's actions were simply a but-for cause of his injury; the proximate-cause requirement mandates the showing of a sufficiently "direct relationship" between the defendant's misconduct and the plaintiff's injury. *Id*. at 268. The Court explained that the directness of the relationship is a "central element" of proximate causation because "the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent factors." *Id.* at 269.

The district court properly recognized that the requisite direct relationship cannot be established based solely on an allegation that injury to the Funds was a "foreseeable" result of AbbVie's actions. SA15. The Funds contend that a direct relationship existed here because they allege not only foreseeability but also that they "were the intended victims of [Abbott's] wrongful conduct." Funds Br.9. But that latter assertion is based on nothing more than a claim that the injury they assert was foreseeable. It is not based on any factual allegation that AbbVie set out purposely to injure them (or even knew they existed) or that the causal chain was

[2] RICO's civil action provision states that "[a]ny person injured in his business or property *by reason of* a violation of [18 U.S.C. § 1962] may sue therefor ..." 18 U.S.C. § 1964(c) (emphasis added).

particularly direct.

While it is arguably foreseeable that a TPP might incur increased costs when a drug company misrepresents to doctors and patients the safety risks of one of its prescription drugs, the Funds cannot plausibly be viewed as the "intended victim" of such a scheme. Rather, if there is an "intended" victim, it is the patient—who may be injured by being administered an inappropriate drug and who bears primary responsibility for paying for the drugs he purchases. More importantly, the relationship between the alleged wrongdoing and the plaintiffs' injuries simply cannot be deemed "direct" when no injury can occur in the absence of the discretionary acts of numerous intervening actors. In particular, unless the treating physician who writes a prescription for an off-label use of Depakote did so in direct response to AbbVie's alleged misrepresentations—and not because, for example, the physician read in a respected medical compendium that credible medical evidence supported that particular off-label use—those misrepresentations cannot be deemed to have been the cause of the Funds' injuries.

The Funds contend that disputes regarding whether a Depakote prescription written for one of their beneficiaries was for an on-label or off-label use, or whether a doctor's decision to prescribe Depakote for an off-label use was caused by AbbVie's alleged misrepresentations, "is a damages question, not an issue

relating to proximate causation." Funds Br. 21. RICO decisions in both this Court and the Supreme Court have squarely rejected such efforts to divorce the presence of damage-computation difficulties from proximate-cause determinations. "The general tendency of the law, in regard to damages at least, is not to go beyond the first step"—in large measure because extending a cause of action to indirectly injured parties often gives rise to intractable damages issues. *Holmes*, 503 U.S. at 272-73. This Court has concluded that "speculative damages claims ... are precisely [what] the Supreme Court was trying to avoid ... when the court instituted [RICO's] proximate-cause requirement." *Evans v. City of Chicago*, 434 F.3d 916, 933 (7th Cir. 2006).

The Supreme Court has repeatedly held that the "central question" in determining proximate cause in RICO cases "is whether the alleged violations led 'directly' to the plaintiffs' injuries." *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 461 (2006); *Hemi Group*, 559 U.S. at 12 (plurality); *Bridge*, 553 U.S. at 658. *Bridge* explained that RICO's "direct relationship" requirement does not in all cases require that the defendant interact personally with the injured party, so long as the claimed injury is the *inevitable* result of the misconduct and there is no risk of competing injury claims. *Ibid.* But *Bridge* made clear that the requisite direct relationship cannot be established when, as here, there exist "independent factors

that [could] account for the [plaintiffs'] injury." *Ibid*.

This Court should be particularly wary of recognizing RICO claims of this nature because they threaten to undermine effective health care. Off-label use of FDA-approved drugs and medical devices is well accepted as an important aspect of the nation's health-care system. *See, e.g., Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350, 351 n.5 (2001). Yet unless drug manufacturers and others are permitted to speak freely regarding off-label uses, doctors will be unlikely to acquire all the information they need to treat their patients effectively. RICO suits of this sort—in which reputable manufacturers are accused of "racketeering" and face potentially massive treble-damage awards—are likely to chill the dissemination of valuable medical information.

