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Standing Up for Consumers: Whether Third Party Payors Can Establish Standing to Sue Against Drug Manufacturers under Civil RICO

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STANDING UP FOR CONSUMERS: WHETHER THIRD PARTY PAYORS CAN ESTABLISH STANDING TO SUE AGAINST DRUG MANUFACTURERS UNDER CIVIL RICO

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I. INTRODUCTION

More than 131 million Americans use prescription drugs.[2] Third-party payors ("TPPs"), such as health insurance companies, pay for the majority of the cost of these prescriptions; 91.5 percent of Americans had health insurance in 2018.[3]

In recent years, TPPs have discovered a new avenue of bringing suit against untruthful drug manufacturers: the civil provision in the Racketeer and Corrupt Organizations Act ("RICO"). Under that statute, TPPs bring suit against drug manufacturers who either misrepresent the safety of a drug or promote off-label uses. The TPPs allege they have incurred significant financial losses paying for the relevant drug, as opposed to another, sometimes cheaper version.

TPPs are fighting for their right to bring suit and hold untruthful drug manufacturers accountable. The TPPs, though, have an uphill battle. Drug manufacturers argue that because TPPs cannot show proximate cause or establish a proper causal connection between the monetary loss and the alleged fraudulent scheme, the TPPs do not have standing to sue. The United States Courts of Appeals have reached an express disagreement about whether TPPs have established proximate cause. This Article argues that TPPs have properly established proximate cause and are properly bringing RICO suits against drug manufacturers.

Part II of this Article examines the doctrine of standing to sue and the legislative history of the civil provision of RICO. Next, Part II reviews Supreme Court precedent and the current jurisprudence of federal circuit courts regarding TPPs bringing suit against drug manufacturers. Part III then argues that TPPs have properly established proximate cause and have standing to sue drug manufacturers in the relevant circumstances. Part III ends with a brief overview of important policy considerations. Part IV concludes by asserting the necessity of truthfulness in drug manufacturing in order to protect the American consumer.

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1. University of Cincinnati Law Review, Associate Member

2. *Prescription Drugs*, GEO. U.: HEALTH POL'Y INST., https://hpi.georgetown.edu/rxdrugs/# [https://perma.cc/55ZZ-APGZ].

3. EDWARD R. BERCHICK, JESSICA C. BARNETT & RACHEL D. UPTON, U.S. DEP'T OF COMMERCE, U.S. CENSUS BUREAU, P60-267 (RV), HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2018 (Nov. 9, 2019), *available at*https://www.census.gov/library/publications/2019/demo/p60-267.html [https://perma.cc/EJD4-X8XM].

II. BACKGROUND

Section A of Part II briefly summarizes the extensive history and evolution of the concept of standing to sue. Section B discusses the legislative history of RICO, summarizes the RICO statutes, and discusses various modern applications of RICO. Next, Section C covers Supreme Court precedent on issues related to TPPs' RICO suits against drug manufactures. Finally, Section D focuses on the current federal circuit split on the issue of whether TPPs can adequately establish standing and proximate cause under civil RICO against pharmaceutical manufacturers that fail to disclose certain health risks or urge certain uses of drugs not yet approved by the Federal Drug Administration ("FDA").

A. Standing to Sue

Article III of the United States Constitution specifies the jurisdiction of federal courts, rendering these courts of limited jurisdiction.[4] Article III grants the federal courts jurisdiction over specific "cases" and "controversies."[5] The Supreme Court of the United States has wrestled for decades with these enigmatic terms, reaching back to Chief Justice Marshall's famous opinion in *Marbury v. Madison*.[6] The Chief Justice described Article III limitations on federal courts, explaining that a court has the power to declare a statute unconstitutional only if the case is properly before it.[7]

From the "cases or controversies" doctrine came another enigmatic term: standing. The doctrine of standing defines an Article III "case or controversy."[8] Standing to sue particularly focuses on the parties before the court, and whether the parties have suffered a direct injury that can be properly addressed by the court.[9] The "irreducible constitutional minimum" of standing has three elements: (1) the plaintiff has suffered a concrete injury; (2) that injury is fairly traceable to actions of the defendant; and (3) it must be likely—not merely speculative—that the injury will be redressed by a favorable decision.[10] The type of injury

4. Anthony M. O'Connor Jr., *Federal Courts: Standing to Sue*, 1985 ANN. SURV. AM. L. 179, 179-80 (1985).

5. U.S. CONST. art. III, § 2.

6. Marbury v. Madison, 5 U.S. 137, 173-74 (1803).

7. *Id*. at 147. "The constitution vests the whole judicial power of the United States in one supreme court, and such inferior courts as congress shall, from time to time, ordain and establish. This power is expressly extended to all cases arising under the laws of the United States; and consequently, in some form, may be exercised over the present *174 case; because the right claimed is given by a law of the United States."

8. O'Connor, *supra* note 4, at 179-80.

9. *Id*.

10. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992).

needed to invoke jurisdiction of the federal courts has been described as, "some direct injury as the result of [a statute's] enforcement, and not merely that [the plaintiff] suffers in some indefinite way in common with people generally."[11] This sort of injury is often called an "injury in fact."[12] Circuit courts disagree about whether "but-for" causation is sufficient for Article III standing or if the Constitution also requires proximate causation.[13] Generally, though, a plaintiff must "allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief."[14] These two types of causation are discussed in depth in the next two sections dealing with the RICO statute and Supreme Court precedent. For the third element, the Supreme Court has insisted that there must be a "substantial likelihood" that the relief sought from a court, if granted, would remedy the harm.[15]

Put more concisely, in order to have Article III standing, a plaintiff must have suffered some actual or threatened injury, which can fairly be traced to the defendant and is likely to be redressed by a favorable decision by the court.

