

LITIGATING OPIOID ADDICTION AS ORGANIZED CRIME: AN ANALYSIS OF PROXIMATE CAUSE AND PHARMACEUTICAL MISREPRESENTATION UNDER RICO

INTRODUCTION

In 2018, 128 people died every day from an opioid overdose, twenty-five percent of patients misused opioids prescribed for chronic pain, and approximately 1.7 million people developed a substance use disorder directly from prescription opioid use.¹ The effects were so devastating that the opioid epidemic was declared a national emergency.² In response, government officials and courts sought criminal and civil retribution to hold pharmaceutical executives responsible for their roles in the epidemic, most recently with the Racketeer Influenced and Corrupt Organizations Act (“RICO”).³ When applied in the civil context, however, courts disagree on whether a fraudulent misrepresentation can satisfy the proximate cause requirements under RICO.⁴ This Comment seeks to identify whether a misrepresentation of the addictive qualities of opioids would be a sufficient showing of proximate cause for a civil RICO claim to succeed and argues that such misrepresentations would be sufficient.

This Comment proceeds in five parts. Part I explains the progression of the opioid epidemic, pharmaceutical companies’ fraudulent misrepresentations, and the recovery options available to combat the epidemic—particularly RICO. Part II discusses RICO’s role in addressing fraudulent misrepresentations in the pharmaceutical industry. Part III describes the circuit split regarding fraudulent misrepresentations in civil RICO causation. Part IV analyzes the fraudulent misrepresentations that led to the opioid epidemic and argues that those misrepresentations are sufficient to establish proximate cause in a civil RICO claim. Part V recommends that the Supreme Court should grant certiorari on this issue and hold that misrepresentations of a drug’s harmful side effects are sufficient to show proximate cause in civil RICO cases.

1. *Opioid Overdose Crisis*, NAT’L INST. ON DRUG ABUSE (Mar. 11, 2021), <https://www.drugabuse.gov/drug-topics/opioids/opioid-overdose-crisis>.

2. See Edgar Aliferov, Note, *The Role of Direct-Injury Government-Entity Lawsuits in the Opioid Litigation*, 87 *FORDHAM L. REV.* 1141, 1142 (2018).

3. See 18 U.S.C. §§ 1961–1968.

4. See *infra* Part III.

I. BACKGROUND

A. *The United States Opioid Epidemic*

The United States opioid epidemic is a major public health issue that has devastated the country's social and economic welfare.⁵ The epidemic began in the late 1990s when pharmaceutical companies began encouraging the medical community to prescribe prescription opioids to their patients.⁶ During this time, pharmaceutical companies paid physicians to host informational seminars on drugs for their peers.⁷ While hosting these events can be a positive source of information in the medical community, the speakers of these programs often received kickbacks to prescribe the drugs they were promoting.⁸ The more prescriptions the physicians wrote, the more kickbacks they received.⁹ By 2015, nearly fifty percent of physicians received kickbacks for prescribing pharmaceutical drugs.¹⁰

Often, physicians knew little about the drugs they were prescribing.¹¹ Pharmaceutical companies assured physicians of opioid safety, guaranteeing that patients would not become addicted.¹² As a result, physicians prescribed the drugs at high rates and quantities, leading to widespread addiction.¹³ Newly addicted and reliant, patients soon turned to more potent drugs—like cocaine and heroin—culminating in the opioid epidemic now overtaking the United States.¹⁴

5. Societal costs soared in recent years, rising from roughly \$55.7 billion in 2011 to \$78.5 billion in 2016. Aliferov, *supra* note 2, at 1144; see also NAT'L INST. ON DRUG ABUSE, *supra* note 1.

6. See NAT'L INST. ON DRUG ABUSE, *supra* note 1.

7. Aaron Kessler et al., *The More Opioids Doctors Prescribe, the More Money They Make*, CNN (Mar. 12, 2018, 8:45 AM), <https://www.cnn.com/2018/03/11/health/prescription-opioid-payments-eprise/index.html>.

8. *Id.* Hosting such events is not illegal until and unless physicians receive kickbacks in exchange for prescribing the drugs. *Id.* A kickback is any form of payment provided in exchange for an action or transaction that is usually illegal or improper. See *What Is Kickback?*, THE LAW DICTIONARY, [https://thelawdictionary.org/kickback/#:~:text=Black's%20Law%20Dictionary\)-.What%20is%20KICKBACK%3F.job%2C%20contract%2C%20or%20order](https://thelawdictionary.org/kickback/#:~:text=Black's%20Law%20Dictionary)-.What%20is%20KICKBACK%3F.job%2C%20contract%2C%20or%20order) (last visited Aug. 24, 2021) (defining kickback as “a bribe for routing a job, contract, or order.”).

9. Kessler et al., *supra* note 7.

10. *Id.*

11. NAT'L INST. ON DRUG ABUSE, *supra* note 1.

12. *Id.*

13. *Id.*

14. *Understanding the Epidemic*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugoverdose/epidemic/index.html> (last visited Aug. 24, 2021).

