

CLAIMS AGAINST PHARMACEUTICAL MANUFACTURERS UNDER THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT (RICO): ESTABLISHING PROXIMATE CAUSATION

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I. INTRODUCTION

The U.S. is a world leader in biopharmaceutical research and development.² The biopharmaceutical industry in the U.S. accounts for approximately one third of the global market, making it the largest market in the world.³ Accordingly, the economic power of the biopharmaceutical industry within the U.S. is significant, and this economic aspect of the industry has generated substantial profits for U.S. pharmaceutical companies.⁴ The competitive and profit-driven nature of the pharmaceutical industry has led companies to deploy strategies to increase their profits by expanding drug sales.⁵ While pharmaceutical companies are legally and ethically bound to engage in safe and truthful promotion strategies, history proves that the current pharmaceutical regulation system is not perfect, and many entities have taken advantage of the system's loopholes.⁶ The resulting harms of pharmaceutical companies' fraudulent promotion strategies on society and individuals are immense.⁷ There is no doubt that pharmaceutical innovations developed in the U.S. have had immeasurable beneficial impact on public health and global health. At the same time, however, without an

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² See *Biopharmaceutical Spotlight: The Biopharmaceutical Industry in the United States*, SELECTUSA, <https://www.selectusa.gov/pharmaceutical-and-biotech-industries-united-states> [<https://perma.cc/V9C2-4P9A>] (last visited Nov. 24, 2020).

³ *Id.*

⁴ *Id.*

⁵ See Teresa Leonardo Alves, et al., *Medicines Information and the regulation of the Promotion of Pharmaceutical*, 25 SCI. ENG. ETHICS 1167, 1167 (May 2, 2018).

⁶ See BRIAN T. YEH, CONG. RSCH. SERVS., LEGAL AUTHORITIES UNDER THE CONTROLLED SUBSTANCES ACT TO COMBAT THE OPIOID CRISIS (Dec. 18, 2018) (discussing the origination of the opioid epidemic which partly stemmed from pharmaceutical manufacturers falsely advertising the addictive effects of opioids in the 1990s).

⁷ *Id.*

adequate level of governmental oversight or regulation, the pharmaceutical industry is capable of creating substantial harms on a national or global scale.

Along with the rising number of civil claims against pharmaceutical manufacturers under various federal and state liability statutes are circuit courts' drastically different approaches when interpreting the proximate causation requirement under the Racketeer Influenced and Corrupt Organizations Act (RICO). This note's main objective is to address the current circuit split on the issue of establishing proximate causation in claims against pharmaceutical manufacturers under the RICO. Before discussing the proximate causation issue, Section II provides an understanding of the overall structure of the pharmaceutical industry, including federal and state regulations governing pharmaceutical approval processes and promotion strategies. This section also takes a close look at the current customary drug promotion strategies utilized by pharmaceutical manufacturers. In the spotlight of this section is the issue of pharmaceutical manufacturers engaging in negligent or fraudulent promotion claims, including off-label drug use promotion. From the time a prescription drug enters the market and is promoted by the manufacturer to when a patient receives a prescription to take the drug, there are several steps and parties involved. This multifactorial process is the basis for courts' disagreements on the issue of establishing proximate causation under RICO.

The specific issue giving rise to the circuit split is the question of whether a prescribing physician's independent action of prescribing a certain drug constitutes an intervening cause, which severs the causal link between a pharmaceutical manufacturer's allegedly wrongful conduct and the alleged financial injuries claimed by a patient or a third-party payor (TPP).⁸ As explained in Section III, a number of circuits are sharply divided on this issue.⁹ The First, Third, and Ninth Circuits held that a prescribing physician's independent action should not constitute an intervening cause relieving pharmaceutical companies from liabilities under RICO.¹⁰ On the other hand, the Second and Seventh Circuits found that the relation between a pharmaceutical manufacturer's allegedly wrongful conduct and the alleged financial injuries claimed by a patient or a TPP is too attenuated to satisfy the proximate causation requirement under RICO.¹¹

This note takes the stance that a physician's action of prescribing a drug should not constitute an intervening cause severing the causal link. Siding

⁸ *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co. Ltd.*, 943 F.3d 1243, 1246 (9th Cir. 2019).

⁹ *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21 (1st Cir. 2013); *In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 804 F.3d 633 (3d Cir. 2015); *Painters*, 943 F.3d 1243; *UFCW Loc. 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010); *Sidney Hillman Health Ctr. of Rochester v. Abbott Lab'ys*, 873 F.3d 574 (7th Cir. 2017).

¹⁰ *Neurontin*, 712 F.3d 21; *Avandia*, 804 F.3d 33; *Painters*, 943 F.3d 1243.

¹¹ *Eli Lilly*, 620 F.3d 121; *Sidney*, 873 F.3d 574.

with the First, Third, and Ninth Circuits, Section IV of this note aims to address the argument that the relation between a pharmaceutical manufacturer's negligent promotion claim and the alleged financial injuries incurred by a patient or a TPP is direct enough to satisfy the proximate causation requirement under RICO. Lastly, Section V addresses policy arguments related to the economic impact of finding liabilities against pharmaceutical manufacturers under RICO and other applicable statutes.

II. BACKGROUND

This section provides a foundational understanding of the overall structure of the pharmaceutical approval process regulated by the U.S. Food and Drug Administration (FDA). The rigorous testing and approval processes indicate the importance of balancing the interests of promoting medical advancements and protecting public health. Drugs have both beneficial and harmful effects, and it is crucial for patients and physicians to be aware of all of a drug's effects in order to make informed decisions. A drug manufacturer's negligent practice of disseminating false or misleading drug information to promote drug sales hinders doctors' and patients' ability to make informed decisions.

A. *The Role of the U.S. Food and Drug Administration (FDA)*

Before a drug enters the market, it has to undergo a rigorous testing process conducted by the drug manufacturer.¹² This process generally involves several phases, including trials performed on animals in laboratories, and humans in clinical trials.¹³ Once the drug is proven to be safe and effective, the drug manufacturer may submit the required data and the proposed label of the drug to the FDA for approval.¹⁴

The main division of the FDA in charge of overseeing drug approvals is the Center for Drug Evaluation and Research (CDER).¹⁵ After the CDER receives data from the drug manufacturer, a multidisciplinary team comprised of physicians, statisticians, chemists, and other scientists is assembled to review the data and the manufacturer's proposed label of the drug.¹⁶ The approval process consists of three main assessments: (1) assessment on whether the benefits of the drug outweigh the risks; (2) assessment on the "current treatment landscape" of the intended condition or illness; and (3) the assessment of the drug manufacturer's Risk Management

¹² See *Development & Approval Process*, F.D.A., <https://www.fda.gov/drugs/development-approval-process-drugs> [<https://perma.cc/445N-H6HJ>] (last visited Nov. 24, 2020).