B. Racketeer Influenced and Corrupt Organizations Act

1. Legislative History

RICO's purpose is the "elimination of the infiltration of organized crime and racketeering into legitimate organizations operating in interstate commerce."[16] Organized crime was an issue in the forefront of the 1960s and 1970s, the decades leading up to the enactment of the RICO statute.[17] The Kefauver Committee, which the United States Senate appointed to conduct a study on organized crime, concluded that a separate supplement to federal antitrust law was needed to address the

11. Massachusetts v. Mellon, 262 U.S. 447, 488 (1923).

12. Valley Forge Christian Coll. v. Ams. United for Separation of Church &State, 454 U.S. 464, 472 (1982).

13. *Compare* Lac Du Flambeau Band of Lake Superior Chippewa Indians v. Norton, 422 F.3d 490, 500-01 (7th Cir. 2005), *and* Loggerhead Turtle v. Cnty. Council of Volusia Cnty., Fla., 148 F.3d 1231, 1247 (11th Cir. 1998), *and* Amador Cnty., Cal. v. Salazar, 640 F.3d 373, 378 (D.C. Cir. 2011), *and* The Pitt News v. Fisher, 215 F.3d 354, 361 (3d Cir. 2000), *and* Ivy v. Williams, 781 F.3d 250, 253 (5th Cir. 2015), *with* Nat'l Council of La Raza v. Mukasey, 283 Fed. App'x 848, 851-52 (2d Cir. 2008), *and* Frank Krasner Enter., Ltd. v. Montgomery Cnty., Md., 401 F.3d 230, 236 (4th Cir. 2005), *and* San Diego Cnty. Gun Rights Comm. v. Reno, 98 F.3d 1121, 1130 (9th Cir. 1996).

14. Allen v. Wright, 468 U.S. 737, 751 (1984).

15. Duke Power Co. v. Carolina Envtl. Study Grp., Inc., 438 U.S. 59, 79, 75 n.20 (1978) (plaintiff must show "substantial likelihood" that relief requested will redress the injury).

16. PAUL BATISTA, CIV. RICO PRACTICE MANUAL § 2.04 (2007).

17. Craig M. Bradley, *Racketeers, Congress, and the Courts: An Analysis of RICO*, 65 IOWA L. REV. 837, 837-39 (1980).

issue of businesses being affected by criminal methods.[18]

During Congressional debates, the scope of RICO slowly began to broaden. The bill's original stated purpose was "[t]o aid in the pressing need to remove organized crime from legitimate organizations in our country. . . ."[19] Lawmakers specifically wanted to allow litigants to reach the financial power of organized crime members, leading to the proposal of the civil remedy provision discussed in the next subsection of this Article.[20] Some lawmakers argued for a more expansive application, recognizing that adding a civil remedy would significantly broaden the scope of the original bill.[21] Yet, the civil remedy remained and is found in the statute today.[22]

2. The Statutes

RICO contains eight sections. Section 1962 of RICO makes it unlawful for any person to receive or maintain an interest in an enterprise engaged in interstate commerce through a pattern of racketeering[23] activity or through collection of unlawful debt.[24] The statute also makes it unlawful to have any interest in or control of such an enterprise.[25] Notably, there are no express limitations on the statutes' application.[26] Consistent with Congress's intent to defeat organized crime, Section 1963 contains criminal penalties for a violation of Section 1962 up to 20 years in prison, a monetary fine, or both.[27]

The statute also contains a civil cause of action.[28] Section 1964 of RICO states that any person injured in his business or property *by reason of* a violation of Section 1962 may bring suit in a federal district court and potentially recover threefold the damages sustained, the cost of the suit,

18. Batista, *supra* note 16. The Kefauver Committee was the first modern group to study organized crime in a systematic fashion.

19. *Id.*

20. Danene Tushar, *RICO - Standing to Sue and Something More: Civil Claims under Rico in the Eighth Circuit*, 18 CREIGHTON L. REV. 1283, 1284 (1984).

21. Batista, *supra* note 16.

22. 18 U.S.C. § 1964(c).

23. Section 1961 of RICO provides an expansive definition of "racketeering," in relevant part as follows, "(1) "racketeering activity" means "… (B) any act which is indictable under any of the following provisions of title 18, United States Code:… Section 1341 (relating to mail fraud), Section 1343 (relating to wire fraud)…" The relevant parts of the mail fraud statute and wire fraud statute deal with using such services to introduce false representations.

24. 18 U.S.C. § 1962(a) (1970).

25. 18 U.S.C. § 1962(b) (1970).

26. Tushar, *supra* note 20.

27. 18 U.S.C. § 1963(a) (1970).

28. 18 U.S.C. § 1964 (1970).

and attorney's fees.[29] Put simply, a plaintiff bringing suit under civil RICO must show: 1) a violation of Section 1962(a), (b), (c), or (d); (2) injury to her business or property; and (3) causation of the injury by the violation.[30] As Supreme Court precedent has revealed, the statute's application isn't as straight forward as it may seem at first glance.

The RICO statutes require causation. In RICO, two types of causation are required. The first is called but-for causation, which requires a simple inquiry: but-for the defendant's negligence or wrongful act, would the plaintiff have suffered this injury?[31] This is also called "actual cause" or "cause in fact."[32] The second required causal link is "proximate cause," which determines whether the injury was the natural and probable consequence of the wrongful act, without any effective intervening causes.[33]

3. Modern Applications

The civil remedy provision of RICO lay dormant for almost a decade before becoming used as a vehicle for a variety of civil claims.[34] In 1998, the Supreme Court allowed a pro-choice activist group to maintain a civil RICO claim against anti-abortion groups seeking to close abortion clinics, holding that civil RICO contains no economic motive requirement.[35] Another unique attempted use of a civil RICO claim involved union health funds and hospitals seeking to recover the costs of treating tobacco-related illnesses from tobacco companies.[36] Finally, TPPs like union health and welfare funds have brought suit under the civil remedy provision of RICO against pharmaceutical companies that allegedly failed to disclose certain health risks or urged non-FDA approved uses of certain drugs.[37] Some of these RICO applications, although not originally contemplated, have proven to be an effective way to address crimes that fall outside the usual realm of organized crime. The following Sections discuss the civil RICO provision in the context of TPPs and drug

29. *Id*. (emphasis added).

30. Ross Bagley, Dorian Hurley & Peter Mancuso, *Racketeer Influenced and Corrupt Organizations*, 44 AM. CRIM. L. REV. 901, 942-43 (2007).

31. 74 AM. JUR. 2D *Torts* § 26 (1962).

32. *Id*.

33. 65 C.J.S. *Negligence* § 188 (1936).

34. Tushar, *supra* note 20, at 1283.

35. Nat'l Org. for Women v. Scheidler, 510 U.S. 249, 262, 262 n.6 (1994) ("We hold only that RICO contains no economic motive requirement.").

36. Bagley, *supra* note 30, at 949-51. *See* Laborers Loc. 17 Health & Benefit Fund v. Philip Morris, Inc., 191 F.3d 229, 239-41 (2d Cir. 1999). In this case, though, the Second Circuit determined that those brining the suit did not have standing under civil RICO.

