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When Does the Chain Break? Prescribing Around Drug Manufacturer Fraud

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WHEN DOES THE CHAIN BREAK? PRESCRIBING AROUND DRUG MANUFACTURER FRAUD

INTRODUCTION

Approximately eleven million prescriptions are written every day in the United States,[1] and each prescription decision represents one link in a long and complex chain that begins with drug manufacturers and ends with the patient.[2] What happens when that first link, the drug manufacturer, misleads healthcare systems, physicians, and the Food and Drug Administration (FDA) regarding a drug's side effects?[3] Over the past decade, several pharmaceutical companies have been subject to Racketeer Influenced and Corrupt Organizations Act (RICO) claims for engaging in fraudulent and misleading practices.[4] RICO prohibits the generation of income from racketeering activity[5] including mail and wire fraud,[6] which are common methods of misleading and fraudulent conduct.[7]

Third Party Payors (TPPs),[8] such as healthcare plans and insurance companies, have actively brought claims against manufacturers as TPPs pay a percentage of or the entire cost of their members' prescriptions.[9] RICO claims have proven profitable for plaintiffs,[10] with

1. Alexandra Sifferlin, *Americans Spent a Record Amount on Medicine in 2014*, TIME (Apr. 13, 2015), http://time.com/3819889/medicine-spending/.

2. *See In re* Avandia Mktg., Sales Practices & Prod. Liab. Litig., 804 F.3d 633, 645–46 (3d Cir. 2015); *In re* Neurontin Mktg. & Sales Practices Litig., 712 F.3d 21, 38 (1st Cir. 2013); UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121, 134 (2d Cir. 2010); United Food & Commercial Workers Cent. Pa. & Reg'l Health & Welfare Fund v. Amgen, Inc., 400 F. App'x 255, 257 (9th Cir. 2010).

3. *In re Avandia*, 804 F.3d at 635–36; *In re Neurontin*, 712 F.3d at 27–29; *UFCW Local 1776*, 620 F.3d at 124–25, 127–28; *In re* Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig., 590 F. Supp. 2d 1282, 1290–91 (C.D. Cal. 2008).

4. *See, e.g.*, *In re Avandia*, 804 F.3d at 635; *In re Neurontin*, 712 F.3d at 27–29; *UFCW Local 1776*, 620 F.3d at 134–36; *United Food & Commercial Workers Cent. Pa.*, 400 Fed. App'x at 257.

5. 18 U.S.C. § 1962(a) (2016).

6. § 1961(1).

7. *See, e.g.*, Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP, 806 F.3d 71, 74 (2d Cir. 2015); *In re Avandia*, 804 F.3d at 636; *In re Neurontin*, 712 F.3d at 34; *In re Epogen*, 590 F. Supp. 2d at 1287.

8. Third Party Payors (TPPs) are organizations, both public and private, which pay or insure health and medical expenses for consumers. Common examples of TPPs are insurance companies, healthcare plans and Medicare. *Third Party Payor*, AM. HEALTH LAW ASS'N, https://www.healthlawyers.org/hlresources/Health%20Law%20Wiki/Third%20Party%20Payor.aspx (last visited Jan. 10, 2017).

9. *In re Avandia*, 804 F.3d at 634–35; *In re Neurontin*, 712 F.3d at 38–39; *UFCW Local 1776*, 620 F.3d at 134–36; *United Food & Commercial Workers Cent. Pa.*, 400 F. App'x at 257.

courts awarding damages as high as $147 million to a single plaintiff.[11] Recent data indicates total expenditures for prescription medication in the United States exceeds $374 billion annually.[12] Thus, drug manufacturers are incentivized to aggressively market their products, obtain market share, and maximize profits.[13] Accordingly, they spend over $20 billion each year on drug promotion.[14] Conversely, healthcare systems and insurance companies are suffering multi-million dollar losses because of manufacturer fraud.[15]

A federal circuit split exists as to whether TPPs are permitted to bring RICO claims against drug manufacturers. The underlying issue is whether the independent decisions of physicians to prescribe the manufacturer's drug to patients severs the chain of causation and precludes TPPs from bringing a RICO claim against that manufacturer.[16] The First and Third Circuits hold that TPPs may bring RICO claims against pharmaceutical companies because the presence of intermediaries does not break the chain of causation.[17] In 2013, the First Circuit held in *In re Neurontin* that the prescription decisions of doctors do not effect RICO causation.[18] This approach was echoed by the Third Circuit in *In re Avandia* when it held the presence of intermediaries, such as doctors and patients, does not disrupt causation in RICO claims.[19]

The Second and Ninth Circuits have a different approach.[20] In *UFCW Local 1776 v. Eli Lilly & Co.*, the Second Circuit held that physician prescription decisions sever the chain of causation.[21] Similarly, in *United Food & Commercial Workers Central Pennsylvania v. Amgen, Inc.*, the Ninth Circuit dismissed a complaint because it al-

10. This data is based on 2014 expenditures. Sifferlin, *supra* note 1.

11. *In re* Neurontin Mktg. & Sales Practices Litig., 799 F. Supp. 2d 110, 112 (D. Mass. 2011).

12. This data is based on 2014 expenditures. Sifferlin, *supra* note 1.

13. *Id.*

14. Brief for AARP et al. as Amici Curiae Supporting Petitioners, Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP at 3–4, 137 S. Ct. 140 (2016) (mem) (No. 15-1525) (citing *Persuading the Prescribers: Pharmaceutical Industry Marketing and its Influence on Physicians and Patients*, PEW CHARITABLE TRUSTS (Nov. 11, 2013), http://tinyurl.com/mac4o5d).

15. *See, e.g.*, *In re Neurontin*, 712 F.3d at 32 (noting Kaiser estimated it suffered $60 million in losses as a result of Pfizer's misrepresentations).

16. Petition for Writ of Certiorari, Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis United States LLP at 2–5, 137 S. Ct. 140 (2016) (mem) (No. 15-1525).

17. *In re Avandia*, 804 F.3d at 643–46; *In re Neurontin*, 712 F.3d at 34–36.

18. *In re Neurontin*, 712 F.3d at 38–39.

19. *In re Avandia*, 804 F.3d at 645.

20. *UFCW Local 1776*, 620 F.3d at 132; *United Food & Commercial Workers Cent. Pa.*, 400 F. App'x at 257 (holding that prescription decision by doctors break the chain of causation).

21. *UFCW Local 1776*, 620 F.3d at 135.

leged a weak causal chain between the drug manufacturer and TPPs and therefore failed to meet RICO's proximate cause requirements.[22] In June 2016 in *Sergeants Benevolent Association Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, a healthcare plan appealed the dismissal of its RICO claim.[23] The Supreme Court denied the petition for certiorari leaving the split unresolved.[24]

This Comment contends the First and Third Circuits' approach, that the presence of intermediaries does not break the chain of causation, should be adopted because pharmaceutical manufacturer's marketing efforts target TPPs. In turn, when manufacturers engage in fraudulent behavior TPPs suffer economic injury by paying the majority of the drug's cost once it is prescribed.[25] Part II provides an overview of the RICO statute and describes the methodology used by TPPs to determine whether to pay for a drug prescribed to its members.[26] In addition, Part II details both sides of the Circuit split.[27]

Part III argues the Supreme Court should adopt the First and Third Circuits' approach because: (1) TPPs are directly injured by the fraudulent conduct of drug manufacturers[28] and (2) such an injury is cognizable under RICO.[29] Part IV explains the impact of adopting the First and Third Circuits' approach on: (1) the protection of healthcare consumer health and safety through deterrence of drug manufacturer fraud and (2) the ability of TPPs to obtain compensation for economic loss suffered due to manufacturer fraud when the causal chain between manufacturers and TPPs is kept intact.[30] Finally, Part V concludes that allowing TPPs to bring RICO claims regardless of physician prescription decisions will ensure drug manufacturers are accountable for their fraudulent actions, will protect consumers from

22. *United Food & Commercial Workers Cent. Pa.*, 400 F. App'x at 257.