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

and Mitigation Strategy (REMS).¹⁷ Once the CDER has affirmed that the drug's benefits outweigh the risks, and it is effective for its intended purposes, FDA may grant approval for the drug.¹⁸ Finally, the drug may enter the market for physicians to prescribe, TPPs to include in their formularies, and patients to use. This time-consuming process with multiple safeguards is necessary to protect consumers while promoting medical advancements.

The current understanding of medicine is that any choice to take a drug involves assessing the benefits and harms of the drug.¹⁹ It is essential, therefore, for physicians and patients to become aware of a drug's full effects before making an informed decision as to whether the drug is appropriate.²⁰ Consequently, the information provided by the drug manufacturer on a particular drug is crucial in helping a patient or a physician understand the drug's harms and benefits. However, drug manufacturers are not always reliable and truthful with respect to the information they disseminate concerning certain drugs. False or misleading promotional information regarding the efficacy of drugs provided by drug manufacturers is capable of creating substantial financial injuries to the public, and omission of safety risks could cause serious physical injuries or deaths to patients consuming the drugs.

B. *Pharmaceutical Manufacturers' Promotion of Prescription*

Drugs

The competitive nature of the pharmaceutical industry has created profit-driven pressure on drug manufacturers forcing them to enhance or revamp their promotional strategies in order to increase drug sales.²¹ The World Health Organization (WHO) defines pharmaceutical promotion as "all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs."²² Drug promotion is the most direct way to increase drug sales. Consequently, pharmaceutical companies spend an enormous amount of money and effort on promotional activities. National data shows that pharmaceutical companies spent a range of approximately \$57.5 billion in 2004 to \$27.7 billion in 2010 on pharmaceutical promotion.²³

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ See Alves et al., *supra* note 5, at 1168.

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

²³ *Id.* at 1169. The decrease in the amount of money spent on pharmaceutical promotion from 2004 to 2010 was likely due to increasingly stringent regulations and oversight on drug promotions.

Pharmaceutical manufacturers generally promote a drug's efficacy and benefits to physicians and patients through various means, including print advertisements, broadcasts, and direct communications with physicians by sales representatives.²⁴ To promote the safe use of these prescription drugs, the field of pharmaceutical promotion is subject to regulations by the FDA.²⁵ More specifically, the Office of Prescription Drug Promotion (OPDP) is the division in charge of regulating and overseeing all prescription drug promotional activities.²⁶ The stated mission of the OPDP is to protect "the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated."²⁷ In light of the issues associated with false and misleading pharmaceutical promotion, the FDA and the OPDP have implemented regulations and programs to further strengthen the oversight of prescription drug promotion, including the implementation of an outreach program called The Bad Ad Program to help healthcare providers identify and report potentially false or misleading promotion.²⁸

Meanwhile, there are several enforcement strategies the FDA deploys to regulate promotional activities on prescription drugs. One of the means is the issuance of warning letters for perceived promotional claim violations.²⁹ According to the FDA, "a warning letter should be issued for violations which are of regulatory significance in that failure to adequately and promptly take corrections may be expected to result in enforcement action should the violation(s) continue."³⁰ In a research study conducted to evaluate warning letters issued by the FDA to pharmaceutical companies from 2003 to 2008, a total number of 65 warning letters were issued with an average of 11 issued per year.³¹ Among all the warning letters issued during this six-year period, the most common perceived violation was the omission of risk information concerning a prescription drug (30.6%).³² More than half of the violations involved promotional activities directed toward physicians.³³ These statistics indicate that, despite all the regulations and rules

²⁴ Satabdi Chatterjee et al., *An Analysis of the Warning Letters Issued by the FDA to Pharmaceutical Manufacturers Regarding Misleading Health Outcomes Claims*, 10(4) PHARM. PRACT. (Granada) 194, 195 (2012).

²⁵ *Id.*

²⁶ See *The Office of Prescription Drug Promotion (OPDP)*, F.D.A., <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp> [<https://perma.cc/8C3F-HZF9>] (last visited Mar. 7, 2021).

²⁷ *Id.*

²⁸ *Id.*

²⁹ See Chatterjee et al., *supra* note 24, at 195.

³⁰ *Clinical Investigations Compliance & Enforcement*, F.D.A., <https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/clinical-investigations-compliance-enforcement> [<https://perma.cc/A6GW-BNSA>] (last visited Mar. 7, 2021).

³¹ See Chatterjee et al., *supra* note 24, at 194.

³² *Id.*

³³ *Id.*

implemented to provide safety guidance for pharmaceutical manufacturers, many pharmaceutical companies continue to engage in false or misleading pharmaceutical promotion for the purpose of expanding drug sales. These careless promotion practices have great negative implications on individuals' health and public health.

The issue of false or misleading promotion is especially problematic because physicians rely heavily on drug information provided by drug manufacturers, which ultimately affects their prescribing practices. Unsurprisingly, a systematic review of empirical studies on the relationship between physicians' interactions with pharmaceutical representatives, including meetings with sales representatives, drug company-sponsored continuing medical education, and educational symposia, and their subsequent prescribing practices showed concerning results.³⁴ The review indicated that physicians with greater level of exposure to pharmaceutical promotion were more likely to prescribe higher volumes of more costly drugs that were being promoted, and they were more likely to request the drugs to be added to formularies.³⁵ Moreover, TPPs also rely on information provided by pharmaceutical manufacturers when making the decision to include a drug in their formularies.

To further illuminate the danger of false or misleading drug promotion, the current opioid epidemic in America is a harsh consequence of many pharmaceutical companies' careless and fraudulent marketing strategies in the 1990s. The National Institute on Drug Abuse has suggested that pharmaceutical companies played a major role in starting the opioid epidemic, stating:

In the late 1990s, pharmaceutical companies reassured the medical community that patients would not become addicted to prescription opioid pain relievers, and healthcare providers began to prescribe them at greater rates. This subsequently led to widespread diversion and misuse of these medications before it became clear that these medications could indeed be highly addictive.³⁶

The pharmaceutical companies' negligent marketing strategies in the 1990s, while bringing them economic profits, marked the beginning of a crisis this country has not yet recovered from. Over the next decades, various aspects of the society would be impacted by the effects of the opioid epidemic, including lost lives, sufferings, and enormous healthcare costs.