37. *See In re* Neurontin Mktg. & Sales Practices Litig., 712 F.3d 21, 28-29 (1st Cir. 2013)..

manufacturers.

C. Supreme Court Precedent

The Supreme Court has given guidance on how the civil provision of RICO should be applied. A prominent civil RICO case in 1992 dealt with RICO's causation element.[38] In *Holmes v. Securities Investor Protection Corporation*, the Court determined that in order to have standing under the civil provision of RICO, litigants must meet the requirements of both but-for causation and proximate causation.[39] The proximate cause requirement, the Court opined, demands a direct relation between the asserted injury and the alleged wrongful conduct.[40] The Court established three factors upon which the "direct relation" requirement is based:

> 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. Second, quite apart from problems of proving factual causation, recognizing claims of the indirectly injured would force courts to adopt complicated rules apportioning damages among plaintiffs removed at different levels of injury from the violative acts, to obviate the risk of multiple recoveries. And, finally, the need to grapple with these problems is simply unjustified by the general interest in deterring injurious conduct, since 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.[41]

The Supreme Court cited this language in each subsequent civil RICO case that came before it.[42] *Holmes* dealt specifically with securities fraud and held that the link between the alleged stock manipulation and the asserted losses to non-purchasing customers was too remote to satisfy proximate cause.[43]

Next, the Court in *Anza v. Ideal Steel Supply Corporation* determined that a steel mill product manufacturer did not have standing to sue its competitors who were not charging their customers New York State sales tax.[44] Although the steel mill asserted competitors not charging their customers sales tax caused the mill to lose customers and profit, the Court held that the true injured party was the State of New York.[45] The main

38. Holmes v. Sec. Investor Prot. Corp., 503 U.S. 258, 267-68 (1992).

39. *Id*.

40. *Id*. at. 268.

41. *Id*. at 269-70 (internal citation omitted).

42. Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co. Ltd., 943 F.3d 1243, 1249 (9th Cir. 2019).

43. *Holmes*, 503 U.S. at 268-69.

44. Anza v. Ideal Steel Supply Corp., 547 U.S. 451, 457-48 (2006).

45. *Id*. at 458.

problem was that the injury (losing customers) was entirely distinct from the competitors defrauding the State of New York.[46] The Supreme Court once again emphasized the need for a direct relation between the conduct and the subsequent injury.

In a 2010 case, *Hemi Group v. City of New York, New York*, the City of New York brought a civil RICO action against an out-of-state cigarette retailer that sent cigarettes directly to residents, thus circumventing the $1.50-per-pack tax imposed by the city.[47] The Supreme Court determined that the link between an out-of-state retailer's failure to properly inform New York City about the identity of the retailer's customers and New York City's loss of cigarette tax proceeds was too attenuated to satisfy proximate cause.[48] The Court determined that the true cause of New York City's loss was residents within the city failing to pay taxes as required.[49]

Another prominent case in the Court's civil RICO jurisprudence dealt with an alleged scheme to use multiple agents to circumvent a county's one-bidder-per-tax-lien auction rule.[50] The defendants allegedly used agents to submit simultaneous bids, leading to the defendants receiving a higher share of tax liens at the county auction.[51] The plaintiffs, property owners in Cook County, Illinois, alleged that these deceptive practices deprived them of their fair share of tax liens.[52] Defendants argued that if the allegations were true, the misrepresentations were made to the county, not the plaintiffs suing.[53] However, the Supreme Court determined that it was a foreseeable consequence of the defendants' scheme that the plaintiffs and other similarly situated bidders would receive less than their fair share of liens.[54] Further, unlike the situations in *Anza* and *Hemi Group*, no other parties suffered more direct injuries than the plaintiffs.[55] The Supreme Court deemed that the plaintiff properly alleged proximate cause.[56]

Overall, the Supreme Court has determined that in order to bring a civil RICO claim, the plaintiff must be able to properly allege but-for causation and proximate causation. In order to do so, courts should consider whether there is a direct relation between the alleged RICO violation and the subsequent harm. Courts should use the three factors laid out in *Holmes*

46. *Id.*
47. Hemi Grp. v. City of New York, N.Y., 559 U.S. 1, 4-5 (2010).
48. *Id.* at 11.
49. *Id.*
50. Bridge v. Phoenix Bond & Indem. Co., 553 U.S. 639, 643 (2008).
51. *Id.* at 643-44.
52. *Id.*
53. *Id.* at 648.
54. *Id.* at 658.
55. *Id.*
56. *Id.* at 661.

to determine whether such direct relation existed.[57]

D. The Circuit Split

The federal circuit courts disagree about whether TPPs like health insurance companies and health and welfare funds have standing under RICO to sue drug manufacturers that allegedly fail to disclose serious health risks or promote non-FDA-approved uses of certain drugs. The First, Third, and Ninth Circuits agree that TPPs have standing to sue drug manufacturers under RICO. The Second and Seventh Circuits disagree. This Section will take each relevant case in turn.

1. TPP Formularies

Before discussing the relevant case law, the intricate methodology of determining which drugs TPPs will cover warrants discussion. A formulary is a list of medications, created by TPPs, that physicians may prescribe to the TPPs' members.[58] Whether a TPP will cover the cost of a member's prescription depends on whether the drug is listed on the TPP's formulary.[59] Often, formularies are prepared through rigorous research regarding a drug's cost efficiency, advantages and disadvantages of competing drugs, and the particular drug's efficacy.[60] Weighing all these factors, if a TPP determines that one drug is "better" than the other, the drug receives preferred status; thus, the TPP is more likely to cover the costs of that drug.[61] The FDA only approves certain medical conditions that a drug may be used to treat, and drug manufacturers can only promote those uses.[62] Physicians, though, may prescribe the drug for off-label conditions or a condition that has not been approved by the FDA for the drug to treat.[63] Some cases deal with a drug manufacturer's promotion of off-label uses, and some deal with nondisclosure of certain health risks induced by the manufactured drug. This process is highly relevant to a court's determination of the existence of proximate cause.