23. Sergeants brought suit against Sanofi-Aventis, a pharmaceutical company, for allegedly misleading doctors and the FDA regarding the safety of an antibiotic developed by the company in an effort to boost its prescriptions. Petition for Writ of Certiorari, *Sergeants Benevolent Ass'n Health & Welfare Fund* at 10–12, 137 S. Ct. 140 (2016) (mem) (No. 15-1525).

24. *Sergeants Benevolent Ass'n Health & Welfare Fund*, 137 S. Ct. 140 (2016) (mem) (No. 15-1525) (denying petition for certiorari).

25. *See In re Avandia*, 804 F.3d at 644; *In re Neurontin*, 712 F.3d at 39.

26. *In re Avandia,* 804 F.3d at 635; *In re Neurontin*, 712 F.3d at 43; *UFCW Local 1776*, 620 F.3d at 134–36; *United Food & Commercial. Workers Cent. Pa.*, 400 F. App'x at 257.

27. *In re Avandia*, 804 F.3d at 635; *In re Neurontin*, 712 F.3d at 26–27; *UFCW Local 1776*, 620 F.3d at 125; *United Food & Commercial Workers Cent. Pa.* 400 F. App'x at 257.

28. Holmes v. Sec. Investor Prot. Corp., 503 U.S. 258, 269–70 (1992); *In re Neurontin*, 712 F.3d at 36.

29. *In re Neurontin*, 712 F.3d 34.

30. *See infra* Part IV.

physical injury resulting from unsafe drugs, and fairly compensate TPPs that have suffered economic loss.[31]

II. Background

This Part explains the circuit split regarding whether prescription decisions of physicians break the chain of causation in RICO claims. Section A describes the relevant RICO provisions.[32] Section B explains how TPPs approve drugs for members.[33] Section C canvasses the approach of the First and Third Circuits.[34] Finally, Section D describes the Second and Ninth Circuits' holdings that prescription decisions by physicians are fatal to the RICO claims of TPPs.[35]

A. A Brief Overview of RICO Claims

The Racketeer Influenced and Corrupt Organization Act, commonly referred to as "RICO,"[36] prohibits the derivation of income from racketeering activity,[37] or association with an enterprise affecting interstate commerce through a pattern of racketeering activity.[38] The term "racketeering activity" includes mail and wire fraud,[39] which are common grounds upon which TPPs bring RICO claims.[40] RICO was initially introduced to combat organized crime by connecting mafia leaders to the criminal enterprises they oversaw.[41] During RICO's legislative hearings, however, the Act's supporters successfully proposed the inclusion of private civil actions.[42] Congress subsequently included a provision allowing private parties injured by racketeering activity to bring a civil action against wrongdoers.[43] This provision enables TPPs to bring RICO claims against pharmaceutical manufacturers.

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31. *See In re Neurontin*, 712 F.3d at 39–40; *UFCW Local 1776*, 620 F.3d at 129.

32. 18 U.S.C. §§ 1961–62, 1964 (2016).

33. *See In re Avandia,* 804 F.3d at 634–35.

34. *See id.; In re Neurontin*, 712 F.3d at 38–39.

35. *UFCW Local 1776*, 620 F.3d at 134; *United Food & Commercial Workers Cent. Pa.,* 400 F. App'x at 257.

36. *In re Neurontin*, 712 F.3d at 26.

37. 18 U.S.C. § 1962(a) (2016).

38. § 1962(c).

39. § 1961(1).

40. *See, e.g.*, *Sergeants Benevolent Ass'n Health & Welfare Fund*, 806 F.3d at 74; *In re Avandia*, 804 F.3d at 636; *In re Neurontin*, 712 F.3d at 34; *In re Epogen*, 590 F. Supp. 2d at 1287.

41. Nathan Koppel, *They Call It RICO, and It Is Sweeping*, Wall St. J. (Jan. 20, 2011, 5:14 PM), http://www.wsj.com/articles/SB10001424052748704881304576094110829882704.

42. John L. Koenig, *What Have They Done to Civil RICO: The Supreme Court Takes the Racketeering Requirement Out of Racketeering*, 35 Am. U. L. Rev. 821, 828–29 & n.33 (1986).

43. 18 U.S.C. § 1964(c) (2016).

In order to recover damages under RICO, a plaintiff must show the following: (1) a substantive RICO violation under 18 U.S.C. § 1962,[44] (2) an injury to the plaintiff's business or property,[45] and (3) that the injury was caused by the substantive RICO violation.[46] The third element constitutes the causation requirement.[47] A party bringing a RICO claim can sue to recover treble damages, court costs, and attorney's fees.[48] It is within this framework that TPPs pursue fraud claims against drug manufacturers.[49]

B. How a Third Party Payor Selects Drugs for its Members

TPPs cover the cost of prescriptions for drugs listed in its "formulary," which is a list of drugs approved for use by the TPP's members.[50] The formulary is prepared by a Pharmacy Benefit Manager (PBM)[51] who carefully analyzes "research regarding a drug's cost effectiveness, safety and efficacy."[52] The PBM uses this research to develop a series of monographs[53] that summarize all the evidence on the drug under consideration for inclusion in the formulary.[54] During the screening process and monograph preparation, PBMs can be directly and indirectly influenced by the input of drug manufacturers.[55]

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44. *UFCW Local 1776*, 620 F.3d at 129. A substantive RICO violation involves engaging in any of the "racketeering" activities listed in 18 U.S.C. § 1961(1), such as mail and wire fraud. This is a common ground for RICO claims against drug manufacturers as they circulate their misrepresentations to TPPs using these methods.

45. Bridge v. Phx. Bond & Indem. Co., 553 U.S. 639, 649 (2008) (clarifying that such injury is economic in nature, and constitutes injury to one's business or property); *UFCW Local 1776*, 620 F.3d at 131.

46. *UFCW Local 1776*, 620 F.3d at 131.

47. *Id.* Although this Comment focuses specifically on proximate cause it should be noted that the RICO statute contains both proximate cause and but-for causation requirements. *Holmes*, 503 U.S. at 268 (1992). *See also In re Avandia*, 804 F.3d at 645 (quoting *Bridge*, 553 U.S. at 650, 658); *In re Neurontin*, 712 F.3d at 34.

48. 18 U.S.C. § 1964(c) (2016).

49. *See e.g*,. *In re Avandia,* 804 F.3d at 634–36; *In re Neurontin*, 712 F.3d at 26; *UFCW Local 1776*, 620 F.3d at 132; *United Food & Commercial Workers Cent. Pa.*, 400 F. App'x at 257.

50. *In re Avandia*, 804 F.3d 634–35.

51. *Id.* The formulary is sometimes prepared by a committee, rather than a PBM. For instance, Kaiser formularies were managed by a Pharmacy and Therapeutics Committee. *In re Neurontin*, 712 F.3d at 28–29.

52. *In re Avandia*, 804 F.3d at 634–35.

53. A monograph is a piece of writing typically used to present research on a single subject or aspect of a subject. *See Monograph*, DICTIONARY.COM, http://www.dictionary.com/browse/monograph (last visited Nov. 13, 2016). In the context of drug manufacturing they provide descriptions of drug, development information, treatments it can be used for, and dosage information. *How Drugs are Developed and Approved*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/ (last visited Nov. 13, 2016).

54. *In re Neurontin*, 712 F.3d at 28–29.

55. *Id.* at 28.