C. *Off-Label Drug Use Promotion*

³⁴ See Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283(3) JAMA 373, 373 (Jan. 19, 2000).

³⁵ *Id.*

³⁶ YEH, *supra* note 6, at 5.

After a drug receives FDA approval, its use is not limited to only FDA-approved purposes.³⁷ In fact, it may be prescribed for “off-label” uses.³⁸ Off-label prescribing occurs when a physician prescribes the drug for a use not approved by the FDA, or for an unintended patient population.³⁹ Off-label prescribing is proven to be beneficial in limited circumstances as it permits innovation in clinical practice, and for certain “orphan conditions,” off-label prescribing may be the only available treatment.⁴⁰ Despite the clinical benefits associated with off-label prescribing, the lack of sufficient clinical data supporting a drug’s efficacy for its off-label uses is concerning.⁴¹ Additionally, although an individual physician’s decision to prescribe a drug for an off-label use may be trusted, the promotion of drugs for off-label uses remains a controversial topic.⁴² Off-label prescribing increases healthcare costs when expensive new drugs are promoted and prescribed.⁴³ Most importantly, off-label prescribing takes away the incentives for manufacturers to adhere to the rigorous drug testing process required for FDA approval for a drug’s primary use, because they can instead conduct less complicated trials seeking approval for the drug’s secondary use.⁴⁴

A disheartening example of the level of deliberation and calculation a company is willing to reach while engaging in off-label promotion, without regard for public or individual health, is the promotion of Neurontin by Pfizer, a drug corporation.⁴⁵ Neurontin is a medication used to treat epilepsy, and despite the lack of proof that the drug was safe or effective for other indications promoted by Pfizer, including bipolar disorder, pain, and migraines, the multibillion dollar corporation nonetheless marketed the drug’s off-label uses to patients and physicians.⁴⁶ Due to the company’s “effective” off-label promotion, Pfizer increased its sales of Neurontin from \$97.5 million in 1995 to around \$2.7 billion in 2003.⁴⁷ The Neurontin example also shows that the deliberate and calculated promotion strategies

³⁷ See Bo Wang et al., *The Effect of Federal and State Off-Label Marketing Investigations on Drug Prescribing: The Case of Olanzapine*, 12(4) PLOS ONE 1 (Apr. 7, 2017).

³⁸ *Id.*

³⁹ See John R. Crone, *A Cloud of Uncertainty Over Off-Label Marketing Claims*, AM. ASS’N FOR JUST. (July 2017).

⁴⁰ See Randall S. Stafford, *Regulating Off-Label Drug Use—Rethinking the Role of the FDA*, 358 NEW ENG. J. MED. 1427, 1427 (Apr. 3, 2008).

⁴¹ *Id.*

⁴² See Stephanie M. Greene, *After Caronia: First Amendment Concerns in Off-Label Promotion*, 51 SAN DIEGO L. REV. 645, 647.

⁴³ See Stafford, *supra* note 40, at 1427.

⁴⁴ *Id.* at 1427–28

⁴⁵ See Greene, *supra* note 42, at 651–53.

⁴⁶ *Id.*

⁴⁷ *Id.*

which would draw in an enormous amount of profits eventually pay off from a financial perspective, even after paying fines for violating the law.⁴⁸

Given the potential harmful effects of using a drug for unapproved purposes, there are federal and state laws restricting drug manufacturers' abilities to engage in off-label promotion. For years, drug manufacturers were prohibited from engaging in off-label promotion under the Federal Food, Drug, and Cosmetic Act (FDCA),⁴⁹ but they were allowed to provide published clinical studies concerning a drug's off-label uses to providers.⁵⁰ The defect in these clinical studies, however, was that they were often of limited quality with insufficient trial methods and clinical data as compared to approved clinical trials.⁵¹

Contrary to the evidence pointing to the negative consequences of off-label promotion, the rule is only getting more lax because many pharmaceutical companies have maintained their rights to engage in off-label promotion under the protection of the First Amendment.⁵² More recently, the Supreme Court case *Sorrell* and its progeny have opened a door for pharmaceutical manufacturers to engage in limited off-label promotions based on an asserted First Amendment right to freedom of speech.⁵³ Notably, the *Caronia* court construed the misbranding provisions of the FDCA which prohibited off-label promotion to not include truthful off-label promotion.⁵⁴ After *Amarin*, the FDA changed its strict stance on off-label promotion, allowing pharmaceutical manufacturers to engage in off-label promotion if the statements used are not "false and misleading."⁵⁵

Overall, regulations governing the practice of off-label promotion require a balancing of important interests of ensuring that potential medical advancements are not being delayed and protecting the FDA's role in public health.⁵⁶ In recent years, many pharmaceutical manufacturers have been subject to investigations due to potential unauthorized off-label promotion, and off-label prescribing is still a common practice among providers.⁵⁷ Although off-label prescribing has been proven beneficial in some circumstances, its non-evidence-based practice nature can have detrimental effects on public health.⁵⁸ Lastly, false or misleading off-label promotion is

⁴⁸ *Id.*

⁴⁹ See Crone, *supra* note 39.

⁵⁰ See Wang et al., *supra* note 37, at 2.

⁵¹ See Stafford, *supra* note 40, at 1428.

⁵² See generally Greene, *supra* note 42.

⁵³ See Crone, *supra* note 39.

⁵⁴ United States v. Caronia, 703 F.3d 149, 168 (2d Cir. 2012).

⁵⁵ See Crone, *supra* note 39.

⁵⁶ See generally Greene, *supra* note 42.

⁵⁷ See Wang et al., *supra* note 37, at 2.

⁵⁸ *Id.*

another type of negligent marketing strategy that warrants public attention due to its impact on public health.

III. THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS

ACT (RICO)

A legal claim against a pharmaceutical manufacturer alleging that its drug promotion practice is negligent, false, or misleading can be brought under various federal and state criminal or civil statutes. This section focuses on legal claims against pharmaceutical manufacturers brought under RICO, a federal statute involving patients and TPPs alleging financial injuries as a result of pharmaceutical manufacturers' allegedly wrongful promotional claims.