2. Finding Proximate Cause

The First Circuit dealt directly with the issue of a TPP suing a

57. Holmes v. Sec. Investor Prot. Corp., 503 U.S. 258, 267-69 (1992).
58. *In re* Neurontin Mktg. & Sales Practices Litig., 712 F.3d 21, 28-29 (1st Cir. 2013).
59. *In re* Avandia Mktg., Sales Practices & Prod. Liab. Litig., 804 F.3d 633, 634 (3d Cir. 2015).
60. *Id*.
61. *Id*. at 635.
62. Sidney Hillman Health Ctr. of Rochester v. Abbott Labs., 873 F.3d 574, 575 (7th Cir. 2017)
63. *Id*.

pharmaceutical manufacturer in *In re Neurontin*.[64] Kaiser, a major health plan provider and insurer, sued Pfizer, the manufacturer of a drug called Neurontin, for introducing the prescription of the drug for off-label uses.[65] Kaiser alleged that in order to increase Neurontin's earning potential, Pfizer developed a fraudulent marketing strategy to encourage TPPs like Kaiser to allow the drug to be prescribed for non-FDA approved uses.[66] Kaiser alleged that Pfizer misrepresented the efficacy of the drug's off-label uses.[67] The "fraudulent scheme" was evidenced by Pfizer's marketing team's "Operation Plan" and other evidence.[68] Pfizer, however, alleged that Kaiser could not satisfy proximate cause.[69]

The First Circuit ruled in favor of the TPP, stating that Kaiser had met both the direct relationship requirement and the three *Holmes* factors.[70] The court explained that Pfizer "ha[d] always known that, because of the structure of the American health care system, physicians would not be the ones paying for the drugs they prescribed."[71] The court determined that the fraudulent scheme indeed caused injury to Kaiser because Neurontin, a more expensive drug, was prescribed more often for off-label uses due to Pfizer's marketing scheme.[72] Overall, doctors prescribing the drug did not sever the causal chain between Pfizer's RICO violation and Kaiser's injury.[73]

In the case of *In re Avandia*, the Third Circuit faced a similar inquiry in a case where the drug manufacturer allegedly misrepresented heart-related safety risks of the drug Avandia, a drug used to treat diabetes.[74] Despite the FDA instructing the drug manufacturer to stop minimizing the heart-related health risks in its marketing, the manufacturer widely distributed a campaign attempting to debunk studies that showed how dangerous Avandia was.[75] Avandia was significantly more expensive than other leading diabetes drugs of a similar kind, and the plaintiffs alleged that the manufacturer misrepresented the risks of the drug in an attempt to get Avandia on TPP formularies.[76] Thus, certain TPPs sued the manufacturer for failure to disclose the heart-related risks, which

64. *In re* Neurontin Mktg. & Sales Practices Litig., 712 F.3d 21, 25 (1st Cir. 2013).
65. *Id.*
66. *Id.* at. 27-28.
67. *Id.*
68. *Id.* at 28.
69. *Id.* at 34.
70. *Id.* at 38.
71. *Id.* at 38-39.
72. *Id.* at 39.
73. *Id.*
74. *In re* Avandia Mktg., Sales Practices & Prod. Liab. Litig., 804 F.3d 633, 634-36 (3d Cir. 2015).
75. *Id.* at 635.
76. *Id.* at 636.

predicated multiple RICO violations.[77] The manufacturer alleged that the TPPs did not adequately allege standing.[78]

The Third Circuit determined that the TPPs had satisfied the Supreme Court's direct relation requirement because "the plaintiff's injuries are the same conduct forming the basis of the RICO scheme alleged in the complaint . . . ."[79] Applying the *Holmes* factors, the court determined that the plaintiffs were best situated to sue and that it would not be too difficult to establish damages.[80] The Third Circuit acknowledged that an injury to one person caused by the wrongs of another can satisfy proximate cause, according to the Supreme Court's holding in *Bridge v. Phoenix Bond*.[81] Like the First Circuit, the Third Circuit determined that prescribing physicians did not break the chain of causation and that the proximate cause requirement of civil RICO was satisfied.[82]

The Ninth Circuit most recently faced this standing inquiry in December 2019.[83] In *Painters v. Takeda*, a health insurer sued a pharmaceutical company for failing to change the label on the diabetes drug Actos to warn that the drug caused an increased risk of bladder cancer.[84] Multiple studies revealed the risk of taking Actos, but the pharmaceutical company, Takeda, allegedly failed to inform the public of such risk.[85] Over a decade after FDA approval and in light of further studies alleging the same risk, the FDA released a public warning about Actos.[86] After this warning, sales plummeted by a total of eighty percent.[87] The insurance company brought suit against Takeda and sought to recover economic damages for payments made to purchase the drug for its members.[88]

The Ninth Circuit agreed with the First and Third Circuits, and determined that the physicians served as mere intermediaries in prescribing the drug.[89] Since Actos is a prescription drug that must be prescribed by physicians, it was "perfectly foreseeable" that physicians

77. *Id.*

78. *Id.* at 637.

79. *Id.* at 644.

80. *Id.*

81. *Id.* at 645 (citing Bridge v. Phoenix Bond & Indem. Co., 553 U.S. 639, 650, 658 (2008)).

82. *Id.* at 645-46.

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

84. *Id.*

85. *Id.*

86. *Id.*

87. *Id.*

88. *Id.* at 1247.

89. *Id.* at 1257.

would be involved along the causal chain.[90] Because the insurance company alleged that they would not have paid for the drug had it known of the risks, as evidenced by the plummet in sales after the FDA warning, the insurance company was a directly injured victim of Takeda's conduct that constituted a RICO violation.[91]

Overall, courts that find the proximate cause requirement satisfied follow a similar analysis: (1) whether all of the *Holmes* direct relation factors fall in favor of proximate cause; (2) whether injury can be proven because the TPP paid more for the dangerous drug over another, or would not have listed the drug on the formulary at all; and (3) whether it can be determined that physicians are not effective intervening causes.