PBMs are directly influenced by the evidence and unpublished information regarding drug safety possessed by drug manufacturers.[56] TPPs obtain this data from manufacturers utilizing it to prepare monographs.[57] In turn, PBMs rely heavily on the monographs when making formulary decisions.[58] Additionally, pharmaceutical companies indirectly influence TPPs' formulary determinations.[59] For instance, a pharmaceutical company will build relationships with influential TPP affiliates and also employ physicians associated with TPPs to publish favorable articles about the company's drug.[60]

If a PBM determines a particular drug is more advantageous than a competing drug after the research and monograph phase, the more advantageous drug is given preferred status on the formulary.[61] Consequently, the higher a drug's preferential status on the formulary, the more of its cost a TPP will cover.[62] This, in turn, will reduce the copayment a member must pay when a physician prescribes the drug.[63]

TPPs rely considerably on representations made by, and information obtained from, manufacturers throughout the process of approving a drug for inclusion in its formulary.[64] Doctors then rely on the TPP's formulary, which is directly and indirectly influenced by the drug manufacturers. This raises questions as to whether subsequent doctor prescription decisions are sufficiently independent to sever the causal relationship between drug manufacturers and TPPs.[65]

C. First and Third Circuits: Physicians' Prescription Decisions Keep the Causal Chain Intact

This Section explores the First and Third Circuits' approach to RICO causation. It explores the First Circuit's decision in *In re Neurontin*[66] and then analyzes the Third Circuit's approach in *In re Avandia*.[67]

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56. *Id.* at 29.
57. *Id.*
58. *Id.*
59. *Id.* at 28.
60. *In re Neurontin*, 712 F.3d at 28.
61. *In re Avandia*, 804 F.3d at 635; *In re Neurontin*, 712 F.3d at 28–29.
62. *In re Avandia*, 804 F.3d at 635.
63. Id.
64. *E.g.*, *In re Neurontin*, 712 F.3d at 29.
65. *In re Avandia*, 804 F.3d at 643–46; *In re Neurontin*, 712 F.3d at 29; *UFCW Local 1776*, 620 F.3d at 134–36; *United Food & Commercial Workers Cent. Pa.*, 400 F. App'x at 257.
66. *In re Neurontin*, 712 F.3d at 21.
67. *In re Avandia*, 804 F.3d at 633.

1. First Circuit Approach to RICO Causation

The First Circuit holds that prescription decisions of prescribing doctors pose no bar to RICO causation.[68] In *In re Neurontin*, healthcare giant Kaiser Foundation Health Plan, Inc. (Kaiser) alleged drug manufacturer Pfizer, Inc. (Pfizer) violated RICO § 1962 by fraudulently marketing Neurontin, an anti-epileptic drug, for off-label uses.[69] In 1993, the FDA approved the drug for the treatment of epileptic seizures and set the maximum daily dose at 1800 milligrams.[70] In 1995, Pfizer developed strategies to market the drug for off-label uses such as migraines and bipolar disorder.[71] Over the next few years, Pfizer began marketing to TPPs for such uses in doses exceeding the FDA-approved 1800 milligrams per day.[72] These marketing efforts proved effective as Neurontin sales reached $2 billion in 2003 and over one-third of the prescriptions treated off-label indications.[73] However, throughout this process Pfizer failed to disclose potential depression-related side effects.[74] In 2008, the FDA issued a warning to physicians regarding the possibility of depression, suicidal tendencies, and unusual changes in patient behavior.[75]

Kaiser relied on the manufacturer's misrepresentations in the preparation of its monographs, directly affecting Kaiser's decision to place Neurontin on its formulary without restrictions.[76] Evidence showed that Kaiser's "physicians received and acted upon Pfizer's misrepresentations . . . through information sent [to them] . . . and information provided to [the physicians] at Pfizer-sponsored events."[77] If Pfizer had not misrepresented Neurontin's safety issues, PBM's monograph would have contained more accurate information regarding the drug's risks. As a result, the drug likely would not have been given preferential status on Kaiser's formulary.[78] Consequently, Kaiser suffered an injury by reimbursing its members for Neurontin, rather than cheaper alternatives available on the market.[79] Kaiser estimated Pfizer's fraud

68. *In re Neurontin*, 712 F.3d at 38–39.

69. *Id.* at 27–28. Off-label conditions are those not included in the official FDA-approved drug label. *Id.*

70. *Id.* at 27.

71. *Id.*

72. *Id.* at 28.

73. *In re Neurontin*, 712 F.3d at 27.

74. *Id.*

75. *Id.*

76. *Id.* at 29. Such restrictions, for instance, would have included warnings for the depressive behavior Pfizer failed to disclose. *Id.* at 27.

77. *Id.* at 40–41.

78. *In re Neurontin*, 712 F.3d at 40–41.

79. *Id.*

resulted in over $60 million in damages from prescription reimbursement.[80]

In finding Pfizer's misrepresentations satisfied RICO's proximate cause requirement, the First Circuit relied on common law "directness," as well as three functional factors formulated by the Supreme Court.[81] Regarding the common law standard, the Supreme Court noted in *Holmes* that a proximate cause analysis generally requires a direct relationship between the injury suffered and the alleged injurious conduct.[82] The Court also elucidated the following factors for courts to consider when making the proximate cause inquiry: (1) proof of injury, (2) administrative efficiency, and (3) public policy.[83] Furthermore, the Court in *Holmes* noted the difficulty and complexity of calculating damages when an injury is less direct.[84] The Court noted that "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".[85] However, in *Bridge* the Court unanimously held that first-party reliance on the misrepresentation is *not* required under RICO.[86]

Based on these considerations, the First Circuit held "the causal chain is anything but attenuated" between the drug manufacturer and TPPs.[87] The court emphasized Pfizer understood the structure of the U.S. healthcare system and the fact that TPPs, not physicians, pay for the drugs.[88] Further, Pfizer's fraudulent marketing scheme was dependent upon Kaiser paying for the drug.[89] Accordingly, their economic injury was foreseeable.[90] The Court held the causal link is not automatically broken even if a manufacturer directs its alleged misrepresentations towards prescribing doctors.[91] Therefore, in the First Circuit direct reliance on the misrepresentations by TPPs is not required.[92]

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80. *Id.* at 32.
81. *Id.* at 36 (citing *Holmes*, 503 U.S. at 268).
82. *Id.* (citing *Holmes*, 503 U.S. at 268).
83. *Id.* (citing *Holmes*, 503 U.S. at 269–70).
84. *In re Neurontin*, 712 F.3d at 36 (citing *Holmes*, 503 U.S. at 269).
85. *Id.* (quoting *Holmes,* 503 U.S. at 269).
86. *Id.* at 36–37 (citing *Bridge*, 553 U.S. at 641).
87. *Id.* at 38.
88. *Id.* at 38–39.
89. *Id.*
90. *In re Neurontin*, 712 F.3d at 38–39.
91. *Id.* at 37.
92. *Id.*

2. Third Circuit Approach to RICO Causation

The Third Circuit echoes the First Circuit approach, asserting the presence of intermediaries, such as doctors and patients, does not destroy causation in RICO claims.[93] In *In re Avandia*, TPPs argued GlaxoSmithKline (GSK) misrepresented safety risks associated with Avandia, a Type II diabetes drug.[94] Once the FDA approved Avandia in 1999, GSK marketed the drug as cheaper and more effective than existing Type II diabetes drugs.[95] Consequently, TPPs included Avandia in its formularies and covered the cost of prescriptions at a favorable rate.[96] However, health concerns related to the drug began surfacing in 2001.[97] Following the FDA's request, GSK added a prescription label warning that the drug may cause increased risk of fluid retention.[98] Five years later, Avandia's label required an additional warning that the drug may cause increased risk of heart-related issues, including heart attack.[99] The situation further deteriorated in 2007 when the FDA recommended the addition of "black box" warnings[100] to Avandia's label to warn of the risk of heart failure.[101] Then in 2010, a U.S. Senate Finance Committee report concluded GSK was aware of these cardiac risks for years yet "failed to notify the FDA and the public of these risks despite its duty to do so."[102]

In reaching its decision, the Third Circuit relied on the Supreme Court's holding in *Bridge.*[103] In *Bridge,* Phoenix Bond & Indemnity. Co. (Phoenix) bid for county tax liens in Illinois and brought a RICO claim alleging its competitors committed mail fraud by making misrepresentations during the bidding process.[104] Phoenix claimed its competitors engaged in fraud by mailing notices containing misrepresentations to property owners.[105] However, the competitors argued Phoenix did not rely on those alleged representations—the property