The parties disagree, of course, regarding whether the off-label information disseminated by AbbVie was supported by credible medical studies and thus whether it was of value to doctors. The Court should nonetheless take judicial notice of a federal statute that significantly weakens the TPPs' claim that their injuries were proximately caused by AbbVie's allegedly false-and-misleading information. That statute provides Medicaid coverage for drugs prescribed for off-label indications "supported by" any of several identified medical "compendia." 42 U.S.C. §§ 1396r-8(k)(6), 1396r-8(g)(1)(B)(i). The Funds have not contested

material submitted to the district court by AbbVie (in support of its motion to dismiss) demonstrating that some off-label uses at issue in this case are recognized as medically sound by those Medicaid-approved medical compendia. Those compendia listings demonstrate that doctors may well have written off-label Depakote prescriptions for reasons wholly unrelated to any (allegedly false) information supplied to them by AbbVie. That conclusion is strengthened when one considers that doctors continue to write off-label prescriptions for both the brand-name and generic versions of Depakote—nine years after the expiration of AbbVie's patents all but eliminated any incentive for AbbVie to continue to promote the drug.

Under those circumstances, the Funds cannot plausibly demonstrate that AbbVie's alleged misconduct bore a "direct relationship" to their alleged injury. Thus, RICO's proximate-cause requirement poses an insurmountable hurdle for the Funds' false-and-misleading-information claim. There are simply too many intervening factors that eliminate any "direct" causal connection.

ARGUMENT

I. APPELLANTS CANNOT SATISFY RICO'S PROXIMATE-CAUSE REQUIREMENT

Given the ever-increasing annual expenditures for health care in general and for prescription drugs in particular, it is unsurprising that health insurers are

exploring all options for holding down costs. But if the Court permits this action to proceed, one can reasonably expect that they will turn increasingly to the RICO option: attempting to brand pharmaceutical companies as "racketeers" in an effort to utilize RICO's treble-damage provision. The Funds urge that RICO's causation requirement be interpreted in a manner that conflicts with Supreme Court and Seventh Circuit case law and will make it much easier for future claimants of all stripes to bring gargantuan damage claims before juries.

A. Proximate Cause Requires a RICO Plaintiff to Demonstrate a "Direct Relationship" Between the Defendant's Misconduct and the Asserted Injury, Under Supreme Court and Seventh Circuit Case Law

The Supreme Court held a quarter century ago in *Holmes* that a civil litigant may not recover damages for a RICO violation in the absence of evidence that his injuries were proximately caused by the violation. The statute creating a private right of action for violations of RICO, 18 U.S.C. § 1964(c), provides:

> Any person injured in his business or property by reason of a violation of section 1962 of this chapter may sue therefor ... and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney's fee.

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

recover damages, "simply on showing that the defendant violated § 1962, the plaintiff was injured, and the defendant's violation was a 'but for' cause of plaintiff's injuries," the Court rejected that "expansive" reading, based largely on "the very unlikelihood that Congress meant to allow all factually injured plaintiffs to recover." *Holmes*, 503 U.S. at 265-66.

The Court stated that "the infinite variety of claims that may arise make it virtually impossible to announce a blackletter rule that will dictate the result in every case" regarding whether an injury was "proximately caused" by the defendant's actions. *Id.* at 272 n.20 (quoting *Associated General Contractors of Cal., Inc. v. Carpenters* ["*AGC*"], 459 U.S. 519, 536 (1983)). Nonetheless, the Court concluded that one essential requirement for establishing proximate cause in a RICO case—a requirement that the Court determined Congress had borrowed from antitrust laws—is a showing of a "direct" relationship between the alleged misconduct and the injury:

> [A]mong the many shapes this concept took at common law was a demand for some direct relation between the injury asserted and the injurious conduct alleged. ... Although such directness of relationship is not the sole requirement of Clayton Act causation, it has been one of its central elements, for a variety of reasons. First, the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent factors.

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

Building on *Holmes*, the Supreme Court determined in *Anza* that the plaintiff's RICO action under 18 U.S.C. § 1964(c) failed to adequately allege proximate cause. *Anza*, 547 U.S. at 459. The plaintiff was an entrepreneur who contended that a business rival violated RICO by failing to properly pay New York sales taxes on some of its sales. The plaintiff alleged that it was injured by the RICO violation because by failing to charge sales tax, the competitor was able to undercut the plaintiff's prices and thereby induce customers to reduce their purchases from the plaintiff.

