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CHAIN, CHAIN, CHAIN—CHAIN OF (PHARMA) FOOLS: WHY THIRD PARTY PAYORS MAINTAIN THE PROXIMATE CAUSAL CHAIN UNDER RICO § 1964(C)

Abstract: On December 3, 2019, the U.S. Court of Appeals for the Ninth Circuit in *Painters & Allied Trades District Council 82 Health Care Fund v. Takeda Pharmaceuticals Co.* held that Third Party Payors (TPPs) may satisfy proximate causation in civil Racketeer Influenced and Corrupt Organizations Act (RICO) claims against pharmaceutical companies where they claim that, but for the pharmaceutical company’s failure to indicate a drug’s cancer-causing risk, they would not have incurred expenditures for the drug. In doing so, the Ninth Circuit joined the U.S. Courts of Appeals for the First and Third Circuits and split from the U.S. Courts of Appeals for the Second and Seventh Circuits as to whether TPPs are too far removed from pharmaceutical companies’ alleged fraud to satisfy RICO’s proximate cause requirement. This Comment argues that the Ninth Circuit was correct in concluding that TPPs may properly allege proximate cause, as its approach effectively followed Supreme Court precedent. It further argues that, as a matter of policy, proximate cause should not be allowed to shield pharmaceutical companies from the damages they inflict on TPPs and the healthcare system at large through their fraudulent drug promotion schemes.

INTRODUCTION

The Racketeer Influenced and Corrupt Organizations Act (RICO) prohibits specific conduct constituting “a pattern of racketeering activity.”¹ Section 1964(c) of RICO, in particular, creates a civil cause of action that allows individuals harmed in their “business or property by reason of” a contravention of RICO § 1962 to sue and recover triple damages, expenses, and attorney’s

¹ Racketeer Influenced and Corrupt Organization Act, 18 U.S.C. §§ 1961–1968. According to the statute, “racketeering activity” includes numerous state and federal crimes called predicates. *Id.* Predicates include any conduct “indictable” pursuant to certain federal statutes, specific crimes “chargeable” pursuant to state law, and crimes concerning “bankruptcy or securities fraud or drug-related activity” that are indictable under federal law.” *Id.* § 1961(1). A predicate crime triggers RICO liability when it involves a “pattern of racketeering activity”—a sequence of two or more connected predicates that, in combination, exhibit the presence of, or potential for, ongoing illegal conduct. *Id.*; *see Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 453, 460 (2006) (holding that proximate causation was not satisfied where the plaintiff alleged that the defendant increased its market share to the plaintiff’s detriment through a pattern of racketeering activity). RICO is set forth under Title IX of the Organized Crime Control Act of 1970. Pub. L. No. 91-452, 84 Stat. 922; *see Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 486–87 (1985) (describing RICO’s legislative history).

fees.² Importantly, the Supreme Court has construed the term “by reason of” to require a plaintiff to demonstrate both proximate and but-for causation.³

Congress originally passed RICO as a powerful initiative to strengthen old approaches and develop new strategies to combat organized crime.⁴ Over the last few decades, however, RICO has developed into a tool for bringing common law fraud cases against lawful enterprises, including pharmaceutical companies.⁵ Pervasive pharmaceutical fraud throughout the United States con-

² 18 U.S.C. §§ 1962, 1964(c); *RJR Nabisco, Inc. v. European Cmty.*, 579 U.S. 1, 3 (2016). Section 1964(c) permits a successful plaintiff in a civil RICO matter to recoup “reasonable attorney’s fees.” See JOHN HAMIL, *BUSINESS AND COMMERCIAL LITIGATION IN FEDERAL COURTS* § 108:70 (Robert L. Haig ed., 4th ed. 2016) (describing that when granting attorney’s fees, a court is required to establish an adequate fee quantity and then may assess if a “fee multiplier” is appropriate to apply to the fee quantity); see also Michael P. Kenny, *Rico and Federalism: A Case for Concurrent Jurisdiction*, 31 B.C. L. REV. 239, 250 (1990) (arguing that in drafting the language of § 1964(c), Congress’s purpose was not to strip “state courts of jurisdiction” over civil RICO claims). Section 1962 creates four new crimes targeting the various manners through which a “pattern of racketeering activity” could be utilized to “infiltrate, control, or operate ‘a[n] enterprise which is engaged in, or the activities of which affect, interstate or foreign commerce.’” *RJR Nabisco*, 579 U.S. at 2.

³ 18 U.S.C. § 1964(c); see *Holmes v. Sec. Inv. Prot. Corp.*, 503 U.S. 258, 267–68 (1992) (explaining that standing under § 1964(c) required the plaintiff satisfy both factual causation and proximate causation); *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co.*, 943 F.3d 1243, 1248 (9th Cir. 2019) (explaining the Supreme Court’s requirement of both proximate and but-for causation under § 1964(c)). In defining but-for causation, the Supreme Court has explained that one of the “better established” legal concepts is that which demands that a plaintiff demonstrate causation. *Comcast Corp. v. Nat’l Ass’n of African Am.-Owned Media*, 140 S. Ct. 1009, 1013 (2020). In tort law, this entails the plaintiff showing that his or her harm “would not have occurred but for” the defendant’s prohibited action. *Id.* The Court has defined proximate cause as a mechanism to minimize parties’ liability for the consequences of their actions. *Holmes*, 503 U.S. at 268. The concept of proximate cause embodies “ideas of what justice demands, or of what is administratively possible and convenient.” *Id.* (quoting W. PAGE KEETON ET AL., *PROSSER AND KEETON ON LAW OF TORTS* § 41, 264 (5th ed. 1984)).

⁴ See *Sedima*, 473 U.S. at 498 (noting that RICO was a forceful approach to enhance existing solutions and create novel strategies for combatting unlawful conduct); *Painters*, 943 F.3d at 1248 (explaining that Congress initially passed RICO to reduce “organized crime”); U.S. DEP’T OF JUST., *ORGANIZED CRIME AND GANG SECTION, CRIMINAL RICO 18 U.S.C. §§ 1961–1968: A MANUAL FOR FEDERAL PROSECUTORS* 1, 4 (6th ed. 2016) (explaining that in enacting RICO, Congress recognized that organized crime, and specifically La Cosa Nostra, had intruded numerous industries and unions on a national scale).

⁵ See *Sedima*, 473 U.S. at 498–99 (noting § 1964(c) of RICO should be interpreted to combat unlawful activity in all settings); *Painters*, 943 F.3d at 1248 (explaining that today, RICO is a means to fight common fraud by otherwise lawful businesses); Glenn D. West, *That Pesky Little Thing Called Fraud: An Examination of Buyers’ Insistence Upon (and Sellers’ Too Ready Acceptance of) Undefined “Fraud Carve-Outs” in Acquisition Agreements*, 69 BUS. LAW. 1049, 1055 (2014) (describing common law fraud in the United States). Common law fraud is a tort claim originating from the English cause of action, deceit. See West, *supra*, at 1055. In the majority of states, a plaintiff alleging common law fraud must successfully allege the following six elements:

- (i) the defendant made a representation; (ii) the representation was false; (iii) the defendant acted with scienter (i.e., knew the representation was false or made it recklessly without sufficient knowledge as to whether it was true or false); (iv) the defendant intended that the plaintiff rely on the representation; (v) the plaintiff reasonably or justifi-

tinues to inflict significant public health and economic harm that detrimentally impacts individual patients, payors, and our healthcare system at large.⁶

In response, patients and third party payors (TPPs) have increasingly utilized § 1964(c) to bring civil RICO claims against pharmaceutical companies, alleging fraudulent misrepresentation of drug safety and efficacy.⁷ TPPs are most commonly health insurance companies, health funds, or government programs.⁸ They cover health care expenditures on behalf of their members, including prescription medication costs.⁹

In light of this influx of civil RICO suits against pharmaceutical companies, courts disagree over whether TPPs may properly bring such claims.¹⁰ In

ably relied upon the representation; and (vi) the plaintiff suffered injury as a result of the representation.

Id.

⁶ See *infra* notes 80–84 and accompanying text (noting the public health and economic toll of pharmaceutical fraud in the United States in terms of patient lives lost and growing prescription drug costs).