93. *In re Avandia*, 804 F.3d at 645.
94. *Id.* at 634.
95. *Id.* at 635.
96. *Id.*
97. *Id.*
98. *Id.*
99. *In re Avandia*, 804 F.3d at 635.
100. A black box warning is listed on the label of a prescription drug to warn of serious and life-threatening risks of the drug. U.S. Food & Drug Admin., *A Guide to Drug Safety Terms at FDA*, http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM107976.pdf. (last visited Nov. 13, 2016).
101. *In re Avandia*, 804 F.3d at 635.
102. *Id.* at 635–36.
103. *Bridge*, 553 U.S. at 639.
104. *Id.*
105. *Id.*

owners did.[106] Consequently, the Supreme Court held no general principle states misrepresentation can only cause injury to a party that relies on it, but rather, a "plaintiff's loss must be a foreseeable result of *someone's* reliance on the misrepresentation."[107]

In applying *Bridge*'s holding, the court in *Avandia* considered the TPPs to be the "primary and intended victims of the scheme to defraud." Accordingly, the economic harm suffered was a "foreseeable and natural consequence of [the] scheme."[108] Because the TPPs paid for these drugs they were the intended victims. In fact, GSK's fraudulent scheme could only be successful if the TPPs paid GSK for the drug.[109]

D. Second and Ninth Circuit Courts: Physicians' Prescription Decisions Sever the Causal Chain

This Section explores the Second and Ninth Circuits' approach to RICO causation, which hold prescription decisions of physicians sever causation between manufacturers and TPPs.[110] First, this Section discusses the Second Circuit's decision in *UFCW Local 1776 v. Eli Lilly & Co.*,[111] and then explores the Ninth Circuit's approach in *United Food & Commercial Workers Central Pennsylvania v. Amgen, Inc.*[112]

1. Second Circuit Approach to RICO Causation

Unlike the First and Third Circuits, the Second Circuit held in *UFCW Local 1776* that physician prescription decisions sever the chain of causation.[113] In 1996, the FDA approved Eli Lilly's drug Zyprexa for treating schizophrenia.[114] In 2000, the company began marketing the drug directly to physicians for off-label uses.[115] While physicians are permitted to prescribe drugs for off-label uses, "manufacturers are prohibited from promoting off-label uses in marketing a drug."[116] TPPs argued that Eli Lilly turned its marketing efforts to-

106. *Id.*
107. *Id.* at 655.
108. *In re Avandia*, 804 F.3d at 645 (quoting *Bridge*, 553 U.S. at 658).
109. *Id.* at 645.
110. *UFCW Local 1776*, 620 F.3d at 134; *United Food & Commercial Workers Cent. Pa.*, 400 F. App'x at 257.
111. *UFCW Local 1776*, 620 F.3d at 135.
112. *United Food & Commercial Workers Cent. Pa.*, 400 F. App'x at 257.
113. *UFCW Local 1776*, 620 F.3d at 135.
114. *Id.* at 124.
115. *Id.* at 127.
116. *Id.* Manufacturers are prohibited from advertising or promoting drugs for off-label uses in an effort to protect patients from using the drugs to treat conditions for which there is little to no clinical evidence to support such use. *Off-label Use: The Fine Line Between Illegal Promotion*

wards physicians to promote off-label uses of Zyprexa.[117] For example, Eli Lilly targeted the nursing home industry and instructed 280 sales representatives to suggest to physicians that Zyprexa was beneficial for diseases such as dementia.[118] Such assertions were made despite a lack of evidence that the drug was effective for treating dementia—in fact clinical evidence showed it was detrimental to the cognitive function of Alzheimer's patients.[119] This marketing approach yielded some success; by 2002 approximately two-thirds of Zyprexa's prescriptions were for off-label purposes.[120]

In 2003, however, the FDA required labelling changes to Zyprexa to warn of pancreatitis, hyperglycemia, and diabetes.[121] In 2005, a black box warning was added to warn of increased risk of death for elderly dementia patients.[122] Following the label changes, consumption of the drug experienced a 50% decrease between 2003 and 2008.[123]

Unsurprisingly, TPPs brought a RICO claim alleging that Eli Lilly became aware of some harmful side effects during the drug's development and failed to disclose this to the FDA, even after the drug made it to the market.[124] In particular, TPPs asserted the drug was associated with significant weight gain and that Eli Lilly falsely marketed the drug as superior despite knowing of this serious side effect.[125]

In holding that prescription decisions sever proximate cause in RICO cases, the court described the causal chain as follows: "[the manufacturer] distributes misinformation about Zyprexa, physicians rely upon the misinformation and prescribe Zyprexa, TPPs relying on the advice of PBMs and their Pharmacy and Therapeutics Committees place Zyprexa on their formularies as approved drugs."[126] Perhaps fatally, the TPPs did not allege *they* relied on the manufacturer's misrepresentations, but rather that the physicians did.[127] As such, the court found that unless it can be proved that *all* prescription decisions

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and Useful Information, BIOWORLD, http://www.bioworld.com/content/label-use-fine-line-between-illegal-promotion-and-useful-information (last visited Nov. 13, 2016).

117. *UFCW Local 1776*, 620 F.3d at 127.

118. *Id.* at 128.

119. *Id.*

120. *Id.*

121. *Id.* at 125.

122. *Id.*

123. *UFCW Local 1776*, 620 F.3d at 125.

124. *Id.* at 124.

125. *Id.* at 124–25. Confidential internal documents revealed Ely Lilly was aware of these side effects, but did not understand the source of them.

126. *Id.* at 134.

127. *Id.*

by *every* doctor were made in reliance on the drug manufacturer's fraudulent misrepresentations, the chain of causation is severed.[128] The court held that it was the TPPs failure to negotiate the price of Zyprexa with the manufacturer that resulted in overpaying for the drug.[129] Consequently, the conduct giving rise to the harm—the failure to negotiate—was considered distinct from the conduct giving rise to the fraud—the alleged misrepresentations.[130] There was evidence that TPPs requested rebates from the manufacturer or internally restricted the use of Zyprexa for some indications.[131] But even after the drug's side effects were made public most TPPs continued paying full price for its prescription.[132] Further, the court held the TPPs' "theory of liability rests on the independent action of third and even fourth parties," given that physicians, PBMs, and others are all links on the chain between the manufacturer and TPPs thereby making the chain too attenuated.[133]

2. *Ninth Circuit Approach to RICO Causation*

In *In re Epogen*, two TPPs attempted to bring a RICO claim against Amgen, one of the United States' largest pharmaceutical companies.[134] The TPPs' complaint did not survive a motion to dismiss because it alleged a weak causal chain between the drug manufacturer and the TPPs.[135] The court held the causal link pled was insufficient to satisfy the proximate cause requirements for RICO claims set forth by the Supreme Court in *Bridge*.[136]

The TPPs alleged Amgen unlawfully promoted two drugs, Epogen and Aranesp (jointly, EPO), that stimulated the production of red blood cells.[137] In 1989, the FDA approved Epogen for treating anemia in chronic renal failure patients, HIV patients, and cancer patients undergoing chemotherapy.[138] In 2001, Aranesp was approved for similar uses.[139] In 2007, an article was published by The Cancer Letter regarding increased mortality rates in cancer patients that utilized

128. *Id.* at 134–36.
129. *UFCW Local 1776*, 620 F.3d at 134.
130. *Id.*
131. *Id.*
132. *Id.*
133. *Id.*
134. *In re Epogen*, 590 F. Supp. 2d at 1284.
135. *United Food & Commercial Workers Cent. Pa*,. 400 F. App'x at 257.
136. *Id.*
137. *In re Epogen*, 590 F. Supp. 2d at 1284–85.
138. *Id.* at 1285.
139. *Id.*

Aranesp.[140] As a result, the FDA issued a black box warning for off-label uses of EPO.[141] This warning also included results of a study indicating some cancer patients taking EPO died in half the time of patients that were given placebos.[142] The TPPs argued Amgen engaged in racketeering activity, including mail and wire fraud, by unlawfully promoting EPO for unsafe, off-label uses.[143]