3. Against the Existence of Proximate Cause

The Second and Seventh Circuits have strikingly different views on the issue of TPPs alleging proximate cause. The Second Circuit faced similar facts as the other circuit courts, although arising from an appeal of class certification.[92] A TPP sought damages for paying for a higher priced drug that proved to have a dangerous side effect.[93] The pharmaceutical company, Lilly, allegedly misrepresented the drug's efficacy and promoted off-label uses, despite lack of evidence that the drug was effective for such uses.[94] The plaintiff's TPP alleged two different theories of damages: (1) the insurance company charged higher prices for the drug based on Lilly's misrepresentation, coined the "excessive price theory," and (2) the insurance company paid for prescriptions of the drug "that would not have been issued but for the misrepresentations," called the "quantity effect theory."[95] The lower court certified the class based on the excessive price theory, and Lilly appealed.[96]

The Second Circuit determined that the plaintiffs' injuries under both theories were too attenuated to satisfy proximate cause.[97] Because the manufacturer's alleged misrepresentation was not the only source of information physicians used when prescribing drugs, the causal chain was broken by "independent actions of third and even fourth parties."[98] Notably, the Second Circuit did a deep dive into the structure of TPPs and

90. *Id.*

91. *Id.* Interestingly, five patients without insurance who paid out of pocket for the drug sued alongside the insurance company and succeeded.

92. UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121, 129 (2d Cir. 2010).

93. *Id.* at 123.

94. *Id.* at 124.

95. *Id.* at 129.

96. *Id.* at 130.

97. *Id.* at 136.

98. *Id.* at 134-35.

who within the TPP actually determines what drugs end up on the company's formulary.[99] Because a "pharmacy benefit manager" and that manager's committee also made determinations as to what drugs ended up on the formulary, the chain of causation was broken in multiple places by too many independent judgments to satisfy proximate cause.[100]

The Seventh Circuit agreed with the conclusion that a TPP claiming damages against a drug manufacturer for promoting off-label uses did not satisfy proximate cause as mandated by RICO.[101] Because the patients who were prescribed the dangerous drug were the most directly injured parties—not TPPs—the court determined that TPPs were far beyond the "first step" in the causal chain.[102] Further, the drug manufacturer's misrepresentations were made primarily to the physicians, not TPPs.[103] Because there was no guarantee that doctors changed their prescribing practice as a result of the manufacturer's misrepresentations, the alleged damages would have been too difficult to calculate.[104]

The circuits are split on whether TPPs have standing to sue a pharmaceutical manufacturer for misrepresentations on labels or for urging off-label uses of certain drugs. This issue will remain relevant in light of the widespread use of prescription drugs and impeding changes within the American health care system due to the election of President Biden. Therefore, this legal struggle between TPPs and pharmaceutical manufacturers will remain relevant for years to come.

III. DISCUSSION

The weight of relevant case law supports the conclusion that proximate cause exists between TPPs and pharmaceutical companies when pharmaceutical companies misrepresent health risks or encourage off-label usage of a drug. First, Section A highlights the flaws of the Second and Seventh Circuit's arguments against the existence of proximate cause. Section B discusses arguments supporting the existence of proximate cause, including the issues of standing and the statutory text of RICO. Section C discusses the important policy considerations at play.

99. *Id*. at 126.

100. *Id*. at 134.

101. Sidney Hillman Health Ctr. of Rochester v. Abbott Labs., 873 F.3d 574, 576-77 (7th Cir. 2017).

102. *Id*. at 576 (quoting Holmes v. Sec. Investor Prot. Corp., 503 U.S. 258, 271-72 (1992)).

103. *Id.*

104. *Id*. at 577-78.

A. Missteps of the Second and Seventh Circuits

The Second and Seventh Circuits, when determining that the TPP did not meet the requirement of proximate cause, were faced with the issue at different stages in litigation. The Second Circuit considered the issue at the class certification stage, while the Seventh Circuit entertained the issue at the pleadings stage.[105] Regardless of this technical difference, the two courts used similar reasoning in reaching the conclusion that proximate cause was not met in either case.

The courts focused first on the causal chain. Both courts extended the causal chain in a way not contemplated by the doctrine of proximate cause. For example, the Second Circuit stretched the chain, diving into the structure of TPP decision-making.[106] The court discussed the inner workings of TPPs in its unnecessary discussion of Pharmacy Benefit Managers ("PBMs") and their committees.[107] The court considered how a particular manager made recommendations about the what drugs to put on the TPP's formulary and whether this was an intervening cause severing the chain of causation.[108] The Second Circuit further held that the TPP failed to negotiate lower prices for the drug, reaching once again to create an intervening cause.[109]

The Seventh Circuit similarly emphasized the independent decisions of physicians, explaining that these decisions severed the causal chain.[110] The court opined that there was no way to know if some of the off-label prescriptions were actually helpful to the patient or whether the physicians were also influenced by other information sources, not just the pharmaceutical company's fraudulent marketing scheme.[111]

Both courts' discussion of PBMs, physicians, and other alleged intervening causes detract from the main tenant of the proximate cause doctrine: foreseeability. Standing necessarily looks to the parties of the case. In each case, a TPP alleged that the drug manufacturer conducted a fraudulent scheme that cost the TPP money. The pharmaceutical companies absolutely were aware, due to the structure of the American health care system, that TPPs would be the entities paying for the drugs. This is not to say that the adverse effects on patients and loss of business for physicians were unworthy of litigation–these injuries were jarring in their own right. But they did not attenuate the causal chain so far as to

105. *Lilly*, 620 F.3d at 129; *Sidney Hillman*, 873 F.3d at 575-76.

106. *Lilly*, 630 F.3d at 126.

107. *Id*.

108. *Id*. at 134.

109. *Id*.

110. *Sidney Hillman*, 873 F.3d at 576-77.

111. *Id*.

render the TPPs without a proper proximate cause argument.

Further, these courts omitted most of the controlling law of the *Holmes* direct relations factors from their discussions and analysis.[112] This was likely because in each case, the *Holmes* factors would have debunked the courts' ultimate holdings. Yet, the *Holmes* factors continue to remain important, and later Sections in this Article illustrate how the *Holmes* factors favor finding proximate cause in these situations.

Finding that TPPs can assert a direct relation between the asserted injury and injurious conduct alleged is not only supported by the factors laid out in *Holmes*, but also the Supreme Court's opinion in *Bridge.* A unanimous decision in *Bridge* explained that proximate cause is a "flexible concept that does not lend itself to a black-letter rule that will dictate the result in every case." [113] The Second and Seventh Circuits were trying to read proximate cause far too literally, practically determining that each human being involved in a transaction who makes a decision breaks the causal chain. The Supreme Court expressly rejected such an attempt to read a bright-line rule into the proximate cause doctrine.[114] Further, the Court explained that "the common law has long recognized that plaintiffs can recover in a variety of circumstances where . . . their injuries result directly from the defendant's fraudulent misrepresentations to a third party."[115] This debunks the Seventh Circuit's argument determining that the TPP does not have standing to sue if the misrepresentations were made to physicians, not directly to the TPP.