⁷ See, e.g., *Painters*, 943 F.3d at 1248, 1251–52 (holding that TPPs may satisfy the requirement for proximate causation where they are the “immediate victims” of a defendant pharmaceutical company’s purported scheme to cover up drug safety risks); *Sidney Hillman Health Ctr. of Rochester v. Abbott Lab’s*, 873 F.3d 574, 575, 578 (7th Cir. 2017) (holding that fraudulent falsifications toward clinicians may not uphold a RICO action brought forth by TPPs because they are significantly separated in the causal chain); *In re Avandia Mktg., Sales Pracs. & Prod. Liab. Litig.*, 804 F.3d 633, 636, 644 (3d Cir. 2015) (concluding that TPPs properly alleged proximate causation where the actions that supposedly gave rise to the TPPs’ harm constituted conduct identical to that which underlay the RICO violation: fraudulent misrepresentation of drug safety and efficacy); *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21, 25–26, 37–38 (1st Cir. 2013) (concluding that the TPP properly alleged proximate causation where it was the “primary and intended victim” of the manufacturer’s deceitful conduct and where its injury was a “foreseeable and natural consequence” of that conduct (quoting *Bridge v. Phx. Bond & Indem. Co.*, 553 U.S. 639, 650, 657–58 (2008))); *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 129, 134, 136 (2d Cir. 2010) (holding that the link between pharmaceutical fraud and the TPP’s injury too “attenuated” to satisfy proximate cause where it rested upon the autonomous acts of third and, in some cases, fourth parties (quoting *Hemi Grp., LLC v. City of New York*, 559 U.S. 1, 9 (2010))); see also *Mona Ghogomu, When Does the Chain Break? Prescribing Around Drug Manufacturer Fraud*, 67 DEPAUL L. REV. 557, 557–58 (2018) (explaining that TPPs, including insurance companies and healthcare plans, often file lawsuits against drug manufacturers because they must pay a portion of their customers’ prescription costs).

⁸ *Third-Party Payer*, DICTIONARY.APA.ORG (2020), <https://dictionary.apa.org/third-party-payers> [https://perma.cc/JY6L-VPNK]. A TPP is different from the first party, the patient receiving the medical services, as well as from the second party, the clinician or organization providing the care. *Id.*

⁹ *Id.*; see *In re Avandia*, 804 F.3d at 634 (describing how TPPs cover the costs of patients’ medical treatment).

¹⁰ Compare *Painters*, 943 F.3d at 1251 (holding that under the Supreme Court’s holding in *Bridge v. Phoenix Bond & Indemnity Co.*, TPPs may satisfy proximate cause when bringing civil RICO claims against pharmaceutical companies), and *In re Avandia*, 804 F.3d at 644 (holding that the TPPs satisfied proximate cause where the action giving rise to their harm was identical to the action constituting the RICO claims: misrepresentation of drug safety and efficacy), and *In re Neurontin*, 712 F.3d at 37–39 (concluding that the TPP satisfied proximate cause where the pharmaceutical company’s sham marketing scheme only became successful upon the TPP’s payment, the very injury for which the TPP sought recovery), with *Sidney Hillman*, 873 F.3d at 578 (determining that fraudulent

particular, federal circuit courts are split as to whether TPPs sufficiently allege proximate causation when they claim that, but for the defendant pharmaceutical company's misrepresentations, they would not have paid for the drug.¹¹ Central to this disagreement is the question of whether prescribing doctors and pharmacy benefit managers (PBMs) act as intervening causal forces that interrupt the proximate causation between drug manufacturers and TPPs.¹²

This Comment argues that TPPs may properly allege proximate causation under § 1964(c) of RICO in claims brought against pharmaceutical companies for fraudulent misrepresentation of drug safety.¹³ Part I of this Comment introduces RICO, its proximate cause requirement under § 1964(c), and the U.S. Court of Appeals for the Ninth Circuit's 2019 decision in *Painters & Allied Trades District Council 82 Health Care Fund v. Takeda Pharmaceuticals Co.*¹⁴ Part II discusses the circuit split and the varying approaches courts have taken in analyzing proximate cause.¹⁵ Lastly, Part III argues that the Ninth Circuit was correct in holding that TPPs may adequately allege proximate cause when bringing civil RICO claims against pharmaceutical companies.¹⁶

I. SECTION 1964(C) OF RICO AND THE PROXIMATE CAUSATION REQUIREMENT

Section 1964(c) requires that a plaintiff satisfy proximate causation when bringing forth a civil RICO claim against a defendant.¹⁷ In light of this requirement, courts have disagreed whether TPPs may adequately demonstrate proximate cause in lawsuits brought against pharmaceutical companies for

falsifications made to physicians were insufficient to maintain TPPs' RICO claims against pharmaceutical companies), and *UFCW Local 1776*, 620 F.3d at 134 (holding that proximate causation is not met where TPPs are too far removed in the causal chain of pharmaceutical fraud).

¹¹ *Painters*, 943 F.3d at 1251 (holding TPPs may satisfy proximate cause pursuant to *Bridge*); see *Sidney Hillman*, 873 F.3d at 578 (concluding that TPPs may not satisfy proximate cause where the pharmaceutical company made falsifications to doctors, not TPPs); *In re Avandia*, 804 F.3d at 644–45 (holding proximate cause properly alleged where TPPs claimed that the unlawful actions that caused their injury were the same actions constituting the RICO violation); *In re Neurontin*, 712 F.3d at 39–40 (noting that the causal connection between TPP and drug manufacturer was “anything but attenuated”); *UFCW Local 1776*, 620 F.3d at 136 (concluding that the TPPs' causal theory was too remote to satisfy the “direct relation” requirement of proximate cause under RICO).

¹² *Painters*, 943 F.3d at 1257 (defining an “intervening cause” as “a later cause of independent origin that was not foreseeable”); see *Pharmacy Benefit Managers and Their Role in Drug Spending*, COMMONWEALTH FUND (Apr. 22, 2019), <https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending> [<https://perma.cc/5P6R-TMA4>] (explaining that PBMs are “companies that manage prescription drug benefits on behalf of health insurers, Medicare Part D drug plans, large employers, and other payers”).

¹³ See *infra* notes 64–84.

¹⁴ See 18 U.S.C. §§ 1961–1968; *infra* notes 17–48 and accompanying text.

¹⁵ See *infra* notes 49–67 and accompanying text.

¹⁶ See *infra* notes 68–84 and accompanying text.

¹⁷ See *infra* notes 21–36 and accompanying text.

their alleged fraudulent misrepresentations of prescription medication safety and efficacy.¹⁸ Section A of this Part provides a brief overview of RICO and examines § 1964(c) and its proximate causation requirement.¹⁹ Section B introduces the Ninth Circuit’s 2019 decision in *Painters & Allied Trades District Council 82 Health Care Fund v. Takeda Pharmaceuticals Co.*, the most recent federal circuit case on this issue.²⁰

A. A Brief Overview of RICO and Supreme Court Jurisprudence on § 1964(c) Proximate Causation Requirements

RICO criminalizes specific actions involving a “pattern of racketeering activity” through the development of four novel prohibitions under § 1962.²¹ Section 1964(c) provides individuals whose “business or property” was harmed due to one of these § 1962 violations with a civil cause of action, allowing them to file a claim in federal court seeking triple damages, expenditures, and attorney’s fees.²²

To obtain standing for a civil RICO claim pursuant to § 1964(c), a plaintiff must demonstrate (1) a defendant’s § 1962 RICO violation, (2) harm to the plaintiff’s “business or property,” and (3) that this harm was “by reason of” that § 1962 RICO violation.²³ The Supreme Court has construed the statutory expression “by reason of” to mean that a plaintiff must demonstrate both proximate causation and but-for causation.²⁴ The Court has explained that RICO’s

¹⁸ See *infra* notes 49–67 and accompanying text.

¹⁹ See 18 U.S.C. §§ 1961–1968; *infra* notes 21–36 and accompanying text.

²⁰ See *infra* notes 37–48 and accompanying text.

²¹ 18 U.S.C. § 1962(a)–(d); *RJR Nabisco, Inc. v. European Cmty.*, 579 U.S. 1, 1 (2016); *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 453 (2006). Section 1962(a) proscribes the investment of moneys obtained from “a pattern of racketeering activity in an enterprise.” § 1962(a); *RJR Nabisco*, 579 U.S. at 2. Section 1962(b) prohibits obtaining or retaining “an interest in an enterprise through a pattern of racketeering activity.” § 1962(b); *RJR Nabisco*, 579 U.S. at 2. Section 1962(c) prohibits an individual working for or related to an enterprise “to conduct the enterprise’s affairs through a pattern of racketeering activity.” § 1962(c); *RJR Nabisco*, 579 U.S. at 2. Finally, § 1962(d) proscribes conspiracy to contravene any of the previous prohibitions as set forth in § 1962(a)–(c). § 1962(d); *RJR Nabisco*, 579 U.S. at 2.