The Ninth Circuit held the complaint failed to "identify statements or representations made by Amgen that were false or misleading at the time they were made, as required in a civil RICO action based on mail and wire fraud."[144] While the TPPs alleged the manufacturer concealed adverse test results, they failed to identify particular study results that Amgen allegedly promoted.[145] Finally, the causal chain between the manufacturer and TPPs was considered too attenuated because there were at least four separate links: "(1) the manufacturer's listing of Aranesp to treat anemia of cancer, (2) Medicare's consequent decision to cover Aranesp for anemia of cancer, (3) TPPs' decision to cover Aranesp for anemia of cancer (along with heart failure patients and others), and (4) doctors' prescription decisions to prescribe Aranesp and Epogen."[146] The court suggested a drug manufacturer is too remote from a TPP-plaintiff when third parties exist in the chain leading to a particular drug being prescribed.[147] In this case, the involvement of the manufacturer, Medicare, and physicians gave rise to a remoteness the TPPs were unable to overcome in order to establish proximate cause for the economic loss they suffered.[148] The court emphasized the need for a strong causal link between the manufacturer and the alleged injured party which, fatally, the TPPs were unable to establish.[149]

III. Analysis

This Circuit split highlights a potentially disastrous outcome: that fraudulent conduct causing direct harm could go unpunished and un-

140. Paul Goldberg, *FDA's ODAC To Review EPO Agents In May; SEC Probes Amgen Delay In Study Disclosure*, The Cancer Letter, Mar. 2, 2007, at 1, 8.

141. *In re Epogen*, 590 F. Supp. 2d at 1285–86.

142. *Id.* at 1286.

143. *Id.* at 1287.

144. *United Food & Commercial Workers Cent. Pa.*, 400 F. App'x at 257.

145. *Id.*

146. *Id.*

147. *Id.* at 257 (quoting Holmes v. Sec. Investor Prot. Corp., 503 U.S. 258, 268 (1992)).

148. *Id.*

149. *Id.*

compensated.[150] This Part argues that adoption of the approach by the First and Third Circuits is preferable because it (1) increases accountability of drug manufacturers towards TPPs when marketing new drugs, (2) more closely reflects the Supreme Court's characterization of proximate cause, and (3) accurately captures the foreseeability requirement of proximate cause utilized in other areas of tort law.[151]

A. Increasing Drug Manufacturer Accountability

Drug manufacturer marketing often targets TPPs as they ultimately pay for some, if not all, of a prescription's cost.[152] Accordingly, misleading marketing results in significant economic loss for TPPs and they have limited or no effective recourse. Even when marketing is directed towards physicians, its impact is problematic as it interferes with the physician's ability to make independent decisions concerning the patient.[153] While this Comment has explored a relatively small sampling of RICO case law, the reality is that fraudulent and misleading conduct by drug manufacturers in the United States is rampant.[154] First, this Section explores the prevalence of such conduct. Next, this section explores why adopting the First and Third Circuits' approach would more effectively combat the issue.[155]

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150. *UFCW Local 1776*, 620 F.3d at 134; *United Food & Commercial Workers Cent. Pa.*, 400 F. App'x at 255 (both cases illustrating situations where conduct that was clearly fraudulent and misleading on the part of drug manufacturers was nevertheless held to fall short of the standard required to receive RICO reprimand).

151. *Bridge*, 553 U.S. at 639; *Overseas Tankship (U.K.), Ltd., v. Morts Dock & Eng'g Co.* (*The Wagon Mound No. 1*), [1961] AC 388, 1961 WL 20739.

152. This data is based on 2014 expenditures. Sifferlin, *supra* note 1.

153. Brief for AARP et al. as Amici Curiae Supporting Petitioners, *Sergeants Benevolent Ass'n Health & Welfare Fund* at 12, 137 S. Ct. 140 (2016) (mem) (No. 15-1525) (quoting Sheryl Calabro, Note, *Breaking the Shield of the Learned Intermediary Doctrine: Placing the Blame Where It Belongs*, 25 CARDOZO L. REV. 2241, 2259 (2003–2004)). *See also* Lori-Ann Rickard & Amy Fehn, *Recent Developments in Regulation of Pharmaceutical Marketing Practices*, HEALTH LAW., Dec. 2006, at 16, 16 (finding that "physicians' prescribing practices are . . . affected by interactions with drug companies"); Jason Dana & George Lowenstein, *A Social Science Perspective on Gifts to Physicians from Industry*, 290 J. AM. MED. ASS'N 252, 252 (2003).

154. Brief for AARP et al. as Amici Curiae Supporting Petitioners, *Sergeants Benevolent Ass'n Health & Welfare Fund* at 3, 137 S. Ct. 140 (2016) (mem) (No. 15-1525).

155. *See*, *e.g.*, *In re Avandia,* 804 F.3d at 634; *In re Neurontin*, 712 F.3d at 26; *UFCW Local 1776*, 620 F.3d at 132; *United Food & Commercial Workers Cent. Pa.*, 400 F. App'x at 257; Brief for AARP et al. as Amici Curiae Supporting Petitioners, *Sergeants Benevolent Ass'n Health & Welfare Fund* at 7, 137 S. Ct. 140 (2016) (mem) (No. 15-1525).

1. *Prevalence of Fraudulent and Misleading Pharmaceutical Advertising*

Despite FDA regulations squarely prohibiting false or misleading statements concerning drug safety and effectiveness,[156] manufacturers still frequently engage in this conduct.[157] From 2001 to 2005, the FDA sent at least 170 notices to over eighty companies for false and misleading drug advertising.[158] These notices highlighted the companies' concealment of negative clinical trial results and misreporting.[159] Further, between 2003 and 2007, the FDA sent notices to pharmaceutical companies concerning unlawful promotion of off-label drug uses that exposed patients to considerable risk of harm.[160] All the while, TPPs continued to reimburse prescription medications for their insured despite this fraudulent behavior.[161] The FDA has noted, "it is very difficult, if not impossible, for [the] FDA's supplementary monitoring and surveillance efforts to identify all off-label promotion that may occur."[162]

Pharmaceutical companies often utilize industry-funded clinical studies in advertisements.[163] These studies routinely generate biased results instead of objective evidence, which taints decisions made concerning drug efficacy and safety.[164] For instance Neurontin, was promoted[165] via commissioned research.[166] The pharmaceutical company

156. 21 C.F.R. § 99.101(a)(4) (1998); Brief for AARP et al. as Amici Curiae Supporting Petitioners, *Sergeants Benevolent Ass'n Health & Welfare Fund* at 7, 137 S. Ct. 140 (2016) (mem) (No. 15-1525).

157. Brief for AARP et al. as Amici Curiae Supporting Petitioners, *Sergeants Benevolent Ass'n Health & Welfare Fund* at 7, 137 S. Ct. 140 (2016) (mem) (No. 15-1525).

158. *Id. See also* ABIGAIL CAPLOVITZ, TURNING MEDICINE INTO SNAKE OIL: HOW PHARMACEUTICAL MARKETERS PUT PATIENTS AT RISK 7 (2006).

159. Brief for AARP et al. as Amici Curiae Supporting Petitioners, *Sergeants Benevolent Ass'n Health & Welfare Fund* at 7, 137 S. Ct. 140 (2016) (mem) (No. 15-1525). *See also* CAPLOVITZ, *supra* note 158, at 1.

160. Brief for AARP et al. as Amici Curiae Supporting Petitioners, *Sergeants Benevolent Ass'n Health & Welfare Fund* at 7, 137 S. Ct. 140 (2016) (mem) (No. 15-1525). *See also Prescription Drugs: FDA's Oversight of the Promotion of Drugs for Off-Label Uses* at 5–6, U.S. GOV'T ACCOUNTABILITY OFF. (July 2008).

161. *In re Neurontin*, 712 F.3d at 40–41.