B. The History of Fraudulent Misrepresentations in the Pharmaceutical Industry

The pharmaceutical industry has a long history of systemic fraud related to the “testing, marketing, and distribution of dangerous pharmaceutical drugs.”¹⁵ Throughout this history, pharmaceutical representatives have routinely concealed harmful side effects from physicians to convince them to prescribe dangerous drugs using “lies, bribes, and kickbacks.”¹⁶ In fact, in the pharmaceutical industry, it is so common for physicians to be deceived about dangerous products “that it’s often dismissed as the equivalent of driving slightly over the speed limit.”¹⁷

Drug representatives are also targeted as these individuals are often offered large bonuses for selling harmful drugs.¹⁸ For example, to increase sales of OxyContin, Purdue Pharma developed a “bonus system [that] encouraged sales representatives”¹⁹ to use “any means necessary” to increase sales rates, even if it meant downplaying OxyContin’s addictive tendencies.²⁰ In this way, pharmaceutical manufacturers frequently engage in a “coordinated conspiracy to deceive the American public and the medical profession about the efficacy and safety of opioids.”²¹

C. RICO

In 2017, the federal government and state governments began to pursue criminal and civil retribution against pharmaceutical companies for their role in the opioid epidemic.²² These entities often sought to recover for the economic harm they incurred due to increased rates of addiction in their communities.²³ While civil lawsuits were routinely unsuccessful early on, settlements have begun to increase in recent years, indicating their growing success.²⁴ For example, in 2007, Purdue Pharma settled in a civil suit with

15. Eugene McCarthy, *A Call to Prosecute Drug Company Fraud as Organized Crime*, 69 SYRACUSE L. REV. 439, 442 (2019).

16. *Id.*

17. *Id.* at 478 (quoting Stephanie M. Greene, *After Caronia: First Amendment Concerns in Off-Label Promotion*, 51 SAN DIEGO L. REV. 645, 648 (2014) (internal citation omitted)).

18. McCarthy, *supra* note 15, at 478.

19. *Id.* (brackets in original source) (quoting Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221, 222 (2009)).

20. *Id.* (quoting Zee, *supra* note 19, at 222).

21. Richard Ausness, *The Current State of Opioid Litigation*, 70 S.C. L. REV. 565, 586 (2019) (quoting Complaint and Demand for Jury Trial at 135, *City of Lansing v. Purdue Pharma L.P.*, No. 1:17-CV-01114 (W.D. Mich. Dec. 19, 2017)).

22. See Aliferov, *supra* note 2, at 1152–53, 1155.

23. *Id.* at 1144.

24. *Id.* at 1152.

twenty-six states for \$19.5 million.²⁵ In 2016, Cardinal Health and AmerisourceBergen, distributors of prescription opioids, did the same, settling with the State of West Virginia for \$34 million.²⁶

Generally, individual plaintiffs seeking damages for personalized injuries have also sought to recover via direct-injury lawsuits.²⁷ In the pharmaceutical context, direct-injury lawsuits “generally target opioid manufacturers for alleged misrepresentations during advertisement or opioid distributors for an alleged failure to monitor illicit distribution.”²⁸ When asserting direct-injury claims, plaintiffs generally rely on tort-based theories, one of which is RICO.²⁹

RICO makes it “unlawful for any person employed by or associated with any enterprise . . . to conduct or participate, directly or indirectly, in the conduct of such [an] enterprise’s affairs through a pattern of racketeering activity” that affects interstate commerce.³⁰ To assert a RICO violation, a claimant must establish an “association-in-fact” enterprise, defined as a “group of persons associated together for a common purpose.”³¹ To be a part of such an enterprise, a defendant must have either made decisions or intentionally performed acts that furthered the enterprise’s common purpose.³² The enterprise’s common purpose must be “separate from the pattern of racketeering activity” that the enterprise is engaging in; otherwise, it will not amount to a RICO violation, only a general conspiracy to commit a crime.³³

To establish a pattern of racketeering activity, there must be two or more acts that are “chargeable’ . . . under a host of state and

25. *Id.*

26. *Id.* at 1153–54 (noting that Cardinal Health was sued for its failure to monitor suspicious orders for opioids, which West Virginia argued “facilitated the operation of pill mills throughout the state”). Cardinal Health agreed to pay \$20 million of the \$36 million settlement. *Id.* at 1154 n.94.

27. *See, e.g., id.* at 1156–57 (“When initiated by a party other than the government, a direct-injury claim is simple: a plaintiff’s personal interests (e.g., health or property) have been injured by a third party and the plaintiff seeks to recover damages flowing from that injury.”).

28. *Id.* at 1156.

29. *See generally id.* at 1160 (noting that “plaintiffs employ either a tort-based theory or equitable theory to complete the direct-injury claim” and subsequently referencing the various tort theories, including RICO). While RICO was enacted primarily to combat organized crime, its use in other contexts—including the opioid epidemic—has grown substantially, particularly because of its ability to “prosecute an entire criminal enterprise and its constituent members at once.” McCarthy, *supra* note 15, at 471, 441.

30. 18 U.S.C. § 1962(c).

31. *In re Nat’l Prescription Opiate Litig.*, No. 1:17-md-2804, 2019 WL 4279233, at *2 (N.D. Ohio Sept. 10, 2019) (quoting *Boyle v. United States*, 556 U.S. 938, 946 (2009)).

32. *Id.* at *3; *see also* 18 U.S.C. § 1962(c) (stating that defendants must participate “directly or indirectly”).