²² See § 1964(c) (setting forth that any individual harmed through a § 1962 violation has a civil cause of action and may recover treble damages, expenses, and attorney’s fees).

²³ See *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 131 (2d Cir. 2010) (quoting *City of New York v. Smokes-Spirits.com, Inc.*, 541 F.3d 425, 439 (2d Cir. 2008)). RICO implements its relevant prohibitions through both criminal and civil penalties. G. Robert Blakey & John Robert Blakey, *Civil and Criminal RICO: An Overview of the Statute and Its Operation*, 64 DEF. COUNSEL J. 36, 38 (1997). Unlawful conduct under RICO is laid out in § 1962, whereas the criminal and civil remedies are set forth under § 1963 and § 1964, respectively. *Id.* Civil remedies under RICO include injunctions, triple damages, and attorney’s fees. *Id.* at 41. Defendants convicted of § 1963(a) violations may be incarcerated or fined, and their assets may be forfeited. *Id.*

²⁴ *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co.*, 943 F.3d 1243, 1248–49 (9th Cir. 2019) (noting that proximate cause prohibits suit where the injury claimed is too far separated from the defendant’s alleged RICO violation); see *Holmes v. Sec. Inv. Prot. Corp.*,

proximate cause requirement restrains an individual's responsibility for the results of their acts by prohibiting suit for a claimed injury that is too far removed from the defendants' prohibited conduct.²⁵ As such, proximate causation requires some "direct relation" between the harm claimed and the RICO violation asserted.²⁶

The "direct relation" requirement is based on three pragmatic considerations, referred to as the *Holmes* factors, as set forth in the Supreme Court's 1992 decision in *Holmes v. Securities Investor Protection Corp.*²⁷ First, the more remote a plaintiff's injury is from an alleged RICO violation, the more difficulty the court faces in determining the extent to which that RICO violation actually brought about the plaintiff's injury.²⁸ Second, allowing for claims by plaintiffs less directly harmed, while avoiding the risk of "multiple recoveries," would complicate the court's allocation of damages.²⁹ Third, it is unnecessary to contend with these issues because directly injured plaintiffs can be relied on to uphold the law by bringing suit.³⁰

In *Holmes*, the Court held that the plaintiff did not satisfy the proximate causation requirement because the plaintiff's injury depended entirely upon the harm of more immediate victims who were not parties to the suit.³¹ It reasoned

503 U.S. 258, 268–69 (1992) (explaining that a plaintiff who alleges injury arising from the harm that a defendant inflicted directly on a third party is typically too far separated in the causal chain to successfully plead proximate causation).

²⁵ See *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 133 (2014) (noting that proximate cause typically prevents suits for a plaintiff's claimed injuries that are entirely contingent on the harms the defendant directly inflicted on third parties); *Holmes*, 503 U.S. at 268 (same); *Painters*, 943 F.3d at 1248–49 (same).

²⁶ *Holmes*, 503 U.S. at 268; *Painters*, 943 F.3d at 1248–49.

²⁷ *Holmes*, 503 U.S. at 269–70. The Court has utilized the "direct relation" requirement and the *Holmes* factors in its decisions dealing with the proximate cause requirement for civil RICO claims. *Painters*, 943 F.3d at 1249 (9th Cir. 2019); see *Hemi Grp., LLC v. City of New York*, 559 U.S. 1, 9–10 (2010) (noting plaintiff's theory of proximate cause was much more drawn out than the one the Court dismissed in *Holmes*); *Bridge v. Phx. Bond & Indem. Co.*, 553 U.S. 639, 654 (2008) (noting that the *Holmes* test requires a "direct relation" between the alleged RICO violation and the plaintiff's injury, which courts should examine using the *Holmes* factors); *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 457 (2006) (concluding that the remote link between the plaintiff's harm and the alleged RICO violation raised fundamental issues pertaining to the "direct relation" requirement as set forth in *Holmes*); *Holmes*, 503 U.S. at 269–70 (holding that central to the proximate cause analysis is whether a "direct relation" between the plaintiff's harm and the alleged illegal conduct exists).

²⁸ *Holmes*, 503 U.S. at 269.

²⁹ See *id.* (explaining that allowing indirectly harmed individuals to recover would force the Court to assign damages to plaintiffs separated at diverse degrees of injury from the RICO violation to eliminate the likelihood of numerous recoveries).

³⁰ *Id.* at 269–70.

³¹ *Holmes*, 503 U.S. at 271; see *Canyon Cnty. v. Syngenta Seeds, Inc.*, 519 F.3d 969, 981 (9th Cir. 2008) (noting that the Court in *Holmes* prevented a RICO suit where a plaintiff's harm was wholly conditional on the harms suffered by the "direct victims"). The plaintiff in *Holmes*, the Securities Investor Protection Corporation (SIPC), alleged that the defendants, individuals from a brokerage firm, engaged in a stock manipulation ploy, causing two broker-dealers to become insolvent and forcing the plaintiff to assume their debts. 503 U.S. at 262–63. SIPC is a private nonprofit corporation to

that only the directly injured parties may recover because courts generally hesitate to go beyond the first level of harm when awarding damages.³²

In 2006, in *Anza v. Ideal Steel Supply Corp.*, the Supreme Court clarified that the proximate cause requirement from *Holmes* barred plaintiffs from bringing RICO claims for harms completely derivative of the direct injury the defendants caused.³³ Thus, under *Anza*, courts must closely analyze the causal relationship between the alleged RICO violation and a plaintiff's harm to determine the character of the violation and the precise origin of the plaintiff's harm.³⁴ Where the alleged RICO violation is not the direct cause of the plaintiff's harm, proximate causation is inadequate.³⁵

Finally, in 2008, in *Bridge v. Phoenix Bond & Indemnity Co.*, the Court explained that first-party reliance on the alleged fraud is not necessary to satisfy proximate cause, thereby allowing for RICO recovery in cases where a wrong committed against a third party directly injured the plaintiff.³⁶

B. Factual and Procedural History of Painters

In 2019, in *Painters*, the Ninth Circuit held that in civil RICO suits against pharmaceutical companies, TPPs may satisfy proximate cause where they allege that, but for the defendant's failure to disclose a drug's identified safety risk, they would not have purchased that drug.³⁷

In *Painters*, a group of five individual patients (Patients) and a TPP, Painters and Allied Trades District Council 82 Health Care Fund (Painters

which membership is mandatory for the majority of registered broker-dealers. *Id.* at 261. Pursuant to the Securities Investor Protection Act, SIPC manages the "liquidation of member firms that close when the firms are bankrupt or in financial trouble, and customer assets are missing." *Mission*, SIPC, <https://www.sipc.org/about-sipc/sipc-mission> [<https://perma.cc/873E-K4XF>]; see 15 U.S.C. § 78ccc (setting forth the relevant provisions pursuant to which the SIPC was established). The defendants undertook the alleged stock manipulation ploy between 1964 and 1981 when they "manipulated stock of six companies" by setting forth excessively confident declarations regarding the stock's potential and by selling limited shares to develop the façade of a "liquid market." *Holmes*, 503 U.S. at 262. The broker-dealers purchased significant numbers of the stock themselves. *Id.* When the stocks ultimately crashed, the broker-dealers faced major financial hardship requiring their liquidation and SIPC to pay out approximately \$13 million to meet their clients' claims. *Id.* at 262–63.

³² *Holmes*, 503 U.S. at 271–72 (describing that the broad principle of the law of damages "is not to go beyond the first step").

³³ See *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 459–60 (2006) (explaining that this requirement eliminated the possibility that plaintiffs whose injuries were only remotely linked to the defendant's RICO violation could recover for their injuries).

³⁴ *Id.* at 457–58.

³⁵ *Id.* at 458–60. The Supreme Court's 2010 decision in *Hemi Group, LLC v. City of New York* further solidified this approach. 559 U.S. 1, 15 (2010). There, a plurality of Justices held proximate cause was not satisfied where there were several steps in between the alleged fraud and the plaintiff's injury and where there were third parties involved. *Id.*

³⁶ *Bridge v. Phx. Bond & Indem. Co.*, 553 U.S. 639, 648–49, 661 (2008).

³⁷ *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co.*, 943 F.3d 1243, 1246, 1257 (9th Cir. 2019).