162. Brief for AARP et al. as Amici Curiae Supporting Petitioners, *Sergeants Benevolent Ass'n Health & Welfare Fund* at 7, 137 S. Ct. 140 (2016) (mem) (No. 15-1525). *See also Prescription Drugs: FDA's Oversight*, *supra* note 160.

163. Brief for AARP et al. as Amici Curiae Supporting Petitioners, *Sergeants Benevolent Ass'n Health & Welfare Fund* at 8, 137 S. Ct. 140 (2016) (mem) (No. 15-1525).

164. *Id.*

165. The drug was promoted at the time by Parke-Davis, a division of Warner-Lambert whose parent company is Pfizer. Press Release, Dep't of Justice, Warner-Lambert to Pay $430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion (May 13, 2004), https://www.justice.gov/archive/opa/pr/2004/May/04_civ_322.htm.

formulated a "publication strategy"[167] whereby academics were solicited with various grants and speaking opportunities[168] to publish and promote Neurontin.[169] Additional marketing tactics involved publishing Neurontin research while disguising its promotional purpose and conducting teleconferences with prescribing physicians that were moderated by well-remunerated contracted physicians involved in the marketing scheme.[170] This initiative proved wildly successful, and resulted in "tremendous sales . . . for uses for which it was not effective."[171] Sales for the drug rose in the U.S. from $98 million to $3 billion.[172] The manufacturer was eventually found to have engaged in "illegal and fraudulent promotion"[173] of Neurontin, which "corrupted the information process relied upon by doctors . . . thereby putting patients at risk [and] depriving health plans of the informed, impartial judgment of medical professionals . . . on which the program relies to allocate scarce financial resources to provide necessary and appropriate care."[174]

Another well-known example of this is a study of the drug Vioxx funded by Merck & Company (Merck).[175] Prior to the FDA approving the drug in 1999, Merck conducted the study[176] in an effort to prove Vioxx was a superior painkiller that resulted in fewer gastrointestinal issues compared to its competitors.[177] The apparent purpose of the study was to test the drug's safety, but it was later discovered

166. Seth Landefeld & Michael A. Steinman, *The* Neurontin *Legacy—Marketing through Misinformation and Manipulation*, 360 NEW ENG. J. MED. 103, 103–06 (2009).

167. *Id.*; Brief for AARP et al. as Amici Curiae Supporting Petitioners, *Sergeants Benevolent Ass'n Health & Welfare Fund* at 9, 137 S. Ct. 140 (2016) (mem) (No. 15-1525).

168. Landefeld & Steinman, *supra* note 166, at 104.

169. *Id.*; Brief for AARP et al. as Amici Curiae Supporting Petitioners, *Sergeants Benevolent Ass'n Health & Welfare Fund* at 9, 137 S. Ct. 140 (2016) (mem) (No. 15-1525).

170. Landefeld & Steinman, *supra* note 166, at 104 (some of these physicians were paid upwards of $170,000 over four years to moderate these phone calls and market the "benefits" of Neurontin to prescribing physicians).

171. Brief for AARP et al. as Amici Curiae Supporting Petitioners, *Sergeants Benevolent Ass'n Health & Welfare Fund* at 9, 137 S. Ct. 140 (2016) (mem) (No. 15-1525); Landefeld, *supra* note 166, at 104.

172. Landefeld & Steinman, *supra* note 166, at 104.

173. Brief for AARP et al. as Amici Curiae Supporting Petitioners, *Sergeants Benevolent Ass'n Health & Welfare Fund* at 9, 137 S. Ct. 140 (2016) (mem) (No. 15-1525).

174. DOJ Press Release, *supra* note 165.

175. Kevin P. Hill et al., *The ADVANTAGE Seeding Trial: A Review of Internal Documents*, 149 ANNALS INTERNAL MED. 251, 251–58 (2008); Brief for AARP et al. as Amici Curiae Supporting Petitioners, *Sergeants Benevolent Ass'n Health & Welfare Fund* at 8, 137 S. Ct. 140 (2016) (mem) (No. 15-1525).

176. Claire Bombardier et. al., *Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis*, 343 NEW ENG. J. MED. 1520, 1528 (2000).

177. Snigdha Prakash & Vikki Valentine, *Timeline: The Rise and Fall of Vioxx*, NPR (Nov. 10, 2007), http://www.npr.org/templates/story/story.php?storyId=5470430.

Merck's marketing department designed the study to boost sales.[178] The study eventually indicated Vioxx caused heart attacks, strokes, and even death.[179] Both the study's result and purpose were not disclosed to the participants or the New England Journal of Medicine (NEJM) which published the study.[180] Five years after the drug was released, Merck discontinued sale of Vioxx.[181] Unfortunately, Vioxx had already generated billions of dollars in sales worldwide, in part due to the clinical study.[182] The NEJM's Editor-in-Chief later revealed the journal was "hoodwinked" by the manufacturer and the authors of the study should have disclosed the side effects prior to initial publication.[183]

These illustrations demonstrate misconduct is ongoing and costing TPPs millions of dollars as they are paying for prescription drugs they would not have included in their formularies absent pharmaceutical fraud.[184] The First and Third Circuits offer a solution for TPPs targeting the deep pockets of pharmaceutical companies. This approach could further deter unlawful drug promotion and advertising practices.

2. The Approach that Leaves Intact the Causal Chain

The First and Third Circuits' approach adheres to the Supreme Court's RICO jurisprudence,[185] while sufficiently deterring drug manufacturers from fraudulently exaggerating drug safety and efficacy.[186] The Supreme Court has held that RICO contains both but-for and proximate causation requirements.[187] While not articulating an ex-

178. Hill, *supra* note 175, at 251–58; Brief for AARP et al. as Amici Curiae Supporting Petitioners, *Sergeants Benevolent Ass'n Health & Welfare Fund* at 8, 137 S. Ct. 140 (2016) (mem) (No. 15-1525).

179. Prakash, *supra* note 177.

180. Brief for AARP et al. as Amici Curiae Supporting Petitioners, *Sergeants Benevolent Ass'n Health & Welfare Fund* at 8, 137 S. Ct. 140 (2016) (mem) (No. 15-1525).

181. Prakash, *supra* note 177.

182. *Id.*

183. *Id.*

184. Brief for AARP et al. as Amici Curiae Supporting Petitioners, *Sergeants Benevolent Ass'n Health & Welfare Fund* at 7, 137 S. Ct. 140 (2016) (mem) (No. 15-1525). *See e.g.*, *In re Neurontin*, 712 F.3d at 41 (Kaiser estimated it suffered $60 million in losses as a result of Pfizer's misrepresentations); *Prescription Drugs: FDA's Oversight*, *supra* note 160.

185. *UFCW Local 1776*, 620 F.3d at 131. A substantive RICO violation involves engaging in any of the "racketeering" activities listed in 18 U.S.C. § 1961(1), such as mail and wire fraud. This is a common ground for RICO claims against drug manufacturers as they circulate their misrepresentations to TPPs using these methods. *See, e.g.*, *Sergeants*, 806 F.3d at 74; *In re Avandia*, 804 F.3d at 636; *In re Neurontin*, 712 F.3d at 34; *In re Epogen*, 590 F. Supp. 2d at 1287.

186. Petition for Writ of Certiorari, *Sergeants Benevolent Ass'n Health & Welfare Fund* at 15, 137 S. Ct. 140 (2016) (mem) (No. 15-1525).