A. *A Brief Overview of RICO*

As part of the Organized Crime Control Act of 1970, the Racketeer Influenced and Corrupt Organizations Act (RICO) was enacted "to combat the infiltration of organized crime into legitimate businesses."⁵⁹ Not only does RICO impose substantial criminal penalties, but it also authorizes individuals or entities to bring civil lawsuits.⁶⁰ Under section 1964(c) of RICO, a claimant may bring a private cause of action to recover damages related to his injury "in his business or property by reason of a violation of section 1962."⁶¹ At the heart of the Act, section 1962 sets forth all the prohibited activities that would result in a violation of RICO.⁶² To summarize the four different types of prohibited activities under section 1962, in order for a plaintiff to successfully plead a defendant's violation of RICO, they:

must allege the existence of seven constituent elements: (1) that the defendant (2) through the commission of two or more acts (3) constituting a 'pattern' (4) of "racketeering activity" (5) directly or indirectly invests in, or maintains an interest in, or participates in (6) an "enterprise" (7) the activities of which affect interstate or foreign commerce.⁶³

Subsection 1961(1) of the Act sets forth the definition of "racketeering activity" to include various crimes chargeable under state law and acts indictable under a host of federal statutes.⁶⁴

⁵⁹ Mark Stephen Poker, *Reaching a Deep Pocket Under the Racketeer Influenced and Corrupt Organizations Act*, 72 MARQ. L. REV. 511, 511 (1989).

⁶⁰ *Id.* at 513–15.

⁶¹ 18 U.S.C.A. § 1964.

⁶² 18 U.S.C.A. § 1962.

⁶³ *Moss v. Morgan Stanley, Inc.*, 719 F.2d 5, 17 (2d Cir. 1983).

⁶⁴ 18 U.S.C.A. § 1961.

Relevant to civil RICO claims against pharmaceutical manufacturers is the prohibition of activities associated with mail fraud and wire fraud, in violation of 18 U.S.C.A. §§ 1341 and 1343.⁶⁵ Wire and mail frauds generally involve defrauding or attempting to defraud someone through the use of interstate communication such as mail, postal service, telephone, e-mail, etc.⁶⁶ The allegations against pharmaceutical companies generally focus on their engagement in fraudulent drug promotional activities via interstate communication which would constitute RICO violations under section 1962, including false or misleading representations on drugs' benefits, risks, and off-label promotion. Because of these fraudulent representations on drugs, individuals or entities may allege that they have suffered injuries as a result of such RICO violations.

B. *Proximate Causation Under RICO*

In addition to successfully alleging a civil RICO violation, a plaintiff must also satisfy a standing requirement. In order to satisfy the RICO standing requirement, a plaintiff must show that they suffered an injury to their "business or property," and the injury was "by reason of" the RICO violation.⁶⁷ The Supreme Court's interpretation of the phrase "by reason of" requires a plaintiff to show both proximate and but-for causation in order to recover under a civil RICO claim.⁶⁸ Generally speaking, but-for causation is easier to prove than proximate causation. Thus, the issue of proving proximate causation has been heavily litigated in civil cases brought against pharmaceutical manufacturers under RICO. The fundamental rule courts abide by is that proximate causation requires a showing of direct relation between the alleged injury and wrongful conduct under RICO.⁶⁹

Courts often apply the *Holmes* factors to determine whether proximate causation has been established. Under the *Holmes* factors, a court has to consider (1) whether it would be too difficult to ascertain the damages that are attributable to defendants' alleged RICO violation, (2) the risk of multiple recoveries by plaintiffs at different levels of injury due to defendants' acts, and (3) whether there are more directly injured parties that should be held accountable for bringing suits for the purpose of deterring defendants' injurious conduct.⁷⁰ With respect to the first factor, it would be difficult to ascertain the amount of damages a plaintiff is fairly entitled to if the relation between the alleged injury and wrongful conduct is not so direct.⁷¹ The

⁶⁵ *Id.*

⁶⁶ 18 U.S.C. §§ 1341–1343.

⁶⁷ *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co. Ltd.*, 943 F.3d 1243, 1248 (9th Cir. 2019).

⁶⁸ *Id.*

⁶⁹ *Id.* at 1249.

⁷⁰ *Id.* at 1251–52.

⁷¹ *Id.* at 1249.

practical reason behind the second factor is that, in order to avoid the risk of multiple recoveries, the court has to limit recovery to those parties who were directly injured due to a RICO violation.⁷² Lastly, the general interest in deterring the wrongful conduct is not enough to justify a ruling in favor of a claim by an indirectly injured party, because those individuals who were in fact directly injured should be accountable for bringing suits themselves.⁷³

C. *The Circuit Split*

In the case of a legal claim against a pharmaceutical manufacturer brought by a patient or a TPP, the relation between an alleged financial injury and the manufacturer's wrongful conduct involves several steps and parties. This multifactorial relationship complicates the process of proving proximate causation in a civil RICO claim. When pharmaceutical manufacturers market and promote drugs toward physicians, the goal is to influence physicians' prescribing practices to prescribe the promoted drugs to their patients. It is also foreseeable that the influenced physicians are likely to change their prescribing practices as a direct result of being exposed to drug promotion. In some instances, drug manufacturers market their drugs toward TPPs, and the goal is to encourage the TPPs to include the promoted drugs in their formularies. Without a physician's prescription, a patient may never be able to access the prescribed drug, and a TPP may never need to cover the cost of the drug. On the other hand, without a drug manufacturer's false or misleading representation concerning a prescription drug, a physician may never prescribe the drug for patients. Throughout the promotion process, it is sometimes unclear the extent of which a physician actually relies on the drug information provided by the manufacturer when making prescribing decisions. Thus, the involvement of a third-party in the supply chain from a pharmaceutical manufacturer to a patient gives rise to a proximate causation issue under RICO.

Currently, there is a circuit split on the issue of whether an independent action of a prescribing physician constitutes an intervening cause severing the causal link between the drug manufacturer's conduct and a financial injury alleged by a patient, or a TPP.

In *Sidney Hillman Health Center of Rochester v. Abbott Laboratories*, two TPPs brought suit against the drug manufacturer for Depakote, alleging that the manufacturer unlawfully promoted the drug for its off-label uses, in violation of RICO.⁷⁴ The Seventh Circuit, while deciding on the issue of proximate causation, concluded that it would be too difficult to ascertain whether the physicians' actions of prescribing the drug were based on the

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Sidney Hillman Health Ctr. of Rochester v. Abbott Lab'ys*, 873 F.3d 574, 575 (7th Cir. 2017).

drug manufacturer's unlawful promotion.⁷⁵ Thus, the relation between the TPPs' alleged financial injuries from insuring the drug and the drug manufacturer's unlawful promotion was not direct enough to establish a proximate causation.⁷⁶