Standing and proximate cause are some of the hurdles plaintiffs must surpass to bring suit. The pharmaceutical company is still able to fight the allegations on their merits. On the whole, in light of the *Holmes* factors, foreseeability, and the Court's decision in *Bridge*, the TPPs in these cases allege a direct enough injury to at least be able to present their case in court. The Supreme Court has made clear that proximate cause is flexible; therefore, the Second and Seventh Circuits' attempts to create a much stricter, sole cause requirement does not bode well.

B. Existence of Proximate Cause and Supporting Explanations

Having already pointed out the issues with the Second and Seventh Circuits' justifications, this Article will examine the arguments that support the opposite conclusion—namely, the First, Third, and Ninth Circuits' holdings. This Section discusses multiple issues, each supporting the conclusion that TPPs have standing to sue pharmaceutical

112. Holmes v. Sec. Investor Prot. Corp., 503 U.S. 258, 269 (1992).

113. Bridge v. Phx. Bond & Indem. Co., 553 U.S. 639, 654 (2008).

114. *Id.* at 659.

115. *Id.* at 653.

companies that commit fraudulent misrepresentations. Subsection 1 discusses the injury aspect of the standing doctrine. Subsection 2 discusses the causation aspect of standing. Finally, Subsection 3 discusses the statutory text of RICO.

1. Injury

One aspect of standing is injury-in-fact, which is "some direct injury as the result of [a statute's] enforcement and not merely that [the plaintiff] suffers in some indefinite way in common with people generally."[116] Section 1964(c) of the RICO statute specifically requires an injury to business or property caused by the defendant's violation of the statute.[117] Notably, injury to person is left out of the statute's text. The Ninth Circuit, in past opinions, has interpreted the lack of recovery for personal injury as having a "restrictive significance, which helps to assure that RICO is not expanded to provide a federal cause of action and treble damages to every tort plaintiff."[118] The Seventh Circuit posits that patients may receive adverse care due to fraudulent pharmaceutical marketing strategies, and thus their injury is more direct than the TTPs.[119] But, as made clear by the statute's language, patients cannot sue for physical harm due to RICO violations. Perhaps the patients may sue under malpractice law, but in an assessment of RICO and who is in the best spot to sue under *this statute*, the patient should not be a factor. Any discussion of adverse effects on a patient's health, although entirely worthy of concern, is an unsuccessful attempt to pinpoint an intervening cause and break the causal chain. But regarding injury-in-fact, and specifically when assessing RICO standing, courts should look to the parties in the case and determine whether the TPP suffered injury because of the RICO violation.

In order to have standing under civil RICO, "a showing of injury requires proof of a concrete financial loss and not mere injury to a valuable intangible property interest."[120] Injury can be shown by allegations and proof of actual monetary loss.[121] Concrete injury will not be found if the economic harm is contingent on some future event that something *might* occur.[122] When TPPs sue pharmaceutical companies under RICO, the injury is not contingent upon "the effectiveness of the

116. Massachusetts v. Mellon, 262 U.S. 447, 489 (1923).

117. 18 U.S.C. § 1964(c) (West).

118. *In re* Avandia Mktg., Sales Practices & Prod. Liab. Litig., 804 F.3d 633, 638 (3d Cir. 2015) (quoting Steele v. Hosp. Corp. of Am., 36 F.3d 69, 70 (9th Cir. 1994)).

119. Sidney Hillman Health Ctr. of Rochester v. Abbott Labs., 873 F.3d 574, 576 (7th Cir. 2017).

120. *Avandia*, 804 F.3d at 638 (quoting Steele v. Hosp. Corp. of Am., 36 F.3d 69, 70 (9th Cir. 1994)).

121. *Id.*

122. *Id.*at 639.

[drug] that they purchased, but rather on the inflationary effect that [the pharmaceutical company's] allegedly fraudulent behavior had on the price of [the drug]."[123] Thus, TPPs satisfy the injury aspect of standing if they can show economic loss attributable to the drug at issue.

2. Causation

The *Holmes* court explained that the civil RICO statute requires a showing of both but-for causation and proximate causation.[124] These are two separate burdens that the plaintiff must show to properly bring a RICO claim before the court. But first, a discussion of damage theories is helpful to grasp the underpinning of proximate cause issues in the cases. Next, this Section will address proximate cause, as it is the most hotly debated aspect of RICO standing. Finally, this Section will discuss but-for causation.

i. Damage Theories

Courts often conflate the finding of proximate cause with the calculation of damages. Although related, the Third Circuit correctly stated, "[t]his issue of damages, rather than demonstrating the lack of proximate causation, raises an issue of proof regarding the overall numbers of prescriptions or amounts of price inflation attributable to [the pharmaceutical company's] action. This is a question of damages and, more specifically, a question for another day."[125] While this is true, it is helpful to explain a few theories of damages that plaintiffs have used. In *Lilly*, which dealt with fraudulent misrepresentation about the safety of a drug, the plaintiffs asserted two theories of damages.[126] First, the quantity effect theory dealt with the sentiment that such a large amount of prescriptions for the drug at issue would not have been written absent the fraud.[127] The second theory, the excessive price theory, explained that due to the misrepresentation of the safety of the drug, the health insurer set an excessively high price for the drug, causing economic loss.[128] These two themes, inflated quantity and excessive price, are found in each case, either mentioned briefly or expounded upon at length.

The amount of consideration given to damages most likely has more to do with litigation strategy as opposed to the standing inquiry. Likely,

123. *Id.* at 640.

124. Holmes v. Sec. Investor Prot. Corp., 503 U.S. 258, 268 (1992).

125. *Avandia*, 804 F.3d at 644.

126. UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121, 131 (2d Cir. 2010).

127. *Id.*

128. *Id.*

theories of damages were presented to satisfy the first of three *Holmes* factors, which deals with the ability to "ascertain the amount of damages attributable to the violation as distinct from other independent factors."[129] Yet, this *Holmes* factor is indeed satisfied. The Court has since clarified this discussion of the connection between the violation and the damages. In *Anza v. Ideal Steel Supply*, the Supreme Court explained that proximate cause would be lacking where the conduct directly causing the injury is distinct from the actions that gave rise to the fraud.[130] In the cases discussed herein, the injury, economic loss, is not distinct from the fraudulent marketing campaigns giving rise to RICO violations. Thus, the first *Holmes* factor is satisfied, and any further discussion of the complicated damage theories is unnecessary. As the Ninth Circuit stated, ascertaining damages is not so difficult that plaintiffs "should be denied the opportunity to prove their damages."[131]

ii. Proximate Cause

The Supreme Court has explained that proximate cause is used "to limit a person's responsibility for the consequences of that person's acts."[132] The Court explained that proximate cause has developed from common law,[133] which describes proximate cause as an inquiry as to whether the injury was the natural and probable consequence of the wrongful act, without any effective intervening cause.[134] Although the doctrine has taken many "shapes," the doctrine generally is "a demand for some direct relation between the injury asserted and the injurious conduct alleged."[135] The foreseeability of the harm is also part of the analysis, where an injury will be considered a direct result if "it was a foreseeable and natural consequence" of the conduct that constitutes a RICO violation.[136]

An interesting aspect of proximate cause, which is specific to misrepresentations, is the requirement of reliance on those misrepresentations. The Supreme Court in *Bridge* explained that if there is a sufficiently direct relationship between the defendant's wrongful conduct and the plaintiff's injury, a RICO plaintiff need not directly rely on a defendant's misrepresentations to establish proximate cause.[137] If

129. *Holmes*, 503 U.S. at 269.

130. Anza v. Ideal Steel Supply Corp., 547 U.S. 451, 458 (2006).

131. Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co. Ltd., 943 F.3d 1243, 1251 (9th Cir. 2019).

132. *Holmes*, 503 U.S. at 268.

133. *Id*.

134. 65 C.J.S. *Negligence* § 188 (1936).

135. *Holmes*, 503 U.S. at 268-69.

136. Bridge v. Phx. Bond & Indem. Co., 553 U.S. 639, 658 (2008).

137. *Id*. at 657-58.

there are intermediaries involved in the causal chain, the chain does not break even though the plaintiffs were not the subject of the misrepresentations, so long as the plaintiffs were "the primary and intended victims of the scheme to defraud."[138]

The three factors set out in *Holmes* are described in many ways. The factors have been described as the "three reasons behind the requirements of a directness relationship between the injury and conduct alleged."[139] The factors have also been described as "three functional factors with which to assess whether proximate cause exists under RICO."[140] In a word, the factors serve as guideposts to assess the facts of a case. The existence of factors show in itself that this concept is pliable and not meant to impose a bright-line test.

The *Holmes* factors have already been discussed briefly, but a summary may be helpful to preface the discussion of the cases finding proximate cause. The first *Holmes* factor is difficulty in ascertaining damages due to indirectness of injury.[141] The second factor deals with the risk of multiple recoveries due to multiple parties being injured.[142] And finally, the third factor calls upon courts to consider whether holding the defendant liable justifies the general interest of deterring injurious conduct or whether there are more directly injured victims that are better suited to hold the defendant accountable.[143]

The First, Third, and Ninth Circuits properly apply the doctrine of proximate cause. While there are quite a few factual differences between the cases, the main dispute is "whether the decisions of prescribing physicians and pharmacy benefit managers constitute intervening causes that sever the chain of proximate cause between the drug manufacturer and TPP."[144] Notably, the pharmaceutical companies did not argue that the intermediary action of physicians caused the TPP's injury.[145] In each case, the injury alleged by a TPP was an economic injury independent of any physical injury suffered by patients for off-label prescriptions or undisclosed health risks.[146] This is the direct relation that *Holmes* and *Bridge* were concerned with: that the injury arose out of the alleged RICO violation.

The Ninth Circuit correctly characterized prescribing physicians as

138. *Id.* at 658.

139. *In re* Avandia Mktg., Sales Practices & Prod. Liab. Litig., 804 F.3d 633, 642 (3d Cir. 2015).

140. *In re* Neurontin Mktg. & Sales Practices Litig., 712 F.3d 21, 35-36 (1st Cir. 2013).

141. Holmes v. Sec. Investor Prot. Corp., 503 U.S. 258, 269-70 (1992).

142. *Id.*

143. *Id.*

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

145. *In re* Avandia Mktg., Sales Practices & Prod. Liab. Litig., 804 F.3d 633, 644 (3d Cir. 2015).

146. *Id.*

"intermediaries."[147] The court noted that an intervening cause that severs the causal chain is "a later cause of independent origin that was not foreseeable."[148] Each drug at issue had been a prescription drug, which was required to be prescribed by a physician to a patient. Physicians don't pay for these drugs, nor do patients with health insurance. The structure of the American health care system makes payment through TPPs not just foreseeable, but inevitable. The goals of these alleged fraudulent marketing schemes are either increasing sales or the price of the drug. The scheme "only becomes successful once [the pharmaceutical manufacturer] receives payment for the additional prescriptions [they] induced," which is the very injury for which TPPs seek recovery.[149] This is surely "some direct relation between the injury asserted and the injurious conduct alleged."[150]

The Supreme Court explained that misrepresentations do not need to be made directly to the TPP. So, as in *Avandia*, the *Bridge* decision precludes the argument that the causal chain is broken because the fraudulent marketing campaign was directed toward prescribing physicians.[151] Again, physicians do not break the causal chain as they are merely intermediaries prescribing the drugs. The prescription of the drug did not cause the harm to the TPP; rather, the misrepresentation that induced the prescription caused the harm.

Finally, the *Holmes* factors all weigh in favor of finding proximate cause in these types of cases. This Article has already discussed the first factor. Courts already must find at the pleading stage that the TPP has put forth sufficient evidence of damages for the case to move forward. The evidence again is usually shown using one of the two theories of damages, often bolstered by extensive expert testimony as seen in *Neurontin*.[152] The TPP is the only entity that paid toward the purchase of the drug influenced by the fraudulent marketing scheme. Therefore, there is no threat of duplicative recoveries, as warned by the second factor. There is not a "more immediate victim" better positioned to bring suit.[153] Finally, the third factor dealing with deterrence of wrongful conduct weighs heavily in the favor of TPPs. Indeed, TPPs are best suited to sue for economic damages because TPPs are the only parties that suffered economic loss.

The Supreme Court's precedent and the *Holmes* factors demonstrate that the First, Third, and Ninth Circuits came to the correct conclusion

147. *Painters*, 943 F.3d at 1257.

148. *Id.* (quoting Exxon Co. v. Sofec, 517 U.S. 830, 837 (1996)).