Fund), filed a class action suit in the U.S. District Court for the Western District of Louisiana against Takeda Pharmaceuticals USA, Inc., its parent company, Takeda Pharmaceutical Co. Ltd., and Eli Lilly & Co. (collectively, Takeda).³⁸ Takeda developed and marketed Actos, a type 2 diabetes prescription drug, whose long-term use the Food and Drug Administration (FDA) subsequently declared to be associated with bladder cancer.³⁹

The plaintiffs represented a class of similarly situated TPPs and patients who spent money on or incurred expenses for Actos.⁴⁰ The plaintiffs asserted

³⁸ *Id.* at 1246–47. Takeda Pharmaceutical Company Limited owns Takeda Pharmaceuticals USA, Inc. and controls 75% of its stock. Brief for Petitioner at ii, *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co.*, 943 F.3d 1243 (No. 19-1069). Takeda Pharmaceuticals International AG owns the other 25% of its stock. *Id.* The Painters Fund is a TPP that provides “health and welfare benefits” to beneficiaries. *Painters*, 943 F.3d at 1247. TPPs, including health insurance companies and health funds, cover medical treatment, which includes prescription drug costs for members and their dependents. *In re Avandia Mktg., Sales Prac. & Prod. Liab. Litig.*, 804 F.3d 633, 634 (3d Cir. 2015). Prescription drug coverage under TPPs depends on the inclusion of a drug in the TPP’s formulary. *Id.* A formulary is a consistently modified catalogue of prescription medications the payor permits for reimbursement. *What Is a Formulary?*, PHARMACEUTICAL CARE MGMT. ASS’N, <https://www.pcmanet.org/pcma-cardstack/what-is-a-formulary/> [<https://perma.cc/SB7S-ZXQL>]. Pharmacy Benefit Managers (PBM)s develop TPP’s formularies by assessing data on a drug’s “cost effectiveness, safety, and efficacy.” *In re Avandia*, 804 F.3d at 634–35. Upon a PBM’s conclusion that a drug provides competitive benefits compared to similar drugs, the PBM will provide the drug favored standing on the formulary. *Id.* at 635. Favored standing on a formulary allows the TPP to offer expanded coverage of the drug. *Id.* Increased coverage on the part of the TPP results in covered members receiving a decreased co-payment for the drug when it is prescribed. *Id.* A co-payment is a specific dollar figure an individual pays for a prescription drug. *See Copayment*, HEALTHCARE.GOV, <https://www.healthcare.gov/glossary/co-payment/> [<https://perma.cc/2T36-NZME>] (describing that co-payments may vary for different types of medical care, such as drugs, labs, and visits).

³⁹ *Painters*, 943 F.3d at 1246. On September 17, 2010, upon subsequent investigations of Actos that demonstrated a potential connection between the drug and bladder cancer, the FDA declared that it was undertaking a safety analysis of Actos. *Id.* The safety analysis entailed assessment of data from a “ten-year epidemiological study” to determine whether an association existed between Actos and an elevated probability of bladder cancer. *See FDA Drug Safety Communication: Ongoing Safety Review of Actos (pioglitazone) and Potential Increased Risk of Bladder Cancer After Two Years Exposure*, FOOD & DRUG ADMIN. (Sept. 17, 2010), <https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-ongoing-safety-review-actos-pioglitazone-and-potential-increased-risk> [<https://perma.cc/V9EF-DDW8>] (describing that evidence from animal and human investigations demonstrated a possible safety risk requiring further assessment). The FDA released an official warning on June 15, 2011, which declared that long-term use of Actos may be associated with bladder cancer in patients. *Painters*, 943 F.3d at 1246. Shortly after issuance of the FDA’s alerts, sales of Actos dropped by roughly 80%. *Id.*

⁴⁰ *Painters*, 943 F.3d at 1247. Similarly situated TPPs and patients were those who incurred expenditures for Actos for uses besides resale and did not include consumers currently pursuing a personal injury action stemming from their use of the drug. *Id.* The patients all suffered from type 2 diabetes, and their clinicians prescribed them Actos to decrease their blood sugar. *Id.* The patients alleged that they paid “out-of-pocket” expenditures for Actos and that neither they nor their clinicians were aware of the connection between Actos and bladder cancer when they started taking the medication. *Id.* The patients claimed that as soon as they learned of the increased risk of bladder cancer, they stopped using Actos. *Id.* Patients further alleged that had they been aware of the possibility of bladder cancer caused by Actos, they would not have consumed the drug nor submitted reimbursement claims to their individual TPPs. *Id.* The Painters Fund reimbursed their members’ claims for Actos, which covered healthcare providers and

that Takeda “conspired to commit mail and wire fraud” by intentionally deceiving clinicians, patients, and TPPs into thinking that Actos did not elevate an individual’s risk for bladder cancer.⁴¹ Pursuant to § 1964(c) of RICO, the plaintiffs sought to recoup the costs they incurred when they purchased Actos under the notion that it was harmless.⁴² The court held that the plaintiffs failed to establish that Takeda’s “acts and omissions” proximately caused their sought-after damages.⁴³

The plaintiffs appealed to the Ninth Circuit Court of Appeals, which reversed the dismissal of the RICO claims.⁴⁴ The Ninth Circuit followed Supreme Court precedent in focusing its analysis on whether a “direct relation” existed between the claimed RICO violation and the plaintiff’s injury.⁴⁵ In reaching its decision, the Ninth Circuit determined that although prescribing physicians act as intermediaries between the pharmaceutical fraud and the

pharmacies submitted. *Id.* Painters Fund alleged it depended on members to file claims for prescriptions that were clinically required, as well as safe and effective. *Id.* In other words, the Painters Fund assumed that patients and clinicians would make educated choices about which medication would be prescribed and, thus, filed for reimbursement. *Id.*

⁴¹ *Id.*; see 18 U.S.C. §§ 1341, 1343 (setting forth the relevant provisions of the mail and wire fraud statutes, respectively). To be found guilty of mail or wire fraud, a plaintiff must prove beyond a reasonable doubt that the defendant (1) undertook a ploy to defraud that involved “material deception”; (2) with the requisite “intent to defraud”; (3) through utilization of the mail or wires in actualizing the ploy; (4) and that the ploy caused or would have caused the relevant economic harm. William M. Sloan, *Mail and Wire Fraud*, 48 AM. CRIM. L. REV. 905, 908 (2011). Here, the plaintiffs claimed that although Takeda learned through various investigations that Actos elevated patients’ risk of getting bladder cancer, it did not modify Actos’s warning label or notify the public. *Painters*, 943 F.3d at 1246. The plaintiffs asserted that Takeda deceived the FDA, prescribing physicians, patients, and TPPs into believing that Actos did not increase bladder cancer risk to maximize profits from Actos sales. *Id.* The plaintiffs claimed that the patients depended on Takeda’s falsifications about Actos when they purchased the drug, that clinicians depended on these misleading statements when prescribing the drug, and that TPPs depended on these falsifications when covering the drug’s costs for beneficiaries. *Id.* at 1247. Moreover, the plaintiffs claimed that had they known that Actos elevated a patient’s chance of bladder cancer, they would not have bought the drug. *Id.*

⁴² *Painters*, 943 F.3d at 1247; see 18 U.S.C. § 1964(c) (setting forth the requirements for recovery in civil suits under RICO). The plaintiffs did not, however, seek to recoup any damages associated with any patient’s ingestion of the drug. *Painters*, 943 F.3d at 1247.

⁴³ *Painters*, 943 F.3d at 1247–48. The district court dismissed the RICO claims with prejudice under Federal Rule of Civil Procedure 12(b)(6). *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co.*, No. 17-cv-07223-AS, at 1–2 (C.D. Cal. Feb. 1, 2018) (order partially granting motion to dismiss); see FED. R. CIV. PROC. 12(b)(6) (explaining that one affirmative defense a defendant may assert is the “failure to state a claim upon which relief can be granted”). The court cited to several cases as persuasive authority, including *Sidney Hillman Health Center of Rochester v. Abbott Laboratories* when dismissing the case. *Painters*, 17-cv-07223-AS, at 1–2; see *Sidney Hillman Health Ctr. of Rochester v. Abbott Lab’s*, 873 F.3d 574, 578 (7th Cir. 2017) (holding that TPPs are too far removed from the causal chain of a pharmaceutical company’s fraud to satisfy proximate cause). ⁴⁴ *Painters*, 943 F.3d at 1247–48, 1260.