33. *In re Nat’l Prescription Opiate Litig.*, 2019 WL 4279233, at *2 (quoting *Frank v. D’Ambrosi*, 4 F.3d 1378, 1386 (6th Cir. 1993)).

federal laws,”³⁴ as well as interrelated, continuous, and occurring within a ten-year period.³⁵ Otherwise, the acts will be deemed “isolated” and will fail to constitute a pattern.³⁶ Furthermore, either the enterprise itself or the predicate acts of the enterprise must have a *de minimis* impact on interstate commerce.³⁷ This is generally a low threshold, as courts routinely find that most, if not all, economic behavior impacts interstate commerce.³⁸ Thus, to prosecute a defendant under RICO, a plaintiff must show that (i) a defendant performed two or more acts, (ii) those activities together formed a pattern of racketeering activity, (iii) the defendant benefitted from or participated in an enterprise, and (iv) the activities of that enterprise affected interstate commerce.³⁹

II. RICO AND THE PHARMACEUTICAL INDUSTRY

In the pharmaceutical context, defendants participate in a RICO enterprise when they give or follow a directive to engage in fraud or when they exert influence or control in a scheme to fraudulently profit from the sale of prescription drugs.⁴⁰ Thus, a RICO enterprise is formed when pharmaceutical companies conspire to misrepresent the efficacy and risks of opioids and opioid addiction.⁴¹ While pharmaceutical executives are typically the easiest to implicate in such an enterprise, any person engaged in “false claims, kickback schemes, and acts of clinical and publication bias” are potential defendants for inclusion.⁴²

34. David Farve et al., *Racketeer Influenced and Corrupt Organizations*, 57 AM. CRIM. L. REV. 1191, 1195, 1197 (2020) (quoting *Nat'l Org. for Women, Inc. v. Scheidler*, 510 U.S. 249, 256–57 (1994)).

35. *Id.* at 1197. Such acts could include murder, robbery, bribery, extortion, or federal offenses involving bankruptcy or securities fraud. *Id.* at 1195–96. In the criminal context, the required acts that amount to racketeering activity can also include “mail fraud, wire fraud, insurance fraud, false claims, and honest services fraud.” McCarthy, *supra* note 15, at 465.

36. Farve et al., *supra* note 34, at 1197–98.

37. *Id.* at 1207.

38. McCarthy, *supra* note 15, at 466.

39. Farve et al., *supra* note 34, at 1194.

40. McCarthy, *supra* note 15, at 476. In the pharmaceutical context, “[pharmaceutical] [e]xecutives, sales representatives, doctors, lawyers, and politicians” often make up such enterprises. *Id.*

41. *See, e.g., In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-2804, 2019 WL 4279233, at *3 (N.D. Ohio Sept. 10, 2019) (holding that the plaintiffs “produced sufficient evidence for a reasonable jury to conclude that all [d]efendants . . . associated together for the common purpose of expanding the prescription opioid market,” thereby forming a RICO enterprise).

42. McCarthy, *supra* note 15, at 477–78.

A. *Proving Causation in Civil RICO Claims*

Standing to bring a civil RICO claim is stated under 18 U.S.C. § 1964(c).⁴³ Under the statute, a plaintiff has standing for a civil RICO claim when their injury (i) is to their business or property, and (ii) was caused “by reason of” the RICO violation.⁴⁴ The Supreme Court’s interpretation of “by reason of” requires the plaintiff to prove both proximate and but-for causation.⁴⁵ But-for causation asks whether the plaintiff’s injury would have occurred *but for* the defendant’s conduct.⁴⁶ Proximate causation serves to prevent liability when the link between the defendant’s conduct and the plaintiff’s injury has been severed.⁴⁷ Thus, proximate causation requires a plaintiff to show some sort of direct relationship between the defendant’s actions and the plaintiff’s injury.⁴⁸

*Holmes v. Securities Investor Protection Corp.*⁴⁹ sets out three principles to guide the causation analysis⁵⁰:

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, . . . 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 general⁵¹

The first *Holmes* principle asserts that an injured party must be readily identifiable with readily apparent damages.⁵² Damages are

43. 18 U.S.C. § 1964(c); *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharmas.*, 943 F.3d 1243, 1248 (9th Cir. 2019).

44. 18 U.S.C. § 1964(c); *Painters*, 943 F.3d at 1248.

45. *Painters*, 943 F.3d at 1248 (citing *Holmes v. Sec. Inv. Prot. Corp.*, 503 U.S. 258, 268 (1992)).

46. Ausness, *supra* note 21, at 595 (asking “whether the injury would have occurred in the absence of the defendant’s conduct”).

47. *Id.* at 599. In *Ashley County v. Pfizer, Inc.*, drug companies selling over-the-counter cold medicines used to produce methamphetamine were said not to have proximately caused the counties’ increased costs even though they knew the medicine would be used to make methamphetamine. 552 F.3d 659, 662–73 (8th Cir. 2009). The court held that the act of selling cold medicine was “totally independent” from the defendant’s production of methamphetamine. *Id.* at 670; *see also* Ausness, *supra* note 21, at 599–600 (discussing the *Ashley County* opinion).

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

49. 503 U.S. 258.

50. *See id.* at 269.

51. *Id.* at 269–70 (citations omitted).

52. *Id.* at 269.

considered to be readily apparent when the action that caused the plaintiff's injury has already occurred, because this negates the need for factual speculation.⁵³ The second principle requires damages to be awarded to the plaintiffs without fear that multiple parties will receive overlapping damages.⁵⁴ To conform with this principle, a court can award damages when only one party is seeking recovery for their payments towards a drug or when each individual plaintiff seeks only to recover for the damages they individually paid for a prescription drug.⁵⁵ Finally, the third principle requires that those most directly injured are bringing the suit; thus, the parties bringing the suit must be those best suited to do so.⁵⁶