149. *Id.*

150. Holmes v. Sec. Investor Prot. Corp., 503 U.S. 258, 268-69 (1992).

151. *In re* Avandia Mktg., Sales Practices & Prod. Liab. Litig., 804 F.3d 633, 658 (3d Cir. 2015).

152. *In re* Neurontin Mktg. & Sales Practices Litig., 712 F.3d 21, 41-42 (1st Cir. 2013).

153. Bridge v. Phx. Bond & Indem. Co., 553 U.S. 639, 658 (2008).

that proximate cause exists in cases where a TPP brings suit under civil RICO against a pharmaceutical company for a fraudulent marketing scheme.

iii. But-For Causation

But-for causation is less hotly debated in the case law. The *Holmes* court required more than but-for causation because of the breadth of possible suits that may qualify. If only but-for causation was required, RICO may "be read to mean that a plaintiff is injured 'by reason of' a RICO violation, and therefore may recover, simply by showing that the defendant violated § 1962, the plaintiff was injured, and the defendant's violation was a 'but-for' cause of the plaintiff's injury."[154] This led the Supreme Court to require proximate cause as well. Yet, a discussion of how but-for causation is met in these cases is necessary, as it is still an essential part of civil RICO standing.

The but-for causation question for civil RICO has been described as "whether, absent [the pharmaceutical manufacturer's] fraud, [the TPP] would have paid for fewer off-label prescriptions."[155] Of course, in situations involving concealment of health risks, the question is as follows: but for the fraudulent marketing campaign promoting the drug's safety, would the TPP have paid for a higher quantity of the drug or for a higher price than a cheaper, similar drug? In other words, but for the fraud, would the TPP have experienced the economic loss, regardless of how that loss came about?

The answer to these questions is more straightforward than the proximate cause inquiry. The main showing required is a connection between the dissemination of the misrepresentations and a significant increase in sales. In *Neurontin,* prescription sales of the drug increased by sixty-two percent after physicians attended a medical education conference where the physicians were exposed to misrepresentations from the drug manufacturer.[156] Then, when negative information about the safety of the drug was disseminated, the number of prescription sales dropped by thirty-three percent.[157] This shows that, but for the misrepresentations, the amount of prescriptions for the drug the TPP paid for would not have increased, and the TPP would not have incurred economic losses due to the drug.

The Ninth Circuit opined, "logically, a plaintiff cannot even establish but-for causation if *no one* relied on the defendant's alleged

154. *Holmes*, 503 U.S. at 265-66.

155. *Neurontin*, 712 F.3d at 34.

156. *Id.* at 41.

157. *Id.*

misrepresentation." [158] Thus, a plaintiff must show the necessary reliance in order to show the effect that the misrepresentations had. The physicians necessarily would have to be induced by the misrepresentations. Just as the Court held in *Bridge*, even if the misrepresentations were made only to physicians and not the TPP, this indirect reliance still properly establishes proximate cause.[159]

3. RICO Legislative History and Text

The text and legislative history of the statute also supports this conclusion. The legislative history reveals that a civil remedy was introduced to reach the financial power of RICO violators.[160] Pharmaceutical manufacturers make these unlawful misrepresentations for one reason: profit. RICO lawsuits are incredibly expensive for these manufacturers. For example, the trial jury in the case of *In Re Neurontin* in the First Circuit rewarded the TPP $47,463,092, which the court trebled under the statute to $142,089,276.[161] This large sum acts as a meaningful deterrence for the wrongdoings of the manufacturer, not only so this particular manufacturer ceases to execute fraudulent schemes, but for every other manufacturer in the similar line of business. This conclusion, allowing TPPs to sue in the situations discussed above, is powerful deterrence that satisfies the purpose of the civil RICO provision.

C. Policy Considerations

The *Holmes* court especially took into account deterring injurious conduct.[162] The misrepresentations or concealments from drug manufacturers have serious, if not fatal, consequences that merit consideration. In *Avandia*, the risk of heart attacks and heart-related diseases increased when patients took the drug, but the manufacturers concealed this information and promoted the safety of the drug.[163] In *Painters*, the drug caused an increased risk of bladder cancer, but the drug manufacturer failed to inform consumers of the risk.[164] It is not far-fetched to say that these misrepresentations have likely cost people their lives or at least their quality of life. Thus, the motivation of deterring this conduct

158. Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co. Ltd., 943 F.3d 1243, 1259 (9th Cir. 2019) (emphasis in original).

159. Bridge v. Phx. Bond & Indem. Co., 553 U.S. 639, 658-59 (2008).

160. Tushar, *supra* note 20, at 1284.

161. *Neurontin*, 712 F.3d at 26.

162. Holmes v. Sec. Investor Prot. Corp., 503 U.S. 258, 269-70 (1992).

163. *In re* Avandia Mktg., Sales Practices & Prod. Liab. Litig., 804 F.3d 633, 635-65 (3d Cir. 2015).

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

is even stronger, and the finding of standing to sue is even more justified even though RICO only provides a remedy for financial harm.

There is an asymmetry of information between drug manufacturers and consumers. More than sixty-six percent of adults in the United States use prescriptions drugs.[165] That is over half of Americans who rely on what the physicians tell them. Thus, when the physician is given half-truths and misrepresentations by drug manufacturer representatives, the consumer suffers. The TPPs are in the best, most direct position, to sue for monetary damages. As the cases have made clear, these drug manufacturers are primarily profit-driven. In the end, the finding of standing for TPPs will protect millions of Americans from potentially concealed health risks or unsafe off-label prescription drug uses, assuming suing for monetary damages is sufficient deterrence.

IV. CONCLUSION

TPPs, such as health insurance companies, have standing to sue against drug manufacturers who misrepresent health risks or promote off-label usage of drugs. Proximate cause is established because there is a direct relation between the monetary loss incurred by the TPP and the conduct that constitutes a RICO violation, often a fraudulent marketing scheme. Physicians are merely foreseeable intermediaries who do not suffer any concrete monetary loss from the wrongdoings of drug manufacturers. The structure of the health care system makes it absolutely foreseeable and necessary for certain drugs to be prescribed to certain patients. Consequently, prescribing physicians will not break the causal chain, and TPPs can establish proximate cause. The integrity of health care depends on the truthfulness of drug manufacturers. Consumers deserve transparency and honesty during the prescription drug sales process that is an integral part of the American health care system.

165. *See Prescription Drugs* , *supra* note 2.