The *Anza* Court explained that in evaluating a RICO claim for proximate causation, the "central question" a court must ask is whether the alleged violations led "directly" to the plaintiff 's injuries. *Id*. at 461. The Court did not contest the dissent's contention that the plaintiff's injuries were an entirely foreseeable result

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[3] *Holmes* went on to conclude that the plaintiff could not demonstrate that its injury was proximately caused by the defendant's alleged racketeering activity (stock manipulation) because the link between the stock manipulation and its injury was "too remote"—the harm only arose because the stock manipulation caused harm to third parties who were thereby rendered insolvent and thus unable to meet their obligations to individuals in whose shoes the plaintiff claimed to stand. *Id.* at 271. The Court said that recognizing RICO claims by such "indirectly" injured plaintiffs "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 (citations omitted).

of the defendant's fraudulent scheme. It nonetheless concluded that no "direct" relationship existed between the fraudulent scheme and the plaintiff's injuries, and thus that proximate cause was lacking. *Ibid.* Among the reasons the Court cited for determining that the relationship was insufficiently direct: "Businesses lose and gain customers for many reasons, and it would require a complex assessment to establish what portion of [the plaintiff's] lost sales were the product of [the defendant's] decreased prices." *Id.* at 459.

The Court again invoked proximate-causation principles to dismiss a civil RICO action in *Hemi Group*. The plaintiff, New York City, sought to recover RICO damages from out-of-state cigarette retailers who allegedly violated New York law by failing to file customer information with New York State. The plaintiff alleged that the failure to file caused it injury (in the form of lost tax revenue) because the failure deprived it of the opportunity to contact cigarette purchasers to demand that they pay city taxes on their purchases. In rejecting a claim that proximate cause was established by allegations that the city's loss of tax revenue was a highly foreseeable result of the defendant's misconduct, the plurality opinion explained that "in the RICO context, the focus [of the proximate cause inquiry] is on the directness of the relationship between the conduct and the harm," not simply on whether the plaintiff was a foreseeable victim of the defendant's

misconduct. *Hemi Group*, 559 U.S. at 12 (plurality).

This Court has similarly emphasized the requirement that a RICO plaintiff attempting to show proximate causation must plead facts demonstrating a "direct" relationship between the alleged wrongdoing and the plaintiff's injury. *See, e.g., Int'l Brotherhood of Teamsters v. Philip Morris Inc.* ["*Teamsters*"], 196 F.3d 818, 825-26 (7th Cir. 1999); *James Cape & Sons Co. v. PCC Construction Co.*, 453 F.3d 396, 403 (7th Cir. 2006) (stating that "civil RICO plaintiffs must show that the alleged fraud directly harmed them, lest damages become too difficult to ascertain"); *Empress Casino Joliet Corp. v. Johnston*, 763 F.3d 723, 729 (7th Cir. 2014); *Kaye v. D'Amato*, 357 Fed. Appx. 706, 716 (7th Cir. 2009). Thus, in *Teamsters*, for example, the Court determined that a RICO complaint filed by TPPs failed to establish that their alleged injury (payment of health benefits) was directly related to—and thus proximately caused by—false statements made by tobacco companies. Proximate cause could not be established because the "chain of causation" was too long; any payments by TPPs arose solely because some of their beneficiaries independently decided to smoke, allegedly in reliance on the false statements. *Teamsters*, 196 F.3d at 825-26.

B. Appellants Have Not Adequately Pleaded a Direct Relationship, Where Intervening Acts of Numerous Third Parties Form an Essential Part of Any Causal Chain

The district court properly held that the Funds failed to plead facts sufficient to establish a direct relationship between AbbVie's alleged misrepresentations and their injuries. SA19. The Funds concede that none of the alleged misrepresentations were addressed to them. Rather, they allege that AbbVie's off-label promotion included the dissemination of safety and efficacy claims not supported by credible medical studies, that doctors relied on this misleading information to prescribe Depakote to Funds-beneficiary patients for off-label uses, that the patients decided to fill the prescriptions and to indicate to their pharmacists that some or all of the costs should be billed to the Funds—and so on, down a lengthy causal chain that ultimately led (according to the Funds) to their suffering financial loss. SAC ¶¶213-223.[4] That causal chain is even more attenuated than the causal chains at issue in *Holmes*, *Anza*, *Hemi Group*, and *Teamsters*; and the courts in each of those cases concluded that the relationship between the alleged wrongdoing and the plaintiff's injuries was insufficiently "direct" to support a

[4] As set out in AbbVie's responding brief, there are at least 10 "steps" in the alleged causal chain—involving numerous independent actors—that must occur before AbbVie's alleged statements to doctors could result in injury to the Funds. AbbVie Br.27-28.

proximate cause claim.