Since *Holmes*, however, the Supreme Court has eased the proximate cause standard for plaintiffs bringing RICO claims on mail and wire fraud.⁵⁷ In *Bridge v. Phoenix Bond & Indemnity Co.*,⁵⁸ the Court held that a plaintiff asserting a RICO claim on mail or wire fraud does not need to show that they relied on the defendant's alleged misrepresentations to establish proximate cause.⁵⁹ As such, the plaintiff may recover whether or not they are the direct recipient of the false statements made.⁶⁰ But because a plaintiff must establish both but-for and proximate causation, they often still must show that someone relied on the defendant's misrepresentation.⁶¹

B. Criminal RICO Application

In 2019, a Massachusetts court found John Kapoor ("Kapoor"), former executive of pharmaceutical company Insys, guilty of conducting a national scheme to pay physicians to prescribe a highly

53. *In re Avandia Mktg., Sales, Pracs. & Prod. Liab. Litig.*, 804 F.3d 633, 640 (3d Cir. 2015); *see also* *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs*, 873 F.3d 574, 577 (7th Cir. 2017). In *Sidney Hillman*, the plaintiffs' claim was too speculative to meet the first *Holmes* requirement. 873 F.3d at 577. The court held that it was too difficult for the court to determine whether TPPs would have incurred costs from paying for another medication or whether physicians would have prescribed the drug for off-label uses without solicitation; thus, there was too much speculation for the damages to be readily apparent. *Id.*

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

55. *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21, 37 (1st Cir. 2013); *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharms.*, 943 F.3d 1243, 1251 (9th Cir. 2019).

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

57. *Farve et al.*, *supra* note 34, at 1235.

58. 553 U.S. 639 (2008).

59. *Id.* at 649 (citing *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 476 (2006) ("Because an individual can commit an indictable act of mail or wire fraud even if no one relies on his fraud, he can engage in a pattern of racketeering activity . . . without proof of reliance.")).

60. *See id.* at 656. The RICO statute "provides no basis for imposing a first-party reliance requirement." *Id.* at 660.

61. *Id.* at 658.

potent and addictive fentanyl-spray.⁶² In Kapoor's case, *United States v. Michael Babich*,⁶³ the Insys executives knowingly instructed physicians to prescribe the fentanyl-spray at six times the FDA-approved limit to guarantee patient reliance.⁶⁴ To ensure compliance, the executives held speaker programs disguised as "educational lunches and dinners," which they used to pay bribes and kickbacks to high-prescribing physicians.⁶⁵ The Insys executives also targeted third-party payors ("TPPs") using fake call centers to trick insurance companies into covering the spray at higher rates than they otherwise would have if they had known of the spray's addictive tendencies.⁶⁶

Kapoor and six other Insys executives were found guilty of racketeering, wire fraud, and mail fraud conspiracy, marking the "first successful prosecution of top pharmaceutical executives for crimes related to the illicit marketing and prescribing of opioids."⁶⁷ As such, this case serves as the beginning of a new era in civil litigation to hold executives responsible for their role in the opioid epidemic.⁶⁸

III. CONFLICTING INTERPRETATIONS OF MISREPRESENTATIONS UNDER RICO

Several federal circuit courts have addressed the question of whether, in the civil context, fraudulent misrepresentation can satisfy the direct-injury requirements necessary to establish proximate cause under RICO.⁶⁹ The First, Third, and recently the Ninth Circuit have held that fraudulent misrepresentations can satisfy the direct-injury requirement, while the Second and Seventh

62. Gabrielle Emanuel, *Opioid Executive John Kapoor Found Guilty in Landmark Bribery Case*, NPR (May 2, 2019, 2:37 PM), <https://www.npr.org/2019/05/02/711346081/opioid-executive-john-kapoor-found-guilty-inlandmark-bribery-case>; see also First Superseding Indictment at 7–8, *United States v. Michael Babich*, Crim. No. 16cr10343ADB (D. Mass. Oct. 24, 2017), <https://www.justice.gov/usao-ma/page/file/1010246/download>.

63. First Superseding Indictment, *supra* note 62 at 16.

64. *Id.* at 25–26. This was especially dangerous due to the potency of the fentanyl-spray; if the fentanyl-spray was prescribed at the same dosage as other fentanyl-based products on the market, then the patient could risk a fatal overdose. *Id.* at 10.

65. *Id.* at 16–17.

66. *Id.* at 32–33.

67. See Emmanuel, *supra* note 62; see also Hannah Kuchler et al., *Insys Executives Are Sentenced to Prison Time, Putting Opioid Makers on Notice*, PBS (Jan. 23, 2020), <https://www.pbs.org/wgbh/frontline/article/opioid-maker-insys-executives-sentenced-prison-subsys/>.

68. See Emmanuel, *supra* note 62.

69. See *infra* Part III.A–B.

Circuit have held that they cannot.⁷⁰ To date, the Supreme Court has not granted certiorari to resolve this issue.⁷¹

A. *Fraudulent Misrepresentation as a Sufficient Assertion of Proximate Cause*

1. *Ninth Circuit*

In *Painters & Allied Trades District Council 82 Health Care Fund v. Takeda Pharmaceuticals*,⁷² the Ninth Circuit reviewed whether patients and TPPs can sufficiently meet the proximate cause requirements in a civil RICO claim when a pharmaceutical manufacturer fraudulently misrepresents a drug's allegedly known safety risks.⁷³ There the defendants allegedly knew of and concealed that Actos, a drug prescribed to regulate blood sugar for Type II diabetics, increased a patient's risk of developing bladder cancer.⁷⁴ The plaintiffs alleged that they would never have paid for or taken the drug if they had known of the risk of bladder cancer.⁷⁵

The court concluded that the plaintiffs were the direct victims of the defendants' alleged misrepresentations and therefore that the defendants' fraudulent misrepresentations were directly related to the plaintiff's harm.⁷⁶ Thus, the Ninth Circuit held that both patients and TPPs who paid for Actos could successfully meet the proximate cause requirements.⁷⁷ In so holding, the Ninth Circuit noted that because physicians commonly prescribe prescription drugs—like Actos—it is foreseeable that physicians would prescribe such a drug and therefore “play a causative role” in the defendant's fraudulent scheme.⁷⁸ Accordingly, physician actions do not sever proximate cause.⁷⁹

The *Painters* decision marked an express change of opinion for the Ninth Circuit.⁸⁰ Ten years prior, in 2009, the Ninth Circuit conversely found that misrepresentation claims could not successfully

70. *See infra* Part III.A–B.