⁴⁴ *Painters*, 943 F.3d at 1247–48, 1260.

⁴⁵ See *id.* at 1257 (noting that the court’s conclusion was aligned with the Supreme Court’s mandate that the proximate cause analysis center around the “direct relation” between the claimed RICO violation and the plaintiff’s alleged harm).

TPP's injury, they do not serve as "intervening causes" that sever proximate causation.⁴⁶ The court reasoned that because the pharmaceutical company manufactured a prescription drug, as opposed to an over-the-counter drug, it was always necessary for clinicians to prescribe the drug.⁴⁷ Therefore, it was probable that prescribing clinicians would in some way contribute to the causal chain of the fraud.⁴⁸

II. MAINTAINING THE CAUSAL CHAIN: HOW COURTS HAVE INTERPRETED RICO'S PROXIMATE CAUSATION REQUIREMENT IN THE CONTEXT OF PHARMACEUTICAL FRAUD

In 2019, in *Painters & Allied Trades District Council 82 Health Care Fund v. Takeda Pharmaceuticals Co.*, the U.S. Court of Appeals for the Ninth Circuit held that a TPP's injuries are not too remote from a defendant pharmaceutical company's alleged scheme to defraud to satisfy § 1964(c)'s proximate causation requirement.⁴⁹ In so doing, it joined the U.S. Courts of Appeals for the First and Third Circuits and split from the U.S. Courts of Appeals for the Second and Seventh Circuits regarding whether TPPs bringing civil RICO claims against pharmaceutical companies may properly allege proximate causation.⁵⁰ Section A of this Part discusses the proximate causation analysis of

⁴⁶ *Id.* The court explained that an intervening cause constitutes a subsequent cause "of independent origin that was not foreseeable." *Id.* The court reasoned that because the clinicians' prescribing of Actos was not only anticipated, but also required, their "causative role" in the pharmaceutical fraud was entirely foreseeable. *Id.* Therefore, the clinicians could not constitute an intervening cause between the fraud and the TPP's harm. *Id.*

⁴⁷ *Id.*

⁴⁸ *See id.* (noting that because Actos was a prescription medication, patients had to obtain a clinician's prescription to acquire the drug). The court also explained that, due to the organization of the U.S. healthcare system, the pharmaceutical company was aware that TPPs, and not prescribing clinicians, would pay for the drug. *Id.* (quoting *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21, 38–39 (1st Cir. 2013)); *see In re Avandia Mktg., Sales Pracs. & Prod. Liab. Litig.*, 804 F.3d 633, 645 (3d Cir. 2015) (noting that TPPs alleged that the pharmaceutical company knew that TPPs would be covering the drug expenditures).

⁴⁹ *See Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co.*, 943 F.3d 1243, 1257, 1259 (9th Cir. 2019) (holding that a TPP meets the proximate cause requirement where it is an "immediate victim[]" of a defendant pharmaceutical company's fraudulent scheme).

⁵⁰ *Compare Painters*, 943 F.3d at 1257 (noting the First and Third Circuits' approaches to proximate causation were correct as they were better aligned with Supreme Court jurisprudence), *and In re Avandia Mktg., Sales Pracs. & Prod. Liab. Litig.*, 804 F.3d 633, 644, 646 (3d Cir. 2015) (holding that the TPPs properly alleged proximate causation where the conduct that directly harmed them was the same conduct that gave rise to the RICO violation), *and In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21, 37 (1st Cir. 2013) (concluding that a TPP properly alleged proximate causation where it was the principal and anticipated victim of the pharmaceutical company's fraudulent ploy and where its injury was a "foreseeable and natural consequence" of the ploy (quoting *Bridge v. Phx. Bond & Indem. Co.*, 553 U.S. 639, 657–58 (2008))), *with Sidney Hillman Health Ctr. of Rochester v. Abbott Lab'ys*, 873 F.3d 574, 578 (7th Cir. 2017) (holding that misrepresentations made to clinicians do not satisfy proximate cause for TPPs because these actions are too removed from the sequence of events), *and UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 134, 136 (2d Cir. 2010) (holding that the

the Second and Seventh Circuits.⁵¹ Section B explores the contrasting approach of the First and Third Circuits in evaluating whether a direct relationship exists between TPPs and drug manufacturers.⁵² Finally, Section C discusses how the Ninth Circuit adopted the First and Third Circuits' approach.⁵³

A. The Second and Seventh Circuits' Approach

In 2010, in *UFCW Local 1776 v. Eli Lilly & Co.*, the Second Circuit held that too many levels of independent actions separated a pharmaceutical company's fraudulent scheme and TPPs' drug payments to uphold proximate cause under Supreme Court precedent.⁵⁴ Similarly, in 2017, in *Sidney Hillman Health Center of Rochester v. Abbott Laboratories*, the Seventh Circuit joined the Second Circuit, holding that the TPPs' injury was too remote from the fraudulent conduct to uphold proximate causation.⁵⁵

The common thread between the Second and Seventh Circuits' decisions is their determination that the numerous levels of independent actions between fraudulent drug promotion and TPPs' drug payments make TPPs too far removed in the line of causation to satisfy proximate cause.⁵⁶ The Second Circuit, in particular, emphasized the fact that the pharmaceutical company's alleged improper marketing was directed toward physicians, not TPPs.⁵⁷ Be-

link between pharmaceutical fraud and the TPPs' injury was too "attenuated" to satisfy proximate cause because third and fourth parties, in part, caused the injury).

⁵¹ See *infra* notes 54–60 and accompanying text.

⁵² See *infra* notes 61–63 and accompanying text.

⁵³ See *infra* notes 64–67 and accompanying text.

⁵⁴ *UFCW Local 1776*, 620 F.3d at 134. In a class action lawsuit, covered members and TPPs brought civil RICO claims against a pharmaceutical company, alleging that it distorted its drug's safety and efficacy and encouraged its off-label use despite a lack of safety data. *Id.* at 123. Off-label promotion is a strategy wherein pharmaceutical manufacturers and other entities promote "FDA-approved drugs for unapproved uses." Stephanie M. Greene & Lars Noah, *Off-Label Drug Promotion and the First Amendment*, 162 U. PA. L. REV. ONLINE 239, 239 (2014), <https://www.pennlawreview.com/2014/04/07/off-label-drug-promotion-and-the-first-amendment/> [<https://perma.cc/B5KR-3Q5G>]. Unapproved uses are those that the FDA has not yet authorized as safe and effective. See Elizabeth Richardson, *Off-Label Drug Promotion*, HEALTH AFFS. (Jun. 20, 2016), <https://www.healthaffairs.org/doi/10.1377/hpb20160630.920075/full/> [<https://perma.cc/5LD2-J86B>] (describing how the FDA does not regulate the process by which clinicians prescribe medications and the extent to which off-label prescribing occurs in the United States).

⁵⁵ *Sidney Hillman*, 873 F.3d at 578. The plaintiffs, various TPPs, requested class certification to bring civil RICO claims against a pharmaceutical company for covering up its role in endorsing off-label uses to clinicians. *Id.* at 575.

⁵⁶ *Id.* at 578; *UFCW Local 1776*, 620 F.3d at 134.

⁵⁷ See *UFCW Local 1776*, 620 F.3d at 134 (noting that, critically, the TPPs did not claim they actually relied on the pharmaceutical company's fraud, which was specifically targeted toward clinicians). The Second Circuit noted the numerous causal steps between a pharmaceutical company's fraud and TPPs' economic injury, including physicians depending on the falsifications, TPPs depending on the medical opinion of PBMs, and TPPs declining to negotiate drug price. *Id.* The court concluded that the actions directly harming the plaintiffs were independent from the action that constituted the fraud. *Id.*

cause the TPPs did not depend on the misstatements, the Second Circuit determined that they were too far removed from the fraud to satisfy proximate cause.⁵⁸ Similarly, the Seventh Circuit noted that improper “off-label promotion” affected the doctors’ actions rather than the actions of the TPPs.⁵⁹ The Seventh Circuit also emphasized that because it was unclear whether TPPs were the first or only party injured by the pharmaceutical fraud, they could not establish proximate cause.⁶⁰

B. *The First and Third Circuits’ Approach*

In contrast, in 2013, in *In re Neurontin Marketing & Sales Practices Litigation*, the First Circuit held that when a TPP is the principal and deliberate victim, and the harm is “foreseeable,” a clinician’s independent decisions do not sever the “direct relation” required to establish proximate cause under RICO.⁶¹ Similarly, in 2015, in *In re Avandia Marketing, Sales Practices, & Prod-*

⁵⁸ *Id.*

⁵⁹ See *Sidney Hillman*, 873 F.3d at 578 (noting that the inappropriate promotion of drugs for unapproved uses impacted clinicians’ actions, as some clinicians would alter their prescribing behavior as a result).