Similarly, in *UFCW Local 1776 v. Eli Lilly & Co.*, when TPPs brought a class action against a drug manufacturer under RICO, alleging that the manufacturer misrepresented drug Zyprexa's side effects and effectiveness for its off-label uses resulting in an excessive price, the Second Circuit concluded that the relation was "too attenuated" because of the involvement of independent actions of third parties and even fourth parties.⁷⁷ The Court emphasized that the TPPs did not allege a reliance on defendant's misrepresentations, and it was irrelevant whether the prescribing physicians relied on the misrepresentations because only the TPPs could negotiate the price paid for Zyprexa.⁷⁸

On the other hand, the First, Third, and Ninth Circuits hold a divergent view on the same issue.⁷⁹ In *In re Neurontin Marketing, Sales Practices & Product Liability Litigation.*, a TPP was entitled to recover financial damages incurred in relation to Neurontin's off-label uses promoted by Pfizer, the drug manufacturer.⁸⁰ The First Circuit found that there was a direct relation between Pfizer's fraudulent misrepresentation of Neurontin's off-label uses and the financial damages incurred by the TPP; thus, proximate causation was established.⁸¹ The Court emphasized the ultimate goal of Pfizer's fraudulent marketing plan, which was to induce payments from patients and TPPs, not the doctors.⁸² Although the prescribing doctors were the ones writing drug prescriptions, they were not the direct financial victims of Pfizer's fraudulent marketing scheme.⁸³ Additionally, the Court accepted the expert testimony stating a correlation between physicians' prescribing practices and the amount of promotional spending spent on a particular drug.⁸⁴

In *In re Avandia Marketing*, the drug manufacturer of Avandia, the defendant, deliberately concealed material safety risks associated with the

⁷⁵ *Id.* at 577.

⁷⁶ *Id.*

⁷⁷ *UFCW Loc. 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 136 (2d Cir. 2010).

⁷⁸ *Id.*

⁷⁹ *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21 (1st Cir. 2013); *In re Avandia Mktg., Sales Pracs. & Prod. Liab. Litig.*, 804 F.3d 633 (3d Cir. 2015); *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co. Ltd.*, 943 F.3d 1243 (9th Cir. 2019).

⁸⁰ *Neurontin*, 712 F.3d 21.

⁸¹ *Id.* at 37.

⁸² *Id.* at 39.

⁸³ *Id.*

⁸⁴ *Id.* at 30.

drug.⁸⁵ As a direct result of this misrepresentation, the TPP plaintiffs in this case were blindsided and included Avandia in their formularies without knowing the full extent of the drug's harmful effects.⁸⁶ The Third Circuit explicitly rejected the manufacturer's argument that doctors' independent decisions to prescribe the drug and patients' decisions to take the drug were the proximate causes of the plaintiffs' financial injuries.⁸⁷ Similar to the First Circuit's finding, the Third Circuit also concluded that prescribing physicians did not suffer RICO injury as a result of the manufacturer's negligent promotional claims, and it would be unjustifiable to sever the causal chain because of the involvement of physicians.⁸⁸

Lastly, the most recent case joining the circuit split came from the Ninth Circuit.⁸⁹ In *Painters*, the Ninth Circuit sided with the First and Third Circuits in ruling that a prescribing physician's independent action does not constitute an intervening cause that severs the chain of proximate causation.⁹⁰ In *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharms. Co.*, five patients and a TPP brought suit against the drug manufacturer of Actos seeking financial damages they incurred by paying for the drug.⁹¹ In this particular case, the drug manufacturer deliberately concealed Actos' significant risk of increasing bladder cancer.⁹² Again, the Ninth Circuit concluded that the plaintiffs were the direct financial victims, not the doctors.⁹³ The plaintiffs' damages were not difficult to assess, and there was no concern of potential "duplicative recoveries by plaintiffs removed at different levels of injury from the violation."⁹⁴

IV. ARGUMENT

The underlying issue giving rise to the circuit split discussed in the previous section is that courts have not been consistent with applying Supreme Court precedents regarding establishing proximate causation in civil RICO claims. More specifically, the courts' interpretations of the four Supreme Court landmark cases – *Holmes*, *Bridge*, *Anza*, and *Hemi* – have led to their divergent views on the issue. This section aims to set forth some of the legal arguments under the current case law in support of the conclusion that a physician's action of prescribing a drug should not constitute an

⁸⁵ *Avandia*, 804 F.3d at 635–37.

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co. Ltd.*, 943 F.3d 1243, 1246–47 (9th Cir. 2019), *cert. denied*, 141 S. Ct. 86 (2020).

⁹⁰ *Id.* at 1257–59.

⁹¹ *Id.* at 1246–47.

⁹² *Id.*

⁹³ *Id.* at 1258–59.

⁹⁴ *Id.* at 1251.

intervening cause, and that the relation between a drug manufacturer's false or misleading promotion and a financial injury claimed by a patient, or a TPP, is direct enough to satisfy the proximate causation requirement under RICO. Like most circuit splits, there are certainly valid arguments on both sides. Thus, this section also addresses some potential counterarguments.

A. *An Analysis Under Holmes*

The Supreme Court first addressed the issue of proximate causation under RICO in *Holmes v. Sec. Investor Prot. Corp.*⁹⁵ The plaintiff in *Holmes* was the Securities Investor Protection Corporation (SIPC), and one of its roles was to make payments to its broker-dealer members' customers in the event that any broker-dealer member was unable to pay for its customers' claims.⁹⁶ The defendant was one of the several conspirators who engaged in a stock manipulation scheme causing a market crash which allegedly disabled two broker-dealers' abilities to pay their customers.⁹⁷ The two broker-dealers' failure to meet their obligations to the customers would later trigger SIPC's statutory duty to advance funds to reimburse the customers.⁹⁸ The SIPC brought suit against defendant alleging that, because of defendant's participation in the fraudulent stock manipulation scheme, it suffered a financial injury of \$13 million after having to pay the broker-dealer members' customers.⁹⁹ The Supreme Court ruled in favor of the defendant after finding that there were other factors that could have contributed to the broker-dealer members' filings of bankruptcy besides the defendants' fraudulent scheme, and the plaintiff was the last one in the line of injured parties as a result of the defendant's wrongful conduct.¹⁰⁰ The underlying rule was that there must be a direct relation between the wrongful conduct and the alleged injuries.¹⁰¹

In a hypothetical case involving a RICO claim brought against a pharmaceutical manufacturer by a plaintiff patient, or a plaintiff TPP, alleging a financial injury stemming from payments made on a falsely promoted drug, the plaintiff's position is similar to the SIPC's role in *Holmes*. The pharmaceutical manufacturer, as the defendant in the hypothetical case, is comparable to the conspirator in *Holmes*. Lastly, while the third-party actors involved in *Holmes* are the broker-dealers, the third-party actor in the hypothetical case would be a prescribing physician. Drawing an analogy between the two cases certainly offers an analytic perspective concerning the issue giving rise to the circuit split mentioned above. There are, however,

⁹⁵ *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258 (1992).