71. *See* *Sergeants Benevolent Assoc. Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 137 S. Ct. 140 (2016).

72. 943 F.3d 1243 (9th Cir. 2019).

73. *Id.* at 1252–53.

74. *Id.* at 1246 (alleging that defendants misrepresented the risk of bladder cancer to increase sales of Actos).

75. *Id.* at 1247, 1251.

76. *Id.* at 1251.

77. *Id.* at 1252 (reasoning that “all patients and TPPs who paid for Actos on the premise that it did not cause an increased risk of bladder cancer were allegedly defrauded by Defendants and suffered the same direct, economic injury: payments for a drug which would not have been purchased if suitably described”).

78. *Id.* at 1257.

79. *Id.*

80. *See generally In re Epogen & Aranesp Off-Label Mktg. & Sales Pracs. Litig.*, No. MDL 08-1934 PSG, 2009 WL 1703285 (Cal. June 17, 2009) (detailing the contrary holding).

assert proximate cause in civil RICO claims.⁸¹ Now, with the Ninth Circuit basing its decision on policy implications and societal interest, *Painters* introduces new considerations on the issue that cannot be ignored.⁸²

2. *First Circuit*

In *In re Neurontin*,⁸³ the First Circuit considered whether the Kaiser Foundation (“Kaiser”) could recover for an alleged injury arising from Pfizer’s alleged fraudulent marketing of Neurontin for off-label uses.⁸⁴ Kaiser argued that Pfizer’s campaign explicitly targeted TPPs to influence formulary and prescribing decisions and encouraged physicians to serve on speaker’s bureaus and sponsor informational sessions to promote Pfizer drugs, while disguising bribe and kickback payments.⁸⁵ Through expert witness testimony, the court found that three out of ten Neurontin prescriptions made for such off-label uses would not have been written but for Pfizer’s fraudulent marketing scheme.⁸⁶ As such, the court held that Kaiser was a primary, intended, and direct victim that successfully met the proximate cause requirements under RICO.⁸⁷

3. *Third Circuit*

In *In re Avandia*,⁸⁸ GlaxoSmithKline (“GSK”) marketed Avandia as a safer and more effective alternative to existing medications currently available for Type II diabetes treatment.⁸⁹ As a result, TPPs added Avandia to their formularies and covered Avandia prescriptions at preferred rates.⁹⁰ Soon after, however, risks arose regarding heart-related side effects, which GSK actively denied and countered despite knowledge to the contrary.⁹¹

The Third Circuit held that the presence of intermediaries did not sever proximate cause because the TPPs’ injury was a foreseeable result of GSK’s scheme.⁹² Since TPPs covered the costs of Avandia directly because of GSK’s misrepresentations of Avandia’s risks, the TPPs were held to be intended and direct victims.⁹³ Thus, the court

81. See *In re Epogen*, 2009 WL 1703285, at *7–8.

82. See *Painters*, 943 F.3d at 1257–59 (discussing the benefits of deterring wrongful conduct and allowing economic recovery for victims).

83. 712 F.3d 21 (1st Cir. 2013).

84. *Id.* at 25–26.

85. *Id.* at 28.

86. *Id.* at 30.

87. *Id.* at 37–38.

88. 804 F.3d 633 (3d Cir. 2015).

89. *Id.* at 635.

90. *Id.*

91. *Id.* at 635–36.

92. *Id.* at 645.

93. *Id.*

concluded that reliance on GSK’s misrepresentations was sufficient to allege proximate cause.⁹⁴

B. Fraudulent Misrepresentation as an Insufficient Assertion of Proximate Cause

In a Seventh Circuit case, *Sidney Hillman Health Center of Rochester v. Abbott Labs.*,⁹⁵ Abbott Labs allegedly solicited physicians to prescribe Depakote, a drug approved to treat seizures and migraines, for off-label uses.⁹⁶ There the Seventh Circuit reasoned that because it would be too difficult to calculate the plaintiff’s damages due to unknown factors—some patients likely benefitted from taking Depakote for an off-label use, and some physicians would undoubtedly have prescribed Depakote for off-label uses regardless of solicitation—misrepresentations made to physicians fail the first *Holmes* factor and do not constitute a direct injury.⁹⁷ As such, the Seventh Circuit held that such misrepresentations cannot meet the proximate cause requirements of civil RICO claims.⁹⁸ Similarly, in *UFCW Local 1776 v. Eli Lilly & Co.*,⁹⁹ the Second Circuit concluded that a physicians’ reliance on misrepresentations is not a but-for cause of a drug’s higher price because physicians do not consider a drug’s price when they order prescriptions.¹⁰⁰ Thus, the Second Circuit held that fraudulent misrepresentations do not sufficiently establish proximate cause for a civil RICO claim.¹⁰¹

IV. ANALYSIS

Painters, *In re Avandia*, and *In re Neurontin* discuss the issue of recovery for TPPs (and patients as well in the case of *Painters*) when dealing with fraudulent misrepresentations of a prescription drug’s harmful side effects.¹⁰² These cases more closely align with the issues arising out of the opioid epidemic—as seen in *Michael Babich*—where pharmaceutical manufacturers and their executives fraudulently misrepresented the addictive qualities of opioids, in the form of a

94. *Id.*

95. 873 F.3d 574 (7th Cir. 2017).