187. *Holmes*, 503 U.S. at 268 (1992); *In re Neurontin*, 712 F.3d at 34.

plicit rule, the Court has held proximate cause requires "some direct relation between the injury asserted and the injurious conduct alleged."[188] Providing further explanation, the Court has noted the link should not be too remote[189] and first-party reliance on the misrepresentation is not necessarily required.[190] Additionally, the Court articulated three factors that emphasize the need for directness between the injury and alleged misconduct: (1) proof of injury, (2) administrative efficiency, and (3) public policy.[191] Finally, the injury[192] must have been caused by the substantive RICO violation.[193]

The First Circuit adopted an approach to proximate cause that is consistent with the Supreme Court in *Holmes*.[194] In *In re Neurontin*, the First Circuit analyzed the three factors discussed by the Court, highlighting the complexity that could arise if courts began recognizing claims from plaintiffs indirectly injured.[195] Additionally, the First Circuit noted the public policy interest in deterring illegal conduct and questioned whether a finding of proximate cause would serve that interest.[196]

Based on its own considerations, informed by the Supreme Court's approach in *Holmes*, the First Circuit held that "the causal chain is anything but attenuated" between the drug manufacturer and TPPs.[197] In explaining why the injury was sufficiently direct, the court emphasized that Pfizer understood the structure of the U.S. healthcare system and that the drugs would be paid for by TPPs rather than physicians.[198] Pfizer targeted TPPs because it knew the drug would only be prescribed and paid for if it landed near the top of the TPPs' formularies.[199] In order to ensure this high ranking, Pfizer funneled the fraudulent information directly to the TPPs, which then included it in their monographs.[200] Thus, the fraudulent marketing scheme would only be successful if the TPP was provided with the false misrepresen-

188. *Holmes*, 503 U.S. at 268 (1992); *In re Neurontin*, 712 F.3d at 34.

189. *Holmes*, 503 U.S. at 268, 271.

190. *Bridge*, 553 U.S. at 639.

191. *Holmes*, 503 U.S. at 269–70; *In re Neurontin*, 712 F.3d at 36.

192. The Supreme Court has clarified that such injury is economic in nature and constitutes injury to one's business or property. *Bridge*, 553 U.S. at 649.

193. *UFCW Local 1776*, 620 F.3d at 131. This element effectively constitutes the causation requirement. *Id.*

194. *Holmes*, 503 U.S. at 268; *In re Neurontin*, 712 F.3d at 36.

195. *Holmes*, 503 U.S. at 268; *In re Neurontin*, 712 F.3d at 36.

196. *Holmes*, 503 U.S. at 268; *In re Neurontin*, 712 F.3d at 36.

197. *In re Neurontin*, 712 F.3d at 38.

198. *Id.* at 38–39.

199. *Id.*

200. *Id.*

tations.[201] Because Kaiser and other TPPs were the intended victims of the racketeering activity, the economic injury they suffered was foreseeable.[202] The court took this approach a step further and held that even if a manufacturer directs its misrepresentations towards *prescribing doctors*, the causal link is not automatically broken because direct reliance on the misrepresentations by TPPs is not required.[203]

The Third Circuit has also followed the Supreme Court's guidance on proximate cause that a "plaintiff's loss must be a foreseeable result of *someone's* reliance on the misrepresentation."[204] In *Avandia,* the manufacturer misrepresented to TPPs the safety risks associated with a diabetes drug and marketed the drug as cheaper and more effective than existing alternatives.[205] As a result, the TPPs included Avandia in its formularies and covered a higher percentage of the prescription's cost; specifically, TPPs paid approximately $140 per month for Avandia prescriptions, as opposed to $40 to $50 for the alternatives.[206] In applying the Supreme Court's approach, the Third Circuit found the TPPs were the drug manufacturer's "primary and intended victims," and the economic harm they suffered was a "foreseeable and natural consequence of [the] scheme."[207] Accordingly, the actions of the manufacturer were deemed a sufficiently direct cause of the TPPs injury to satisfy the proximate cause requirements of a RICO claim.[208]

B. The Approach that Severs the Causal Chain

This Section explores the Second and Ninth Circuit's approach to RICO causation, which holds prescription decisions of physicians sever causation between manufacturers and TPPs.[209] This Section addresses the Second Circuit decision in *UFCW Local 1776* and the Ninth Circuit decision in *United Food*.[210] The Second and Ninth Circuits assert that, even if the TPPs suffer harm as a result of manufacturer fraud, when similar misrepresentations are made to prescribing physicians, TPPs effectively lose their standing to bring a RICO claim as the directness of the TPPs reliance on the misrepresentations is

201. *Id.*
202. *Id.*
203. *In re Neurontin*, 712 F.3d at 37.
204. *In re Avandia*, 804 F.3d at 645 (quoting *Bridge*, 553 U.S. at 655).
205. *Id.* at 635.
206. *Id.* at 636.
207. *Id*. at 645 (quoting *Bridge*, 553 U.S. at 658).
208. *Id.*
209. *UFCW Local 1776*, 620 F.3d at 121; *United Food & Commercial Workers Cent. Pa.*, 400 Fed. App'x at 257.
210. *UFCW Local 1776*, 620 F.3d 121 at 134; *United Food & Commercial Workers Cent. Pa.*, 400 Fed. App'x at 257.

clouded.[211] The approach of these circuits raises concerns for TPPs and consumers alike by limiting TPPs' ability to recover for economic loss suffered as a result of drug manufacturer fraud, and exposing consumers to serious health complications.[212]

The facts in *UFCW* are similar to those in *In re Neurontin* and *In re Avandia*.[213] Drug manufacturers distributed misinformation concerning the drug Zyprexa to TPPs that utilized the information to place the drug on their formularies.[214] Consequently, patients that were prescribed the drug suffered significant weight gain and other side effects that were concealed by the manufacturer.[215] The Second Circuit held that the TPPs made a critical procedural error by alleging *physicians*, rather than TPPs, relied on the manufacturers' misrepresentations thereby precluding TPPs from recovering under RICO.[216] Nevertheless, TPPs were victims of fraud and suffered economic loss because Zyprexa was included in its formularies at a higher price than it would have been if the TPPs were aware of the drug's possible side effects.[217] In effect, TPPs overpaid for Zyprexa at a rate $77 higher than competitor products due to its purported greater efficacy.[218] The Second Circuit created an artificial distinction between the directness of fraud suffered by physicians and TPPs.[219] While marketing Zyprexa, manufacturers engaged in direct misrepresentation to TPPs affecting the drug's pricing by obscuring its side effects.[220] There was evidence that most TPPs continued paying full price for Zyprexa prescriptions even after the drug's side effects were made public, but this does not negate the economic loss suffered by TPPs as a result of the manufacturer's initial fraud.[221] Given the court stated the failure of TPPs to negotiate Zyprexa's price demonstrated a lack of proximate cause, it seems rather unlikely the Second Circuit's decision would have materially changed if TPPs were clearer in alleging their reliance on manufacturers' misrepresentations.[222] This represents a departure from the First and Third Circuits' approach because despite levelling a

211. *UFCW Local 1776*, 620 F.3d at 134.
212. *United Food & Commercial Workers Cent. Pa.*, 400 Fed. App'x at 257.
213. *In re Avandia*, 804 F.3d at 635; *In re Neurontin*, 712 F.3d at 27–29.
214. *UFCW Local 1776*, 620 F.3d at 124–25.
215. *Id.*
216. *Id.*
217. *Id.* at 127.
218. *Id.*
219. *Id.* at 134.
220. *UFCW Local 1776*, 620 F.3d at 134.
221. *Id.*
222. *Id.*

form of fraud directly towards TPPs,[223] the Second Circuit appears to have carved out an additional responsibility for TPPs (that is, to negotiate pricing) in order to bring a successful RICO claim.[224]

The Ninth Circuit in *United Food* also severed the causal chain between drug manufacturers and TPPs because there were other parties in the chain that caused physicians to make prescription decisions.[225] While the manufacturer promoted EPO for unsafe uses,[226] the court nevertheless precluded TPP recovery under RICO due to the existence of third parties, such as Medicare and physicians, that led to the prescription of EPO.[227] In the view of the Ninth Circuit, the presence of these third parties somehow created a remoteness that severed the causal chain between manufacturers and TPPs.[228] The improper promotion of EPO relied on by TPPs, however, appears to be the type of "direct relation" the Supreme Court has found establishes proximate cause.[229]

C. Analogizing Foreseeability in the TPP Context to Personal Injury Claims

To further support implementation of the First and Third Circuit approach, it is helpful to consider the analogous operation of proximate cause in other areas of tort law.[230]