⁹⁶ *Id.* at 261–63.

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.* at 273.

¹⁰¹ *Id.*

some inherent differences between the two cases that should lead a court to a different conclusion in the hypothetical case than the one in *Holmes*.

The structures of the businesses involved in the two cases and the relationships between the respective parties are distinct. In *Holmes*, the defendant conspirator does not gain direct financial benefits from SIPC. On the other hand, a pharmaceutical manufacturer selling prescription drugs on the market obtains direct financial benefits from the patients taking their drugs and the TPPs insuring their drugs. There is the argument that a drug manufacturer generally sells prescription drugs to retail pharmacies, not patients and TPPs. However, this argument is irrelevant, because without consumer demand, there is little to no financial gain for the manufacturer. In *Holmes*, the direct victims of the conspirator's fraudulent stock manipulation scheme are the two broker-dealers. Respectively, this direct injury relationship does not exist between a pharmaceutical manufacturer and a prescribing physician. While a prescribing physician's reputation may be directly harmed as a result of prescribing a falsely promoted drug to patients, the prescribing physician simply does not suffer a direct financial injury. Ultimately, the party responsible for the cost of the drug is the patient, or the TPP.

Lastly, the physician-patient relationship is also distinguishable from the relationship between the broker-dealers and SIPC in *Holmes*. The SIPC serves as an insurer for its broker-dealer members who is responsible for the members' obligations to their customers if they become unable to meet those obligations, meanwhile, a physician-patient relationship is inherently different. A patient is not a prescribing physician's insurer, or anything even remotely similar to that capacity. Thus, a patient does not owe the prescribing physician any financial obligations as the case may be between SIPC and the broker-dealers. The *Holmes* Court offers the explanation that, because the broker-dealers are the direct victims of the conspirator's fraudulent scheme, SIPC should instead seek financial remedy from the broker-dealers after they successfully defend a legal action against the conspirator.¹⁰² The same alternative cannot be offered in the hypothetical case. A patient, or a TPP, who seeks financial remedy from paying for a falsely promoted drug cannot direct the legal claim against a prescribing physician because the physician is not the beneficiary of those payments. Thus, it is fair to say that, in order to make an injured patient or TPP financially whole again, the pharmaceutical manufacturer that benefited from the drug payments should be held responsible for at least returning those payments if it is found to have engaged in fraudulent drug promotion.

B. *An Analysis Based on the Holmes Factors*

¹⁰² *Id.*

Not only did the *Holmes* Court establish a proximate causation requirement for civil cases brought under RICO, but it also set forth three determinative factors for courts to consider when analyzing whether proximate causation is established.¹⁰³ First, the claim of a less direct injury is associated with a higher level of difficulty to ascertain the amount of remedy a plaintiff is fairly entitled to as a direct result of the violation.¹⁰⁴ Second, in order to avoid the risk of multiple recoveries in a case involving multiple injured parties, accepting claims of the indirectly injured would force courts to adopt complex rules in order to apportion damages fairly.¹⁰⁵ Finally, because the directly injured parties are generally accountable for bringing their own legal actions, the interest of deterring the defendant's injurious conduct is not sufficient to justify accepting claims from the indirectly injured parties.¹⁰⁶ The Court's ruling in favor of the defendant in *Holmes* was based on the application of the three factors.¹⁰⁷

An analysis under the *Holmes* three-factor test further supports the conclusion that a pharmaceutical manufacturer's false or misleading promotion of a certain drug constitutes the proximate cause for a subsequent financial injury incurred by a patient, or a TPP. Under the first factor, the relation between a pharmaceutical manufacturer's false or misleading promotion and a related financial injury suffered by a patient, or a TPP, is direct enough to satisfy the proximate causation requirement, and that it would not be difficult to ascertain the amount of remedy a plaintiff is fairly entitled to. As shown in the five cases involved in the circuit split, a plaintiff seeking a financial remedy in a RICO case against a pharmaceutical manufacturer generally bases their damages on the payments made to purchase the manufacturer's fraudulently promoted drug. The argument is that, if the plaintiff had been aware of the full effects of the drug without the manufacturer's misrepresentations or misleading promotion, they would not have purchased or insured the drug. This damage amount is not difficult to ascertain, nor is it outrageous or unreasonable. On the outset, an argument against this conclusion, as discussed by the Second and Seventh Circuits, is that because it is unclear whether a prescribing physician actually relies on the false or misleading promotion when writing a prescription, or the weight of which the physician places on the fraudulent promotional claim, it would be unfair to conclude that the pharmaceutical manufacturer's violation is the sole cause of the plaintiff's financial injury. The First Circuit has addressed this issue through its acceptance of an expert's testimony. Dr. Meredith Rosenthal, a professor at the Harvard School of Public Health, conducted research on evaluating the relationship between pharmaceutical manufacturers' promotional spending and physicians' prescribing practices.

¹⁰³ *Id.* at 269.

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

The result showed “a causal connection between the fraudulent marketing [carried out by pharmaceutical manufacturers] and the quantity of prescriptions for off-label indications.”¹⁰⁸ As discussed in a previous section, outside of the judicial system, research studies and medical literature have shown a positive correlation between the amount of promotion physicians are exposed to and the likelihood of those physicians to prescribe a certain promoted drug. A prescribing physician should not be faulted for relying on false or misleading promotional claims made by a pharmaceutical manufacturer, neither should the patient, or TPP, take on the financial burden of a fraudulently promoted drug in order to benefit the manufacturer. Thus, the sole party responsible for a plaintiff’s financial injury of paying for a falsely promoted drug should be the pharmaceutical manufacturer that has engaged in false or misleading promotion.

Under the second factor concerning the risk of multiple recoveries, the threshold question is whether there are multiple injured parties involved as a result of defendant’s wrongful conduct. In *Holmes*, the court rests its holding partially on the finding that, compared to SIPC’s financial injury, the broker-dealers are the more direct victims. It would be unfair and risky to allow every injured party to recover regardless of the directness of their injury in relation to the wrongful conduct. This issue of directness is not a concern in the hypothetical case. Among the parties involved, the most direct financial victims of a pharmaceutical manufacturer’s false or misleading promotion are the patients and TPPs paying for the falsely promoted drug. The prescribing physicians do not suffer financial injuries. Undeniably, it is likely that there are other financially injured parties. For example, a retail pharmacy may claim that it has suffered a financial injury as a result of the manufacturer’s false or misleading promotion on a certain drug. The presence of other injured parties does not diminish the directness of the relation between the financial injury suffered by a patient, or a TPP, in relation to the manufacturer’s violative act. Unlike the less direct relation between SIPC and the conspirator, patients and TPPs must make direct drug payments that benefit the manufacturer financially. Even with respect to the issue of the presence of other injured parties, courts do not need to establish complex rules apportioning damages among potential plaintiffs. Instead, the courts may determine the positions of the allegedly injured parties in the business chain, and the ultimate goal is to make the financially injured parties fairly whole again. It is simply a math problem.