96. *Id.* at 575. While physicians can prescribe medications to their patients to treat off-label conditions, drug manufacturers are prohibited from promoting drugs for such purposes. *Id.*

97. *Id.* at 577; *see also* *Holmes v. Sec. Inv. Prot. Corp.*, 503 U.S. 258, 269 (1992).

98. *Sidney Hillman*, 873 F.3d at 578.

99. 620 F.3d 121 (2d Cir. 2010).

100. *Id.* at 133–34.

101. *Id.* at 134.

102. *See supra* Part III.A. *Sidney Hillman* and *UFCW* deal with fraudulent promotions of “off-label” uses and pricing decisions rather than a fraudulent failure to warn of a drug’s known risk of harmful side effects. *See supra* Part III.B.

fentanyl-spray, resulting in economic injury to both patients and TPPs.¹⁰³

A. *The Opioid Epidemic Compared to Other Civil Applications*

Like the pharmaceutical manufacturers in *In re Avandia* who falsely promoted Avandia as safe for use, the Insys executives in *Michael Babich* misrepresented the risks of the addictive qualities of their fentanyl-spray to ensure its coverage and use.¹⁰⁴ In *In re Avandia*, the pharmaceutical manufacturer knew of Avandia's increased cardiac complications; in *Michael Babich*, the pharmaceutical manufacturer knew their fentanyl-spray risked addiction and misuse.¹⁰⁵ Like the pharmaceutical manufacturer in *In re Avandia* who promoted Avandia knowing its cardiac risks, the pharmaceutical executives in *Painters* also actively misled physicians, consumers, and TPPs to prescribe and use Actos despite knowing its risk for bladder cancer.¹⁰⁶ Thus, in all three cases, pharmaceutical manufacturers formulated schemes to misrepresent the harmful side effects of their touted drugs to increase prescription rates at the expense of patients and TPPs.

Michael Babich also mimicked these cases' use of speakers' bureaus and physician targeting. Both *Michael Babich* and *In re Neurontin* used speaker programs to target physicians with high prescription numbers and pay bribes and kickbacks to these physicians in exchange for increased prescription orders and dosages.¹⁰⁷ Furthermore, like Pfizer's marketing scheme in *In re Neurontin* that actively targeted TPPs to add drugs to their formularies and influence prescribing decisions, Insys' marketing scheme in *Michael Babich* targeted TPPs through the use of a fake call center that was used to guarantee insurance coverage of their fentanyl-spray.¹⁰⁸ In both cases, the use of these schemes directly targeted TPPs, causing them to prescribe more opioids than they otherwise would have prescribed.¹⁰⁹ In these ways, the facts of

103. See First Superseding Indictment, *supra* note 62, at 7–8.

104. See *id.* at 26–27; see also Kuchler et al., *supra* note 67; Emanuel, *supra* note 62; *In re Avandia Mktg., Sales, Prac. & Prod. Liab. Litig.*, 804 F.3d 633, 635 (3d Cir. 2015).

105. See First Superseding Indictment, *supra* note 62, at 7–8, 26–27; *In re Avandia*, 804 F.3d at 635.

106. See *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharms.*, 943 F.3d 1243, 1246 (9th Cir. 2019).

107. See First Superseding Indictment, *supra* note 62, at 17–18, 20 (quoting Burlakoff telling a sales representative “[t]hey do not need to be good speakers, they need to write a lot of . . . [prescriptions for the Fentanyl-Spray]”); *In re Neurontin Mktg. & Sales Prac. Litig.*, 712 F.3d 21, 28 (1st Cir. 2013).

108. See *In re Neurontin*, 712 F.3d at 40; Emanuel, *supra* note 62; see also First Superseding Indictment, *supra* note 62, at 32–33 (misleading insurers as to their employment, patient diagnoses, and past medications used).

109. *In re Neurontin*, 712 F.3d at 40; First Superseding Indictment, *supra* note 62, at 20–22, 27, 30–31.

Michael Babich reflect those of *Painters*, *In re Avandia*, and *In re Neurontin*.

Thus, as the fraudulent misrepresentations presented in the aforementioned cases all constituted a direct injury,¹¹⁰ it is likely that a civil RICO claim based on the fraudulent misrepresentations of the opioid epidemic would be successful. Therefore, opioid epidemic plaintiffs should bring civil—as well as criminal—suits when seeking retribution for their injuries caused by pharmaceutical companies' fraudulent misrepresentations of the addictive qualities of opioids.

B. Analyzing the Proximate Cause Requirements of Civil RICO Claims

1. How Opioid Epidemic Plaintiffs Can Meet the Damages Attributable Requirement

In situations where plaintiffs can allege damages due to the failure to warn of a drug's harmful side effects, damages are not based on factual speculation and are thus readily apparent.¹¹¹ In these situations, plaintiffs bring suit because they incurred an injury from taking a drug. To have such an injury, a plaintiff must have already taken the drug, meaning that their injury has already occurred and cannot be based on factual speculation. In the context of the opioid epidemic, a plaintiff brings suit asserting injury for the harm incurred from taking a drug with addictive characteristics. Because the factual scenario seen in the opioid epidemic falls squarely into this context, a plaintiff's damages will be readily apparent and meet the damages attributable requirement.