⁶⁰ See *id.* at 576 (noting that TPPs may suffer economic harm as a result of the pharmaceutical fraud, but that it was uncertain whether they were the first or the only injured entity). The Seventh Circuit emphasized that the law of damages tends to award damages only to those directly harmed and avoids recognizing secondary injuries of parties too far removed from the harms of the immediate victims. *Id.*; see also *Holmes v. Sec. Inv. Prot. Corp.*, 503 U.S. 258, 271–72 (1992) (noting the general pattern of the law in relation to damages is “not to go beyond the first step”). The Seventh Circuit held that because the harms the patients suffered, such as adverse health outcomes and financial loss, occurred before the harms the TPPs suffered, TPPs were not the “initially injured party.” *Sidney Hillman*, 873 F.3d at 576. Moreover, the court noted that assessing patients’ health expenditures, in addition to those of the TPPs, may be challenging. *Id.* The court further noted that clinicians may also be harmed by the pharmaceutical fraud due to lost profits resulting from prescribing “ineffective medicine,” thereby impacting their practice as a whole. *Id.* The court additionally remarked that apportioning damages may be difficult where the deceptive marketing scheme may not have influenced some physicians’ prescribing decisions and where some off-label uses of the prescription may have actually helped certain patients. *Id.* at 577.

⁶¹ *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21, 37–38 (1st Cir. 2013). The defendant pharmaceutical company appealed jury and court verdicts amounting to over \$140 million in favor of the plaintiff TPP. *Id.* at 25. The verdicts occurred after a division of the pharmaceutical company agreed to settle criminal cases the United States had brought. *Id.* Through the settlement, the division of the pharmaceutical company pleaded guilty to various counts associated with its unlawful off-label prescription marketing ploy and paid \$140 million in criminal penalties. *Id.* The pharmaceutical company itself incurred \$190 million in civil penalties. *Id.* *In re Neurontin* was one of numerous appeals pertaining to the unlawfully marketed prescription medication. *Id.* The plaintiff TPP suffered economic injury in covering the costs of four different kinds of off-label prescription uses. *Id.* The pharmaceutical company had promoted each of the off-label uses through its fraudulent ploy. *Id.* The pharmaceutical company claimed that, as a matter of law, the TPP’s RICO claim could not stand because proximate causation was lacking. *Id.* at 34. Specifically, it argued that there were an excessive number of steps in the chain of proximate causation between its fraudulent representations of its prescription drug and the TPP’s economic harm. *Id.* The First Circuit rejected this argument and affirmed the award of damages to the TPP. *Id.* at 25, 51. The court relied on *Holmes v. Securities Investor Protection Corp.* and *Bridge v. Phoenix Bond & Indemnity Co.* in noting that the TPP did not have to demonstrate first-party reliance on the

uct Liability Litigation, the Third Circuit held that TPPs satisfied proximate causation.⁶² Specifically, the court noted that TPPs alleged that they maintained the defendant pharmaceutical company's prescription within their formularies and reimbursed it at advantageous prices because they depended on the defendant's falsifications about the drug's safety.⁶³

C. *The Ninth Circuit Joined the First and Third Circuits*

In joining the First and Third Circuits' approach and departing from that of the Second and Seventh Circuits, the Ninth Circuit rejected the notion that the causal chain between a pharmaceutical company's fraud and a TPP's injury is too attenuated to uphold the "direct relation" requirement.⁶⁴ The Ninth Circuit did not accept that the existence of "intermediaries," including prescribing clinicians, severed the chain of proximate causation between pharmaceutical

pharmaceutical company's fraudulent statements to maintain proximate cause. *See id.* at 34–35, 37. Additionally, the court determined that the TPP was the immediate and anticipated target of the pharmaceutical fraud. *Id.* at 39.

⁶² *In re Avandia Mktg., Sales Pracs. & Prod. Liab. Litig.*, 804 F.3d 633, 636, 643, 645 (3d Cir. 2015). The defendant pharmaceutical company appealed a denial of its motion to dismiss a class action suit TPPs brought claiming civil RICO violations predicated on the pharmaceutical company's alleged fraudulent misrepresentation of its drug's safety. *Id.* at 633. The pharmaceutical company claimed that the lower court erred in determining that the TPPs satisfied proximate cause pursuant to RICO's standing requirements. *Id.* at 634. The court disagreed and reasoned that the conduct giving rise to the TPPs' injury was the same conduct constituting the alleged RICO violation: the pharmaceutical company's fraudulent statements regarding its drug's safety risks. *Id.* at 644. The court further reasoned that the mere presence of intermediaries, such as clinicians, was not sufficient to sever the chain of proximate cause because the TPPs' injuries were not dependent on the any injuries suffered by intermediaries. *Id.* at 645–46.

⁶³ *Id.* at 636. The TPPs further alleged the pharmaceutical company purposefully hid major safety risks of its drug and persisted in encouraging its use as a safer medication for diabetes, even though the pharmaceutical company was aware of the drug's established risks, such as its potential to cause heart attacks. *Id.* The TPPs claimed the pharmaceutical company distorted data and scientific publications and issued inaccurate statements to increase profits. *Id.* The TPPs alleged the drug was not valued at the advantageous rates that they were paying and that clinicians would not have prescribed the drug to the extent they did had they known of the relevant safety risks. *Id.*

⁶⁴ *Compare Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co.*, 943 F.3d 1243, 1251 (9th Cir. 2019) (holding that under *Bridge* precedent, a TPP may satisfy the direct relation requirement when bringing civil RICO claims against pharmaceutical companies), and *In re Avandia*, 804 F.3d at 644, 646 (concluding that proximate cause was satisfied where the criminal action giving rise to the TPPs' harm was identical to the action constituting the RICO claims: misrepresentation of drug safety and efficacy), and *In re Neurontin*, 712 F.3d at 38–39 (determining that the TPP satisfied proximate cause where the pharmaceutical company's sham marketing scheme only became successful upon the TPP's payment, the very injury for which the TPP sought recovery), with *Sidney Hillman*, 873 F.3d at 578 (holding falsifications made to physicians were insufficient to maintain TPPs' RICO claims against pharmaceutical companies), and *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 134 (2d Cir. 2010) (concluding that proximate causation was not met where TPPs were too far removed in the causal chain of pharmaceutical fraud).

companies and TPPs.⁶⁵ Instead, it held that the causative chain was not severed because the pharmaceutical companies were well aware that, due to the organization of the U.S. healthcare system, clinicians would not cover drug costs.⁶⁶ As a result, TPPs could meet both the “direct relation” and the *Holmes* factors requirements and sufficiently allege proximate cause.⁶⁷

III. WHY THE NINTH CIRCUIT CORRECTLY MAINTAINED THE CAUSAL CHAIN

In 2019, in *Painters & Allied Trades District Council 82 Health Care Fund v. Takeda Pharmaceuticals Co.*, the Ninth Circuit correctly held that a TPP may satisfy proximate cause in cases involving civil RICO claims against pharmaceutical companies that fraudulently misrepresent drug safety and efficacy.⁶⁸

⁶⁵ See *Painters*, 943 F.3d at 1257 (concluding that although prescribing clinicians may serve as “intermediaries” between the pharmaceutical fraud and the TPP’s payment, they are not an “intervening cause” that severs proximate causation); *In re Avandia*, 804 F.3d at 645 (holding that TPPs satisfied proximate cause where they claimed that pharmaceutical companies knew that TPPs pay for prescription drug costs); *In re Neurontin*, 712 F.3d at 38–39 (determining that proximate cause was satisfied where the economic injury the TPP sought recovery for was that which stemmed from the pharmaceutical company’s RICO violation).

⁶⁶ See *Painters*, 943 F.3d at 1255 (noting that pharmaceutical companies recognize and understand that TPPs cover the costs of their drugs); *In re Avandia*, 804 F.3d at 645–46 (noting that the TPPs claimed that pharmaceutical companies knew that TPPs paid for prescription costs and that their ploy to defraud was accomplished through such payments, which constituted the very harm that TPPs aimed to recover from); *In re Neurontin*, 712 F.3d at 38–39 (reasoning that the pharmaceutical company’s deceptive marketing scheme, which it designed to increase earnings, was effective only upon the TPP’s payments for the additional prescriptions that its fraudulent conduct brought about).