In personal injury cases, a defendant's unreasonable conduct will be the proximate cause of an injury if the injury is reasonably foreseeable given the risk of the conduct, regardless of the extent or manner of the harm.[231] If the injury is too remote from the defendant's unreasonable conduct, it will be unforeseeable and outside the scope of defendant's liability.[232] As noted above, the actions taken by drug manufacturers were calculated and intentional.[233] Drug manufacturers appear to be targeting TPPs because they are the largest financers of prescription medication and TPPs make decisions to include drugs on their formularies based on the fraudulent misrepresentations of

223. *Id.*
224. *Id.*
225. *United Food & Commercial Workers Cent. Pa.*, 400 F. App'x at 257.
226. *In re Epogen*, 590 F. Supp. 2d at 1287.
227. *United Food & Commercial Workers Cent. Pa.*, 400 F. App'x at 257.
228. *Id.*
229. *Holmes*, 503 U.S. at 268.
230. *See, e.g.*, *The Wagon Mound No. 1* [1961] AC 388, 1961 WL 20739.
231. *Id.*; Hughes v. Lord Advocate [1963] A.C. 837 (H.L.).
232. *The Wagon Mound No. 1* [1961] AC 388, 1961 WL 20739.
233. *See, e.g.*, *In re Avandia*, 804 F.3d at 635; *In re Neurontin*, 712 F.3d at 27–28; *UFCW Local 1776*, 620 F.3d at 124; *In re Epogen*, 590 F. Supp. 2d at 1284–85.

manufacturers.[234] Therefore, the economic injury they suffer in paying for prescriptions is clearly foreseeable.[235]

In personal injury cases, a defendant may argue a certain event or action was an intervening cause that severed liability.[236] An intervening cause severs a defendant's liability to the plaintiff when it is a superseding cause.[237] One such intervening cause is a "third party intentional act."[238] Manufacturers may therefore argue the prescribing decisions of physicians constitute third party intentional acts that sever the causal chain destroying a TPP's RICO claim.[239] However, because drug manufacturers directly provide misinformation to TPPs, they effectively lay the foundation for the fraudulent scheme. Providing information to TPPs and physicians alike is so interrelated, that to distinguish them would be a fiction and result in manufacturers unjustly escaping billions of dollars in liability.

IV. IMPACT

This Part canvasses the impact of adopting the First and Third Circuit approach to proximate cause by allowing TPPs to bring RICO claims regardless of physician prescription decisions.[240] First, this Part discusses how this approach protects consumers' health and safety. Second, this Part examines how this approach compensates TPPs for significant economic loss resulting from drug manufacturer misconduct.

A. Protecting Consumers' Health and Safety

Preserving the chain of causation between drug manufacturers and TPPs protects the health and safety of U.S. healthcare consumers. The cases discussed in this Comment share a common thread—consumers have suffered physical injuries as a result of unsafe drugs being intentionally introduced into the market.[241] These injuries were clear in the First and Third Circuit decisions discussed above.[242] In *In re*

234. *In re Avandia*, 804 F.3d at 635–36; *In re Neurontin*, 712 F.3d at 27–29; *UFCW Local 1776*, 620 F.3d at 124–25, 127–28; *In re Epogen*, 590 F. Supp. 2d at 1290–91.

235. *In re Avandia*, 804 F.3d at 638.

236. Derdiarian v. Felix, 417 N.E.2d 1010 (N.Y. 1980).

237. *Id.*

238. *Id.*

239. *See*, *e.g.*, *UFCW Local 1776*, 620 F.3d at 121; *United Food & Commercial Workers Cent. Pa.*, 400 F. App'x at 255.

240. *In re Avandia*, 804 F.3d at 645; *In re Neurontin*, 712 F.3d at 38–39.

241. *In re Avandia*, 804 F.3d at 634; *In re Neurontin*, 712 F.3d at 27; *UFCW Local 1776*, 620 F.3d at 124; *In re Epogen*, 590 F. Supp. 2d at 1286.

242. *In re Avandia*, 804 F.3d at 634; *In re Neurontin*, 712 F.3d at 27.

Neurontin, the manufacturer failed to disclose all possible side effects of the drug and consequently patients suffered from depression and suicidal tendencies.[243] In *In re Avandia*, a diabetes drug touted as safer and more effective than competing products ultimately exposed consumers to a greater risk of heart attack and death caused by heart-related disease.[244] Even though the Second and Ninth Circuits allowed manufacturers to evade liability, these cases nonetheless involved consumers who suffered physical injury at the hands of manufacturers.[245] In *UFCW*, there was evidence that the manufacturer's schizophrenia medication caused significant weight gain, a side effect that the manufacturer withheld from consumers and TPPs alike.[246] Finally, *United Food* involved a drug that treated cancer patients undergoing chemotherapy.[247] The drug was eventually discovered to increase mortality rates in cancer patients, with one study revealing some patients taking the drug died in half the time of those given a placebo.[248]

Ensuring TPPs can continue to bring RICO claims will deter manufacturers from intentionally misleading the public.[249] Even if the manufacturer is not *intentionally* misleading the public, this approach incentivizes manufacturers to submit accurate information and accurately define their products. Under RICO, a party that brings suit can recover treble damages.[250] While consumers could bring a claim against a manufacturer,[251] their damages likely do not rise to the level of TPPs'. Damages suffered by TPPs are routinely hundreds of millions of dollars, and trebling such amounts obviously serves as a greater deterrence.[252]

B. Compensating TPPs for Economic Loss Suffered

Establishing a proximate cause standard that makes it impossible for TPPs to bring RICO claims when they have significant economic loss due to the intentionally misleading, fraudulent behavior of manufacturers leaves TPPs with no judicial recourse for their injuries.

243. *In re Neurontin*, 712 F.3d at 27.
244. *Id.*
245. *UFCW Local 1776*, 620 F.3d at 124.
246. *Id.*
247. *In re Epogen*, 590 F. Supp. 2d at 1285.
248. *Id.* at 1286; Goldberg, *supra* note 140.
249. *In re Avandia*, 804 F.3d at 635.
250. 18 U.S.C. § 1964(c) (2016).
251. *Id.*
252. *In re Neurontin*, 799 F. Supp. 2d at 110 (TPP plaintiff awarded $174 million in damages); DOJ Press Release, *supra* note 165.

When a superior, innovative drug is promoted, TPPs will cover a large portion of the drug's cost.[253] This, in turn, reduces the consumer's co-payment and makes the drug more affordable.[254] Because TPPs are vital to affordable prescription medication, TPPs should be entitled to recover for substantial economic losses suffered at the hands of fraudulent drug manufacturers.[255]

V. Conclusion

This Comment advocates for courts to allow TPPs to hold drug manufacturers accountable for their fraudulent behavior. Manufacturers deliberately target TPPs in their marketing efforts and intentionally mislead and defraud them to increase profits.[256] This should be considered sufficiently direct to establish proximate cause. The economic injury suffered by TPPs and the devastating health consequences to the public are clear.[257] If faced with this circuit split, the Supreme Court should hold the causal chain is intact, and allow those directly harmed by the deceitful actions of manufacturers to receive compensation.

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253. *In re Avandia*, 804 F.3d at 635.

254. *Id.* (discussing reduced co-payments for consumers).

255. *In re Neurontin*, 799 F. Supp. 2d at 110 (TPP plaintiff awarded $174 million in damages); DOJ Press Release, *supra* note 165 (detailing the multi-million dollar losses suffered by TPPs at the hands of drug manufacturers).

256. *See In re Avandia*, 804 F.3d at 636; *In re Neurontin*, 712 F.3d at 27; *UFCW Local 1776*, 620 F.3d at 128.

257. *In re Avandia*, 804 F.3d at 634; *In re Neurontin*, 712 F.3d at 27; *UFCW Local 1776*, 620 F.3d at 124; *In re Epogen*, 590 F. Supp. 2d at 1286.

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