As the Second Circuit explained in rejecting a substantially similar RICO causation claim, doctors have access to numerous sources of information in writing their drug prescriptions. Accordingly, the only means of determining whether statements made by the drug-manufacturer defendant in that case (Eli Lilly and Co.) caused particular prescriptions to be written was to interrogate each of the doctors who wrote those prescriptions, an exceedingly complex task:

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

UFCW Local 1776 v. Eli Lilly and Co., 620 F.3d 121, 135 (2d Cir. 2010). The plaintiffs (several TPPs) asserted that Lilly's dissemination of misleading information caused doctors to write too many Zyprexa prescriptions and thus caused the TPPs to pay for too many prescriptions. *Ibid*. The Second Circuit concluded that because the causal chain "was interrupted by the independent actions of prescribing physicians" who might have written their prescriptions based on any one of numerous sources of information, RICO's proximate-cause requirement limited the TPPs to establishing causation on a prescription-by-

prescription basis.[5]

Both this Court and the Supreme Court have identified avoiding the need to resolve complex damage-allocation issues (of the sort at issue here and in any case in which a doctor's prescription is an intervening causal factor) as a principal reason for adhering to the "direct relationship" requirement. As *Holmes* explained, the "directness of the relationship" is key because "the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent factors." 503 U.S. at 269. Similarly, this Court has concluded that RICO's proximate-cause requirement is designed in substantial part to ensure that courts need not devote substantial resources to resolving "speculative damage claims." *Evans*, 434 F.3d at 933. *See also Mendelovitz v. Vosicky*, 40 F.3d 182, 185 (7th Cir. 1994) (RICO plaintiff failed to demonstrate proximate cause where "[h]is alleged damages pass[ed] through many intermediaries," thereby making it "difficult" to determine what portion of the damages were attributable to the alleged wrongdoing).

The Funds contend that disputes regarding whether a Depakote prescription

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[5] The Second Amended Complaint does not identify any doctors who allegedly relied on AbbVie's alleged misrepresentations in writing Depakote prescriptions, and the Funds have never suggested that they intend to proceed on the basis of such proof.

written for one of their beneficiaries was for an on-label or off-label use, or whether a doctor's decision to prescribe Depakote for an off-label use was caused by AbbVie's alleged misrepresentations, "is a damages question, not an issue relating to proximate causation." Funds Br.21. But that contention is directly contradicted by the case law cited above.

The district court properly recognized that the requisite direct relationship cannot be established based solely on an allegation that injury to the Funds was a "foreseeable" result of AbbVie's actions. SA15. The Funds contend that a direct relationship existed here because they allege not only foreseeability but also that they "were the intended victims of [Abbott's] wrongful conduct." Funds Br.9. But that latter assertion is based on nothing more than a claim that the injury they assert was foreseeable. It is not based on any factual allegation that AbbVie set out purposely to injure them or that the causal chain was particularly direct.

Hemi Group reiterated what the Supreme Court previously stated in *Holmes* and *Anza*: the touchstone of RICO proximate cause is the existence of a "direct relationship" between the fraud and the harm, not foreseeability of the harm or the defendant's intent. 559 U.S. at 12 (plurality). *Cf. ibid* (dismissing the significance of evidence of intent to injure and stating that proximate cause cannot be established in the absence of the requisite direct relationship, "even when the

injuries were the *intended* consequences of the defendant's unlawful behavior") (emphasis in original).