⁶⁷ See *Painters*, 943 F.3d at 1251 (noting that the Supreme Court’s precedent in *Bridge v. Phoenix Bond & Indemnity Co.* was sufficient to conclude that TPPs satisfied the “direct relation” requirement of 18 U.S.C. § 1964(c)); *In re Avandia*, 804 F.3d at 645 (same); *In re Neurontin*, 712 F.3d at 38 (noting that the TPP, as the intended target of the pharmaceutical fraud, experienced direct and foreseeable harm as a result of the fraud). Employing the *Holmes* factors, the Third Circuit noted that differentiating among the damages that the pharmaceutical company’s alleged violations and other unrelated factors caused would not be overly-complex, and that TPPs were best situated to sue because the defendant’s RICO violation did not injure the prescribing clinicians. *In re Avandia*, 804 F.3d at 644, 646; see *Holmes v. Sec. Inv. Prot. Corp.*, 503 U.S. 258, 269–71 (1992) (noting that a direct relation requires (1) a straightforward determination of damages caused by a defendant’s unlawful conduct; (2) a streamlined procedure for allocation of damages; and (3) a justified deterrent effect). The First and Ninth Circuits emphasized the important deterrent effect RICO liability would impose against fraudulent pharmaceutical schemes. See *Painters*, 943 F.3d at 1252 (noting that the pharmaceutical company’s liability promotes the objective of deterring harmful behavior, without including those parties who were not immediately harmed by financial loss); *In re Neurontin*, 712 F.3d at 39 (pointing out that holding the pharmaceutical company liable would deter similar unlawful conduct in the future).

⁶⁸ See *Bridge v. Phx. Bond & Indem. Co.*, 553 U.S. 639, 649 (2008) (holding that 18 U.S.C. § 1964 does not have a first-person reliance requirement); *Holmes v. Sec. Inv. Prot. Corp.*, 503 U.S. 258, 268 (1992) (describing proximate cause as the judicial means by which defendants’ liability is restricted to the consequences of their own conduct); *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co.*, 943 F.3d 1243, 1251 (9th Cir. 2019) (holding that TPPs may satisfy the direct relation requirement when bringing civil RICO claims against a pharmaceutical company).

Though the Second and Seventh Circuits have determined that the causal link between pharmaceutical companies and TPPs is too attenuated to maintain proximate causation, both Supreme Court jurisprudence and policy implications support the Ninth Circuit's holding.⁶⁹

In the Second and Seventh Circuits' proximate cause analysis, the courts emphasized that there were too many levels of "independent decisions" between the pharmaceutical fraud and the TPPs' resulting economic injury to uphold any "direct relation."⁷⁰ Although the decisions of prescribing physicians and PBMs play a role in the causative chain, the Second and Seventh Circuits' narrow focus on these parties overlooked the essential fact that, notwithstanding the role of prescribers, pharmaceutical fraud may still directly relate to a TPP's economic injury.⁷¹

As an initial matter, the Second and Seventh Circuits' emphasis on the fact that the pharmaceutical companies made misstatements to physicians, rather than to TPPs, is inherently contrary to Supreme Court precedent.⁷² In *Bridge v. Phoenix Bond & Indemnity Co.*, the Supreme Court held that first-person reli-

⁶⁹ See *Painters*, 943 F.3d at 1251–52 (holding that, following Supreme Court precedent, a TPP may satisfy the "direct relation requirement" when bringing civil RICO claims against pharmaceutical companies); see, e.g., *Hemi Grp., LLC v. City of New York*, 559 U.S. 1, 14 (2010) (noting that the Supreme Court reiterated the need for a "direct relationship" between the plaintiff's harm and the defendant's alleged RICO violation); *Bridge*, 553 U.S. at 661 (holding that first-party reliance on the defendant's fraud is not required to satisfy proximate cause); *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 461 (2006) (noting that when assessing a RICO claim for proximate causation, the major concern is whether the claimed violation "led directly" to the plaintiff's harm); *Holmes*, 503 U.S. at 269 (holding that proximate cause requires a "direct relation" between the alleged RICO violation and the plaintiff's damages).

⁷⁰ *Sidney Hillman Health Ctr. of Rochester v. Abbott Lab'ys*, 873 F.3d 574, 578 (7th Cir. 2017); *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 136 (2d Cir. 2010).

⁷¹ See *Bridge*, 553 U.S. at 649 (holding that a person may be harmed "by reason of" a RICO violation without having directly relied on the fraud); *Anza*, 547 U.S. at 476 (Thomas, J., concurring in part and dissenting in part) (noting that first-person reliance on the defendant's fraud is not required to satisfy proximate causation under RICO); *Sidney Hillman*, 873 F.3d at 578 (emphasizing that the pharmaceutical company made misrepresentations to clinicians and, therefore, TPPs could not recover under RICO); *UFCW Local 1776*, 620 F.3d at 136 (noting that individual clinicians may have depended on the fraudulent misrepresentations to varying degrees).

⁷² Compare *Bridge*, 553 U.S. at 649 (holding that first-person reliance is not needed to establish proximate cause under civil RICO claims), and *Anza*, 547 U.S. at 476 (Thomas, J., concurring in part and dissenting in part) (noting that a party can commit a RICO violation without anyone directly relying upon the fraud), with *Sidney Hillman*, 873 F.3d at 578 (emphasizing that because the pharmaceutical company made the misrepresentations to clinicians, sufficient separation existed between the fraud and the TPPs so as to sever proximate cause), and *UFCW Local 1776*, 620 F.3d at 134 (highlighting the drawn out nature of the link between the pharmaceutical fraud and the TPPs' injury because the pharmaceutical company made the misrepresentations to clinicians). The Supreme Court's majority opinion in *Bridge* explicitly rejected the need for first-party reliance in establishing proximate causation in civil RICO claims. *Bridge*, 553 U.S. at 649. Instead, the Court focused on the fact that the plaintiff's injury "direct[ly] result[ed]" from the fraud and constituted a "foreseeable and natural consequence" of it. *Id.* at 657–58. The Court noted the extensive precedent that allows a directly injured plaintiff to recover, despite the fact that a "third party," rather than the plaintiff, depended on the fraud. *Id.* at 656.

ance on a defendant's fraud is not necessary to establish proximate causation under RICO.⁷³ The Ninth Circuit, on the other hand, correctly held that a TPP's injury may have a "direct relation" with a pharmaceutical company's fraudulent marketing scheme because TPPs are immediate victims of pharmaceutical fraud and their injury is a "foreseeable" and "natural consequence" of it.⁷⁴

Moreover, the Ninth Circuit accurately applied each of the *Holmes* factors in holding that a "direct relation" may exist between pharmaceutical fraud and a TPP's injury.⁷⁵ First, determining the damages attributable to the pharmaceutical company's fraud would not be overly complicated because previous litigation has demonstrated the feasibility of such calculations.⁷⁶ Second, the court avoided any risk of the plaintiffs receiving "multiple recoveries" because the pharmaceutical fraud did not economically injure clinicians and because the plaintiffs did not include patients already pursuing personal injury claims resulting from their drug consumption.⁷⁷ Third, holding pharmaceutical companies liable under RICO is justified because the civil and criminal penalties they currently face are generally modest and often represent merely the "cost of doing business."⁷⁸ Allowing pharmaceutical companies to be held civilly

⁷³ *Bridge*, 553 U.S. at 649.

⁷⁴ *See id.* (noting that a person may be harmed "by reason of" a pattern of fraudulent activity despite not having depended on the misrepresentation); *Anza*, 547 U.S. at 476 (Thomas, J., concurring in part and dissenting in part) (concluding that first-person reliance on the defendant's fraud was not necessary to establish proximate causation under RICO). Due to the organization of the U.S. healthcare system, pharmaceutical companies are well aware that TPPs, rather than physicians or PBMs, bear the financial burden of covering prescription medications. *Painters*, 943 F.3d at 1257. Furthermore, the Ninth Circuit was correct because disclosing the possibility that TPPs may satisfy proximate cause in these cases runs contrary to the understanding of proximate cause as a "flexible concept" that does not adhere to a "black-letter rule" that will determine the outcome across cases. *See Bridge*, 553 U.S. at 649–50, 654 (noting proximate cause is a malleable principle that does not operate in the same manner across cases).