One of the policy arguments in support of the main conclusion is the need to deter pharmaceutical manufacturers from engaging in false or misleading promotions. Nonetheless, the general interest of deterring an “injurious conduct” is not sufficient to justify accepting claims from indirectly injured parties in RICO cases. Under the third factor, the *Holmes* Court concludes that the broker-dealers are accountable for seeking financial recoveries from

¹⁰⁸ *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21, 30 (1st Cir. 2013).

the conspirator. Thus, there is no need to accept claims from the indirectly injured victim, the SIPC. The recovery chain in *Holmes* should be the following: the financially harmed broker-dealers should seek remedy from the defendant conspirator, and thereafter, SIPC may seek recovery from the broker-dealers based on the amount of money made to their customers. Under this recovery chain, the defendant conspirator is still held accountable for the fraudulent stock manipulation scheme, and the general interest of deterring another similar injurious conduct is achieved without the need to accept a claim from the less directly injured party – SIPC. The same conclusion cannot be reached in the hypothetical case. A patient, or a TPP, who has paid for a falsely promoted drug cannot rely on others to bring suit on their behalf, and a prescribing physician in this case is not a more direct victim with a better standing to bring suit. While the SIPC has the possible remedy of pursuing financial recovery from the broker-dealers, patients and TPPs do not have this alternative. The same recovery chain cannot be applied to the hypothetical case because the structure of the pharmaceutical industry is inherently different. While drawing an analogy between the hypothetical case and *Holmes* allows a clear application of the rules articulated in *Holmes*, it must also be acknowledged that the parties' relationships with each other are drastically different between the two cases, and the same conclusion in *Holmes* cannot be reached in the hypothetical case because of those distinctions. Based on the above analysis under *Holmes* and its three-factor test, a pharmaceutical manufacturer's false or misleading promotion on a certain drug constitutes the proximate cause for a subsequent financial injury suffered by a patient, or a TPP, from paying for the drug.

C. *An Analysis Under Bridge*

Another Supreme Court case relevant to the analysis of establishing proximate causation under RICO is *Bridge v. Phoenix Bond & Indemnity Company*.¹⁰⁹ To ensure fairness to all bidders participating in the county's sales of tax liens, Cook County adopted a rule prohibiting each bidder from using other agents to submit simultaneous bids.¹¹⁰ The plaintiff bidders brought suit against the defendant bidders alleging that the defendants fraudulently obtained a disproportionate share of liens by misrepresenting their compliance with the county rule, and this amounted to a RICO violation based on mail fraud.¹¹¹ The disputed issue of the case was whether there was a first-party reliance requirement under RICO.¹¹² The Court rejected the defendants' argument that because the plaintiffs could not show that they actually relied on the misrepresentations, the case could not proceed under RICO.¹¹³ The Court held that first-party reliance was not a prerequisite to

¹⁰⁹ *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639 (2008).

¹¹⁰ *Id.* at 642–44.

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.*

establishing proximate causation.¹¹⁴ The Court further concluded that the plaintiffs' loss of valuable liens was a direct result of the defendants' misrepresentations, because "[i]t was a foreseeable and natural consequence of [defendants'] scheme to obtain more liens for themselves that other bidders would obtain fewer liens."¹¹⁵ Furthermore, the Court emphasized that its decision was not "to say that a RICO plaintiff who alleges injury 'by reason of' a pattern of mail fraud can prevail without showing that someone relied on the defendant's misrepresentations."¹¹⁶

The *Bridge* rule, as applied to the hypothetical case, offers the conclusion that, in a RICO claim brought against a pharmaceutical manufacturer by a patient or a TPP, the plaintiff is not required to prove that they in fact relied on the false or misleading promotion carried out by the manufacturer. In fact, it would be absurd to require a patient to show first-party reliance because the customary practice is that a patient would receive a prescription from their physician. As mentioned before, prescribing physicians rely heavily on drug information provided by pharmaceutical manufacturers when making prescribing decisions. A prescribing physician, in this case, is comparable to the "someone" discussed by the *Bridge* Court. Similarly, it is also "a foreseeable and natural consequence" of a pharmaceutical manufacturer's false or misleading drug promotion to obtain financial benefits from patients and TPPs through their purchasing of the drug. In fact, the main purpose of a manufacturer's false or misleading promotion is to expand drug sales by attracting more patients. This foreseeability element further supports the proximate causation element in the hypothetical case.

To help one understand the ruling of the case, the *Bridge* Court offers the following example: an enterprise, for the purpose of eliminating rival businesses in the industry, carries out misrepresentations concerning certain aspects of the rival businesses to their customers and supplies.¹¹⁷ "If the rival businesses lose money as a result of the misrepresentations, it would certainly seem that they were injured in their business 'by reason of' a pattern of mail fraud, even though they never received, and therefore never relied on, the fraudulent mailings."¹¹⁸ This example given by the Court offers a great insight to how a court should rule in the hypothetical case. A pharmaceutical manufacturer, as an enterprise, for the purpose of gaining financial benefits from patients and TPPs, carries out misrepresentations concerning the effects of a prescription drug to prescribing physicians. A prescribing physician's role is similar to the role of a supplier in the example. Instead of supplying products to rival businesses, a prescribing physician would be "supplying" prescriptions for the misrepresented drug to patients. While the enterprise in the example benefits from a supplier's reliance on its misrepresentations, a

¹¹⁴ *Id.* at 650–53.

¹¹⁵ *Id.* at 658.

¹¹⁶ *Id.*

¹¹⁷ *Id.* at 649.

¹¹⁸ *Id.* at 649–50.

pharmaceutical manufacturer would benefit from a prescribing physician's reliance on the false or misleading promotion. Similar to the rival businesses' financial losses in the example, the patients or TPPs would also suffer financial injuries as a direct result of the false or misleading drug promotion and the prescribing physicians' reliance on those drug misrepresentations. The analogy between the two cases inevitably leads to the conclusion that, if the patients or TPPs lose money as a result of the misrepresentations, "it would certainly seem that they were injured in their business 'by reason of' a pattern of mail fraud [or wire fraud]." To hold otherwise would be contrary to the precedent set by *Bridge*.