In any event, if a drug company disseminates misleading information for the purpose of promoting inappropriate prescription drug sales, the "intended" victim is the patient, not an insurer who reimburses a portion of the patient's costs. The patient is the one who may be injured by being administered an inappropriate drug and who (as the purchaser) bears primary responsibility for paying for the drugs. Moreover, patients have not been reluctant to file lawsuits whenever they conclude that a drug company's false statements (or failure to provide adequate safety warnings) have caused them injury. This Court has been particularly reluctant to authorize claims asserted by individuals only indirectly injured by a RICO violation when, as here, "the immediate victims of an alleged RICO violation can be expected to vindicate the laws by pursuing their own claims." *James Cape & Sons*, 453 F.3d at 404.[6] *See also Anza*, 547 U.S. at 460 ("Directly injured victims can generally be counted on to vindicate the law as private attorneys general, without any of the problems attendant upon suits by plaintiffs injured more remotely.") Those "problems" include the "risk of duplicative recoveries" and

[6] Moreover, as this case well illustrates, federal officials have shown no reluctance in bringing their own enforcement actions to ensure that pharmaceutical companies do not improperly promote their FDA-approved products.

complex court proceedings necessary to calculate damages suffered by a remote party (*e.g.*, would the Funds have faced even greater drug costs if their beneficiaries had been prescribed other drugs in lieu of Depakote?). *Id.* at 459-60.[7]

In addressing similar issues in antitrust litigation, the Supreme Court has established bright-line rules that significantly limit potential plaintiffs in order to "keep the scope of complex antitrust trials within judicially manageable limits." *AGC*, 459 U.S. at 543. Thus, for example, indirect purchasers of products whose prices have been inflated by a price-fixing conspiracy may not sue under the federal antitrust laws to recover their damages—even though it may well be both foreseeable and inevitable that the conspiracy will injure them. *Illinois Brick v. Illinois*, 431 U.S. 729 (1977). Instead, the cause of action is limited to those who purchase directly from the conspirators. *Id.* at 737-38. The Court has flatly refused to create any exceptions, explaining, "The possibility of allowing an exception, even in rather meritorious circumstances, would undermine the rule." *Kansas v. Utilicorp United, Inc.*, 497 U.S. 199, 216 (1990).

As *Holmes* recognized, Congress modeled 18 U.S.C. § 1964(c), RICO's civil-action provision, on the civil-action provision of the antitrust laws, 15 U.S.C.

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[7] WLF notes that the only "alternative" medication cited by name in the complaint is Lamictal, which the Funds concede was "much more expensive." SAC ¶162.

§ 15. *Holmes*, 503 U.S. at 267. For that reason, *Holmes* concluded that Congress intended to incorporate into RICO the same strict proximate-cause requirements that courts had already read into the antitrust laws. *Id*. at 268. Just as *Illinois Brick* staunchly bars recovery by indirect victims of antitrust violations, so too this Court should strictly adhere to the bar on recovery by indirect victims of RICO violations. The Funds are "indirect" victims, as courts have understood that term in antitrust and RICO case law. As explained above, the relationship between AbbVie's alleged wrongdoing and the Funds' claimed injury cannot be deemed "direct" when no injury can occur in the absence of the discretionary acts of numerous intervening actors.

C. The Decisions in *Bridge* and *BCS* Fully Endorse the Direct-Relationship Requirement

In asserting that they have adequately pleaded proximate clause, the Funds rely primarily on the Supreme Court's 2008 *Bridge* decision and this Court's decision in *BCS Services, Inc. v. Heartwood 88, LLC*, 637 F.3d 750 (7th Cir. 2011). They cite *Bridge* for the proposition that RICO's proximate-cause requirement is satisfied by a showing that the plaintiffs' injuries were "a foreseeable and natural consequence" of the defendant's scheme. Funds Br.12.

The Funds have badly misread *Bridge*. That decision strongly reaffirmed

Holmes's holding that proximate cause cannot be established in a RICO action in the absence of a "direct relation between the injury asserted and the injurious conduct alleged." *Bridge*, 553 U.S. at 654. The existence of proximate cause was not even at issue in *Bridge*. The issue instead was "whether a plaintiff asserting a RICO claim predicated on mail fraud must plead and prove that it relied on the defendant's alleged representations." *Id.* at 641-42. The Court ruled that a showing of first-party reliance is not *always* required. *Ibid*.

The parties in *Bridge* were competing bidders at tax-lien auctions conducted by Cook County, Illinois. The RICO defendants allegedly made false statements to the county as part of a mail-fraud scheme that, by direct operation of the bidding rules, resulted in tax liens being awarded to the defendants that should have been awarded to the plaintiffs. Because the defendants' false statements were directed to the county and not to the plaintiffs, the injured RICO plaintiffs could not allege that they had relied on those statements. The Court held that such reliance is not a necessary component of a RICO mail-fraud claim and unanimously affirmed this Court's reinstatement of the plaintiffs' RICO claim. *Bridge*, 553 U.S. at 661.