Damages in these cases will also be readily determinable.¹¹² When a plaintiff's injury is based on a fraudulent misrepresentation of a drug's harmful side effects, the amount of damages attributable would amount to the difference between the cost of the injurious drug and the cost of a cheaper, alternative drug.¹¹³ Thus, in the context of the opioid epidemic, the damages alleged would amount to the cost between what a patient, or TPPs, would have paid for an alternative drug and what they paid for the harmful drug prescribed. Because this amount is easily determinable, patients and TPPs would likely meet this requirement in any civil litigation arising from the opioid epidemic.

110. *See supra* Part III.A.

111. *See In re Avandia Mktg., Sales, Prac. & Prod. Liab. Litig.*, 804 F.3d 633, 640 (3d Cir. 2015).

112. *See supra* notes 52–53 and accompanying text.

113. *In re Avandia*, 804 F.3d at 644.

2. *How Opioid Epidemic Plaintiffs Can Avoid Duplicative Recovery*

In opioid epidemic cases, multiple parties, including patients and TPPs, will likely look to recover damages. In these cases, each individual plaintiff will be limited in what they can recover while still conforming with the second *Holmes* principle.¹¹⁴ To ensure that there is no duplicative recovery, and thus no violation of the second principle, each plaintiff will only be able to recover damages for what they individually paid for a prescription drug.¹¹⁵ Because both TPPs and patients will have incurred economic injury in a civil litigation suit, such a limitation is the only way to ensure compliance with the second *Holmes* principle and sufficiently assert proximate cause.¹¹⁶

3. *How Opioid Epidemic Plaintiffs Can Meet the Direct-Injury Requirement*

In civil opioid epidemic litigation, patients are directly injured parties because they incur financial and personal injury when they suffer harmful effects from using dangerous drugs.¹¹⁷ Patients suffer financial injury in paying out-of-pocket for expensive, harmful drugs that often lead to complications and further health problems, including addiction and drug misuse. TPPs are directly injured parties that incur financial loss when they are targeted to add drugs to their formularies at preferred rates.¹¹⁸ For the preceding reasons, TPPs and patients are the most directly injured parties of pharmaceutical companies' fraudulent schemes to market and promote harmful drugs; thus, they are the best suited plaintiffs to bring suits against pharmaceutical companies. As such, both patients and TPPs would meet this third and final requirement in any future civil litigation related to the opioid epidemic.

C. *Policy Considerations*

Policy considerations further drive the argument in favor of allowing pharmaceutical companies' fraudulent misrepresentations to sufficiently constitute proximate cause for patients and TPPs in civil RICO claims. For one, if courts hold that the causal chain is too attenuated to constitute proximate cause for TPPs and patients—like

114. See *Holmes v. Sec. Inv. Prot. Corp.*, 503 U.S. 258, 269–70 (1992); see also *supra* notes 54–55 and accompanying text.

115. *Painters*, 943 F.3d at 1251–52; see also *In re Neurontin*, 712 F.3d at 37.

116. *In re Avandia*, 804 F.3d at 645–46; *Painters*, 943 F.3d at 1251–52.

117. See, e.g., *Painters*, 943 F.3d at 1251–52. It does not matter if some plaintiffs incurred extra or less harm from taking a drug that has harmful benefits; all patients are held to suffer the same direct economic injury. *Id.*

118. In *In re Avandia*, the court noted that TPPs are held to “suffer[] direct economic harm when, as a result of [a pharmaceutical company’s] alleged misrepresentations, they pa[y] supracompetitive prices for [brand drugs] instead of purchasing lower-priced generic [drugs].” *In re Avandia*, 804 F.3d at 639–40 (citing *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 531 (3d Cir. 2004)).

the Second and Seventh Circuits do—the implications would effectively allow pharmaceutical companies to avoid liability for their fraudulent marketing schemes.¹¹⁹ In this way, pharmaceutical companies would be shielded from liability and permitted to hide behind the physicians who prescribed their drugs.¹²⁰

For example, in the context of the opioid epidemic, such a holding would allow pharmaceutical companies to go unpunished for encouraging physicians to prescribe opioids at dangerous doses and rates. While arguably physicians should still be held liable for their own roles in the opioid epidemic, by not extending this same liability to pharmaceutical companies there would be no deterrence to stop pharmaceutical companies from engaging in these fraudulent schemes too. As such, pharmaceutical companies are likely to continue utilizing these harmful and fraudulent methods and will undoubtedly continue to use physicians as a proxy for engaging in such methods in the future if such actions are not met with liability.

Fraudulent misrepresentations should also be held to constitute proximate cause in civil RICO claims to allow plaintiffs to recover for their injuries. Patients and TPPs routinely incur economic injury in paying for expensive drugs.¹²¹ Patients often incur additional financial harm when forced to sustain their habits.¹²² For example, following the onset of addiction, patients must often pay to continue to use prescription opioids, or when prescription opioids are unavailable, they must pay for other drugs, such as heroin and cocaine.¹²³ When the financial harm stems from the patients' continued use of prescription opioids, TPPs are also financially affected.¹²⁴ Since addiction to these drugs results in the need for continued use, permitting such recovery would allow patients and TPPs to obtain some compensation for the harms wrongfully inflicted upon them.¹²⁵ Therefore, pharmaceutical companies should not be allowed to cause such extreme harm and avoid responsibility,¹²⁶ especially when the societal harm caused by these misrepresentations

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

120. *Id.*

121. *See, e.g., id.* at 1252 (discussing how patients and TPPs suffered economic injury paying for the drug Actos, which they would not have purchased if not for the fraudulent misrepresentation).