⁷⁵ *See Holmes*, 503 U.S. at 269 (setting forth the three factors for assessing "direct relation": (1) ease of assessing damages from the RICO violation; (2) avoidance of complex rules of allocating damages among plaintiffs; and (3) warranted deterrence of future harmful conduct); *Painters* 943 F.3d at 1251–52 (noting that (1) it would not be overly complicated to determine the TPP's damages; (2) there is no concern for "duplicative recovery" where the injury experienced by the TPPs and the patients "do no overlap"; and (3) the value of deterring the unlawful conduct is justified under the circumstances).

⁷⁶ *See Holmes v. Sec. Inv. Prot. Corp.*, 503 U.S. 258, 269 (1992) (describing the first factor as the need for a straightforward damages calculation pertaining to the defendant's unlawful conduct); *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21, 42, 44–45 (1st Cir. 2013) (holding that expert testimony appropriately utilized "regression analysis" to calculate damages by, among other things, demonstrating the extent to which a pharmaceutical company's fraudulent marketing scheme increased drug prescriptions).

⁷⁷ *See Holmes*, 503 U.S. at 269 (noting RICO's proximate cause requirement seeks to decrease the likelihood that numerous, less directly injured parties would seek to recover); *Painters*, 943 F.3d at 1247 (noting the plaintiffs represented a class of similarly situated TPPs and patients who paid for Actos with their own money for personal use); *In re Neurontin*, 712 F.3d at 37–39 (noting that because clinicians do not pay for the cost of prescription drugs, there is no likelihood for recovery on their part).

⁷⁸ *See Holmes*, 503 U.S. at 269 (emphasizing that proximate cause promotes the principle of deterring harmful behavior); Kevin Outterson, *Punishing Health Care Fraud—Is the GSK Settlement*

liable under RICO and exposing them to the risk of treble damages may create a heightened deterrence effect against future fraudulent behavior.⁷⁹

Finally, the policy implications surrounding pharmaceutical fraud also support the Ninth Circuit's approach.⁸⁰ Mounting prescription drug costs and rampant pharmaceutical fraud represent major problems for the U.S. healthcare system.⁸¹ Private health insurers, including TPPs, constitute the largest group of retail prescription drug payers.⁸² Beyond the economic impact, pharmaceutical fraud has a devastating effect on public health, as it has killed thousands of patients, and it continues to pose a significant threat to patient safety.⁸³ The Supreme

Sufficient?, 367 NEW ENG. J. MED. 1082, 1083–84 (2012) (describing how criminal and civil fines commonly imposed on pharmaceutical fraud tend to constitute only a modest proportion of pharmaceutical companies' total revenues).

⁷⁹ See 18 U.S.C. § 1964(c) (setting forth the treble damages provision); *Holmes*, 503 U.S. at 269 (emphasizing the broad interest in “detering injurious conduct” that RICO’s proximate causation requirement tends to serve); *In re Neurontin*, 712 F.3d at 38 (holding that the TPP was best situated to sue drug manufacturers because it was directly harmed by their fraudulent actions); see also Outterson, *supra* note 78, at 1084 (noting that doubts persist as to the deterrent effect of corporate fines against pharmaceutical fraud where such fines often constitute only a “small percentage of their global revenue”).

⁸⁰ See Juliette Cubanski et al., *How Does Prescription Drug Spending and Use Compare Across Large Employer Plans, Medicare Part D, and Medicaid?*, KAISER FAM. FOUND. (May 20, 2019), <https://www.kff.org/medicare/issue-brief/how-does-prescription-drug-spending-and-use-compare-across-large-employer-plans-medicare-part-d-and-medicaid/#:~:text=In%202017%2C%20total%20U.S.%20retail,insurance%2C%20Medicare%2C%20and%20Medicaid> [<https://perma.cc/A94C-M2SZ>] (noting that private health insurers bear significant costs associated with prescription drug coverage); Press Release, U.S. Dep’t of Just., Justice Department Recovers Over \$3 Billion from False Claims Act Cases in Fiscal Year 2019 (Jan. 9, 2020), <https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019> [<https://perma.cc/8CWY-C97K>] (describing the billions of dollars the Department of Justice (DOJ) recovered from healthcare-related fraud and other matters).

⁸¹ See CTRS. FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH EXPENDITURES 2019 HIGHLIGHTS 1 (2020), <https://www.cms.gov/files/document/highlights.pdf> [<https://perma.cc/D8AN-BJDF>] (describing the staggering increases in healthcare costs in the United States). In 2019, national health care costs increased to \$3.8 trillion with U.S. retail prescription medication expenditures totaling \$369.7 billion or 10% of total health care costs. *Id.* In 2019, the DOJ recovered over \$3 billion from False Claims Act cases, of which \$2.6 billion involved healthcare-related matters. Press Release, U.S. Dep’t of Just., *supra* note 80. Two of the biggest recoveries in healthcare-related matters involved pharmaceutical companies that fraudulently promoted opioid drugs, contributing to the ongoing opioid crisis. *Id.* In one matter, Insys Therapeutics settled civil claims alleging that it provided kickbacks to entice clinicians and nurse practitioners to prescribe its drug to their patients for \$195 million. *Id.* In another matter, Reckitt Benckiser Group plc paid \$1.4 billion to settle criminal and civil claims pertaining to its marketing of the opioid abuse medication Suboxone. *Id.*

⁸² Cubanski, *supra* note 80. Private health insurers, including TPPs, cover 42% of our nation’s retail prescriptions costs, followed by Medicare at 30%, “patient out-of-pocket costs” at 14%, and Medicaid at 15%. *Id.*

⁸³ See Rebecca L. Haffajee et al., *Drug Companies' Liability for the Opioid Epidemic*, 377 NEW ENG. J. MED. 2301, 2301 (2017) (noting a pharmaceutical company’s major role in perpetuating the U.S. opioid epidemic through fraud). Between 2000 and 2017, the opioid epidemic killed 300,000 people in the United States. *Id.* Lawsuits against opioid manufacturers, including Purdue Pharma, began in the 2000s and have increased in recent years. *Id.* Plaintiffs alleged, among other things, that

Court cannot allow pharmaceutical companies to escape responsibility for the consequences of their unlawful conduct and should permit TPPs to utilize RICO as a powerful combatant against pharmaceutical fraud in the United States.⁸⁴

CONCLUSION

In *Painters & Allied Trades District Council 82 Health Care Fund v. Takeda Pharmaceuticals Co.*, the Ninth Circuit joined the First and Third Circuits in holding that a TPP may adequately allege proximate causation in civil RICO claims brought against pharmaceutical companies for their fraudulent misrepresentation of drug safety. The Second and Seventh Circuits, in contrast, have held that TPPs are too far removed from the alleged pharmaceutical fraud to satisfy the proximate causation requirement. The Ninth Circuit correctly rejected this holding and concluded that because TPPs were immediate victims of the pharmaceutical company's fraud, they could uphold both the "direct relation" and *Holmes* factors requirements of proximate cause.

Using its proximate cause jurisprudence, the Supreme Court should resolve the current circuit split by making it clear that pharmaceutical companies may not escape liability by hiding behind the actions of prescribing physicians and PBMs. Until then, pharmaceutical companies will continue to act as modern-day organized crime enterprises, harming not only the lives of individual patients but the wellbeing of our healthcare system at large.

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manufacturers failed to warn consumers regarding the "addiction risks" of their products through drug labeling and marketing. *Id.* Others alleged that manufacturers actively withheld information regarding drug safety. *Id.*; see also Natalie Sherman, *Purdue Pharma to Plead Guilty in \$8bn to Opioid Settlement*, BBC NEWS (Oct. 22, 2020), <https://www.bbc.com/news/business-54636002> [<https://perma.cc/F2QQ-8DYX>] (describing how Purdue Pharma pleaded guilty to facilitating a supply of prescription medication without any actual medical value). Purdue Pharma recently admitted to criminal charges regarding its contribution to the U.S. opioid epidemic, and it continues to face suits from states and individuals. *Id.* Currently, there are about 192 deaths from opioid overdose daily. *In Numbers: Sackler Family, Purdue Pharma and the US Opioid Crisis*, BBC NEWS (Sep. 16, 2019), <https://www.bbc.com/news/world-us-canada-49718388> [<https://perma.cc/9J3E-3ZV3>].

⁸⁴ See *Holmes*, 503 U.S. at 268–70 (describing proximate cause as the tool through which an individual's liability is limited to the results of that individual's own actions); *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co.*, 943 F.3d 1243, 1258 (9th Cir. 2019) (same).