Bridge deemed it obvious, even in the absence of first-party reliance, that the plaintiff's alleged injury was "the direct result of [the defendant's fraud]." *Id.* at 658. Key to that "direct result" determination was the absence of any discretionary

decision-making by Cook County in awarding tax liens in response to bids. It was not merely foreseeable but also inevitable that the plaintiffs would suffer their claimed injury (a decrease in the number tax liens awarded to them) as a result of the defendants' fraudulent scheme. "Unlike in *Holmes* and *Anza*," there were "no independent factors that [could] account for the [plaintiffs'] injury," *ibid*, because the county's extremely limited role as an intermediary between the misconduct and injury had no possible effect on the scope of the plaintiffs' injury.

The facts here differ sharply from those in *Bridge*. The *inevitable* result of the fraud committed by the *Bridge* defendants was injury to the plaintiffs (in the form of a decrease in the number of tax liens awarded to them by Cook County). In contrast, the causal chain between AbbVie's alleged fraud and the Funds' injury is extremely attenuated and requires the discretionary acts of numerous intervening actors. It is the attenuated nature of the causal chain—not the mere fact that AbbVie made no misrepresentations directly to the Funds—that is fatal to the efforts to establish proximate cause.

This Court's decision in *BCS* involved subsequent proceedings in the tax-lien litigation at issue in *Bridge*. It is similarly unhelpful to the Funds. The Court determined that the plaintiffs adequately demonstrated proximate cause, in substantial part because it deemed injury to the plaintiff to be the inevitable result

of the defendants' fraudulent scheme. *BCS*, 637 F.3d at 757. Although the defendants speculated about possible scenarios under which their fraudulent bidding scheme might not lead to a reduction in the number of tax liens awarded to the plaintiffs, this Court dismissed those scenarios as "beyond unlikely" and "implausible speculations." *Ibid*. In sharp contrast, AbbVie has demonstrated that the causal chain relied on by the Funds is highly attenuated and requires the intervening independent decisions of numerous third parties.

II. APPELLANTS' EXPANSIVE RICO CLAIMS THREATEN TO CHILL THE DISSEMINATION OF TRUTHFUL INFORMATION ABOUT OFF-LABEL USES OF FDA-APPROVED PRODUCTS AND THEREBY HINDER EFFECTIVE HEALTH CARE

This Court should be particularly wary of recognizing RICO claims of this nature because they threaten to undermine effective health care. Off-label use of FDA-approved drugs and medical devices is well accepted as an important aspect of the nation's health-care system. *See, e.g., Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350, 351 n.5 (2001) ("'[O]ff-label' usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine. ... Off-label use is widespread in the medical community and often is

essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize."). Yet unless drug manufacturers and others are permitted to speak freely regarding off-label uses, doctors will be unlikely to acquire all the information they need to treat their patients effectively.

RICO suits of this sort—in which reputable manufacturers are accused of "racketeering" and face potentially massive treble-damage awards—are likely to chill the dissemination of valuable medical information.[8] RICO's strict proximate-cause requirement is perhaps the only effective tool that manufacturers can use in defending against such claims. Loosening that requirement in the manner requested by the Funds would remove the last safeguard against the RICO-ization of all state tort law and the resulting chill on speech.

Importantly, the Funds have mischaracterized the nature of the enforcement action undertaken by federal officials against AbbVie in connection with its Depakote promotional activities. FDA takes the position that *any* manufacturer

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[8] This Court has frequently noted that Congress adopted RICO for the purpose of combating organized crime, not for the purpose of federalizing routine business disputes. *See, e.g., Gamboa v. Velez*, 457 F.3d 703, 710 (7th Cir. 2006). The danger of a chilling effect on speech is especially pronounced in cases involving the practice of medicine, because "truth" and "falsity" are less clear cut when cutting-edge questions of science are at issue than in the classic sorts of fraud/racketeering cases that RICO was intended to reach. *Cf. Underwager v. Salter*, 22 F.3d 730, 736 (7th Cir. 1994) ("Scientific controversies must be settled by the methods of science rather than the methods of litigation.").

dissemination of off-label information regarding an FDA-approved product violates the FDCA, without regard to whether that information is supported by credible scientific evidence. Accordingly, the existence of federal enforcement actions does *not* indicate that FDA has determined that challenged promotional statements are false or misleading. Although AbbVie agreed in May 2012 to settle charges filed against it and to pay a large fine for its promotional activities, it has never conceded that Depakote is in fact unsafe or ineffective for any of the off-label uses at issue in this litigation.