122. *See generally* NAT'L INST. ON DRUG ABUSE, *supra* note 1 (discussing the “total ‘economic burden’ of prescription opioid misuse . . . including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement”).

123. *See id.* (stating that roughly five percent of those who developed an opioid addiction transitioned to heroin and roughly eighty percent of those who use heroin misused opioids before using heroin).

124. *See, e.g., In re Neurontin Mktg. & Sales Prac. Litig.*, 712 F.3d 21, 38–39 (1st Cir. 2013) (showing that TPPs incur injury from paying for additional prescriptions due to fraudulent marketing schemes).

125. *Id.*

126. *Id.* at 38–39.

far outweighs the corporate gains. Thus, for society to fully recover, adequate recovery must be allowed.

Ensuring liability would also allow trust to be restored in the medical system. Patients need to feel comfortable seeking care from their physicians. For this to occur, patients and other medical consumers must maintain a certain level of trust in the field of science and medicine. Patients need to feel that their physicians are prescribing them medications for their own betterment, not for the personal gain or profit of the prescribing physician. Thus, if pharmaceutical schemes, aimed to profit to the detriment of patients and TPPs, are ensured to be met with litigation, then pharmaceutical companies' wrongful conduct will be deterred while increasing societal trust in the medical system.

Pharmaceutical executives must be held accountable before progress can be efficiently made. Allowing plaintiffs to satisfy the requirements of proximate cause in civil RICO claims will allow the largest societal benefit. Therefore, this position should be upheld in future civil litigation surrounding the opioid epidemic.

V. RECOMMENDATION

While pharmaceutical companies misrepresenting drugs to consumers and insurers to increase profits is certainly not a new occurrence, the opioid epidemic has arguably been the most widespread incidence of such an event. Because the opioid epidemic can affect anyone and everyone, the opioid epidemic is arguably one of the most transcendent public health issues that the United States has ever encountered. For this reason, the Supreme Court should grant certiorari on the issue of whether a fraudulent misrepresentation can constitute proximate cause in a civil RICO claim, especially regarding recovery for cases dealing with the opioid epidemic and the addictive tendencies of opioids.

The Supreme Court should grant certiorari on this issue because it is crucial for a uniform approach to be created and adhered to in the United States. If the Supreme Court denies certiorari and allows this issue to remain with the various circuits, then pharmaceutical companies could continue to avoid liability. Without a uniform approach, pharmaceutical companies can continue to bypass responsibility, establishing their companies in circuits that do not regard fraudulent misrepresentations as a sufficient means of causation in civil RICO claims. Thus, by failing to grant certiorari on this issue, the Supreme Court would be allowing pharmaceutical companies, and their executives, to avoid prosecution for their wrongful acts by allowing them the opportunity to reside in circuits with favorable precedent. Since the opioid epidemic affects every state on a national level, this sort of piecemeal approach across the circuits is not a suitable option; instead, the only way to truly curb these immense harms is with a uniform, national standard guaranteed to be consistently applied.

Should the Supreme Court grant certiorari to hear this issue of fraudulent misrepresentation as sufficient for proximate cause, the Court should follow the approach taken by the First, Third, and Ninth Circuits. Victims of the opioid epidemic have suffered. Not only have patients suffered physical injury, dealing with increased risk of disease or a newfound lifelong addiction, but patients have incurred financial injury in paying for drugs that not only did not ease their existing medical ailments, but also created new conditions that have further exacerbated their financial situations. States and local communities have also suffered economic injury. These communities have seen spikes in crime rates as consumers seek to maintain their habits and incur increased costs stemming from the need to provide treatment for their constituents. As such, if the Court grants certiorari on the issue, not only should it hold that fraudulent misrepresentations are enough to assert proximate cause, but it should also hold that patients, TPPs, state governments, and municipal communities are all victims of such misrepresentations, and thus, are entitled to recovery.

The Supreme Court should also hold that fraudulent misrepresentations should be sufficient allegations of proximate cause because of the effect that such a holding would have on the legal system moving forward. Allowing pharmaceutical companies to fraudulently misrepresent drugs at the peril of consumers and TPPs effectively contributes to the overburdening of the legal system. With fewer persons addicted to drugs that often lead to addiction of more potent drugs, such as heroin and cocaine, the crime rates in local communities would arguably decrease. With fewer crimes being committed by addicts attempting to maintain their habits, heavily impacted communities and the legal system would become less strained. As such, the deterrence of fraudulent misrepresentations of a harmful drug's side effects, especially opioids, would have immense societal benefit. Thus, not only should the Court grant certiorari on this issue, but it should also hold that fraudulent misrepresentations of the addictive qualities of opioids are sufficient to allege proximate cause in civil RICO claims.

CONCLUSION

The opioid epidemic has recently subjected pharmaceutical companies to increased scrutiny, which will likely result in an uproar of future opioid epidemic litigation. Should this litigation arise, the Supreme Court should grant certiorari on the issue of whether fraudulent misrepresentations of the addictive qualities of opioids are sufficient to show proximate cause for civil RICO claims. Due to the policy considerations and societal implications the opioid epidemic has created, the Supreme Court should hold—as the First, Third, and Ninth Circuits have held—that misrepresentations of the addictive qualities of opioids are sufficient to show proximate cause for a civil RICO claim.

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