WLF notes further that federal courts have repeatedly rejected FDA's position that it is entitled to prevent manufacturers from disseminating truthful information about off-label uses of their FDA-approved drugs. *See, e.g.*, *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012); *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015). Indeed, as the result of a First Amendment lawsuit brought by WLF, FDA is subject to a permanent injunction that bars the agency from interfering with manufacturer dissemination of peer-reviewed journal articles that discuss off-label uses. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000).

The Second Amended Complaint conclusorily alleges that the off-label information at issue in this case was false and misleading. However, the Court is

entitled to take judicial notice of a federal statute that relates directly to the off-label information at issue and significantly weakens the Funds' proximate-causation claim—by significantly increasing the probability that many doctors decided to prescribe Depakote off-label for reasons unrelated to the allegedly misleading information disseminated by AbbVie.

The statute in question, 42 U.S.C. § 1396r-8(k)(6), sets forth the rules regarding when the federal Medicaid program will pay the cost of drugs supplied to Medicaid beneficiaries. It states that payment is appropriate if, *inter alia*, use of the drug is supported by one or more citations included in one of three enumerated medical compendia. Those three compendia are: (1) American Hospital Formulary Service Drug Information; (2) United States Pharmacopeia-Drug Information; and (3) the DRUGDEX Information System. 42 U.S.C. § 1396r-8(g)(1)(B)(i).

As a Declaration attached to AbbVie's motion to dismiss spelled out, off-label uses at issue in this case have been (and continue to be, at least through the date of the Declaration) recognized as medically sound by those compendia.[9]

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[9] *See* Declaration of Adeel Abdullah Mangi. Exhibit C to the Mangi Declaration contains excerpts from DRUGDEX Information System. Recognized off-label uses for Depakote listed therein include "dementia" and pediatric use for Bipolar I and Bipolar II disorder. Exhibit D contains excerpts from AHFS Drug Information. Recognized off-label uses for Depakote listed therein include "bipolar disorder," schizophrenia, and "treatment of aggressive outbursts in children with ADHD."

Those compendia listings indicate that federal Medicaid officials would deem it totally proper for pharmacies to seek Medicaid reimbursement for the prescriptions that the Funds now claim are fraudulent. More importantly, the compendia listings demonstrate that doctors likely have written off-label Depakote prescriptions for reasons wholly unrelated to any (allegedly false) information supplied to them by AbbVie. That strong possibility renders the Fund's causal chain untenably attenuated. The Funds have not suggested any method for determining which doctors prescribed Depakote off-label because they received misleading information from AbbVie and, alternatively, which doctors prescribed Depakote off-label after consulting one of the three authorized medical compendia. In the absence of such information, the Funds have not come close to satisfying RICO's proximate-cause requirement.

Yet, if this RICO claim is permitted to proceed to trial despite wholly inadequate proximate-cause allegations, manufacturers will become increasingly reluctant to disseminate to doctors information that they deem well-supported and potentially life-saving. Manufacturers will be reluctant to incur the substantial litigation costs that would arise whenever a RICO claim survives a motion to dismiss. WLF urges the Court to avoid that chilling effect on truthful and valuable speech by re-affirming a strong proximate-cause requirement in RICO cases.

CONCLUSION

The Court should affirm the judgment below.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I am an attorney for *amicus curiae* Washington Legal Foundation (WLF). Pursuant to Fed.R.App.P. 32(a)(7)(C), I hereby certify that the foregoing brief of WLF is in 14-point, proportionately spaced Times New Roman type. According to the word processing system used to prepare this brief (WordPerfect X5), the word count of the brief is 6,998, not including the corporate disclosure statement, table of contents, table of authorities, certificate of service, and this certificate of compliance.

/s/ Richard A. Samp
Richard A. Samp

Dated: June 12, 2017

CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of June, 2017, I electronically filed the brief of *amicus curiae* Washington Legal Foundation with the Clerk of the Court of the U.S. Court of Appeals for the Seventh 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.

/s/ Richard A. Samp
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