D. *An Analysis Under Anza and Hemi*

The last two Supreme Court cases on the issue of establishing proximate causation under RICO are *Anza v. Ideal Steel Supply Corp.* and *Hemi Group, LLC v. City of New York*.¹¹⁹ In *Anza*, the plaintiff corporation brought suit under RICO against its major competitor after discovering that defendant was not collecting sales taxes from its cash-paying customers.¹²⁰ It was alleged that defendant's fraudulent tax scheme allowed it to lower product prices and open another store at the plaintiff's expense.¹²¹ The Court found a lack of proximate causation based on several factors.¹²² Given the fluidity and complexity of the business industry, plaintiff's asserted lost sales could have been caused by factors other than defendant's fraudulent tax scheme because businesses lose and gain customers for many different reasons.¹²³ Moreover, defendant's lower product prices might not have been a result of its fraudulent tax scheme, and defendant could have spent the fraud money on other business operations that would not necessarily affect plaintiff's profits.¹²⁴ Most importantly, the State was the direct victim of defendant's fraudulent tax scheme because defendant's failure to collect and pay sales taxes directly decreased the State's tax revenues.¹²⁵ In conclusion, the relation between plaintiff's asserted financial losses and defendant's fraudulent tax scheme was too attenuated to establish proximate causation.¹²⁶

In *Hemi*, the City of New York brought suit against out-of-state cigarette vendors for failing to comply with the Jenkins Act which required them to file cigarette sales reports with the State for taxing purposes.¹²⁷ The City would then receive the reports from the State to track down cigarette buyers

¹¹⁹ *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451 (2006); *Hemi Grp., LLC v. City of New York*, 559 U.S. 1 (2010).

¹²⁰ *Anza*, 547 U.S. at 454.

¹²¹ *Id.* at 454–55.

¹²² *Id.* at 461.

¹²³ *Id.* at 459.

¹²⁴ *Id.* at 458–459.

¹²⁵ *Id.* at 458.

¹²⁶ *Id.* at 461,

¹²⁷ *Hemi*, 559 U.S. at 2

in order to tax their purchases.¹²⁸ The City argued that the vendors' failure to supply the required reports to the State was a proximate cause of their lost tax revenues.¹²⁹ The Court rejected the City's argument and held that proximate causation was not established under RICO.¹³⁰ The facts of the case indicated that the cigarette purchasers' failure to pay taxes was a direct cause to the City's asserted injury, and with respect to the vendors' failure to supply the required reports, the State was the directly injured party.¹³¹ The Court refused to accept the City's theory asking the Court to "extend RICO liability to situations where the defendant's fraud on the third party (the State) has made it easier for a fourth party (the taxpayer) to cause harm to the plaintiff (the City)."¹³²

In a case involving a RICO claim against a pharmaceutical manufacturer for engaging in false or misleading promotion brought by a patient or TPP asserting a financial injury, unlike *Anza*, there are no other significant factors contributing to the asserted financial injury besides the manufacturer's false or misleading promotion. In *Anza*, the plaintiff's decreased business profits could have been caused by a variety of factors including its own methods of operating the business. In the hypothetical case, the only relevant "independent" factor is a physician's decision to prescribe the fraudulently promoted drug. But unlike the independent factors in *Anza*, a physician's decision to prescribe a drug is dependent upon the information provided by the manufacturer. Moreover, while the states are directly injured financially in both *Anza* and *Hemi*, a similarly situated third party prescribing physician is not financially injured by the false or misleading drug promotion. Thus, the financially injured patients and TPPs should be able to seek a remedy relating to the drug payments they incurred based on the manufacturer's misrepresentations. Unlike the plaintiff's argument in *Hemi* requiring the Court to extent RICO liability involving a third party and a fourth party, a plaintiff patient or TPP in the hypothetical case asks a court to consider a less complicated theory. That is, the defendant's false or misleading promotion on a third party (a prescribing physician) has made it possible for the third party to play a role in causing harm to the plaintiff (a patient or a TPP). Overall, the case law supports the conclusion that a prescribing physician's action of prescribing a promoted drug does not sever the causal link. While there are robust legal arguments based on case law in favor of establishing proximate causation, a discussion on policy arguments is also warranted.

V. IMPACT ON THE BUSINESS INDUSTRY: A POLICY ARGUMENT

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ *Id.* at 3.

¹³² *Id.*

In 2006, “82 percent of the United States population reported using at least one prescription medication.”¹³³ More than half of the people reporting taking prescription medications were taking five to nine medications.¹³⁴ Based on these remarkable statistics alone, the enormous economic impact of the United States pharmaceutical industry is evident. The unceasing medical advancements and pharmaceutical innovations developed in the recent decades have cured diseases and eased sufferings. Meanwhile, various large pharmaceutical corporations have been subject to scrutiny under federal and state legal liability theories. Policy debates on pharmaceutical liability involve a constant attempt to balance the need for incentives to encourage medical innovations against the interest of deterring injurious conduct by attaching liability.

The economic and social effects of pharmaceutical product liability have generated heated discussions in policy debates for several decades.¹³⁵ In the pharmaceutical industry, there are many types of legal liability that penalize pharmaceutical manufacturers financially for fraudulent marketing affecting individual and public health.¹³⁶ Critics have argued that “pharmaceutical product liability has reduced product availability, increased drug prices, discouraged innovation, and affected drug safety” in economically inefficient ways.¹³⁷ On the other hand, proponents of pharmaceutical product liability argue that “product liability litigation uncovers new information about drug hazards and deters ‘questionable practices’” by the pharmaceutical manufacturers.¹³⁸

One of the claims made by critics of liability is that product liability leads to “overwarning.”¹³⁹ This practice could potentially interfere with drug prescribing practices by reducing the likelihood that a physician is willing to prescribe a certain medication with multiple safety warnings.¹⁴⁰ There is currently no empirical evidence supporting such a claim.¹⁴¹ Moreover, a pharmaceutical manufacturer’s failure to disclose a material risk of a drug is arguably more dangerous than the practice of so-called “overwarning.” The decision to prescribe or take a drug involves weighing the risks and benefits of the drug. Thus, in order to make an informed decision, the prescribing physician and the patient need to be aware of the full effects of the drug. From an economic standpoint, although a reduction in the prescribing of a

¹³³ See Mary J. Davis, *Time for a Fresh Look at Strict Liability for Pharmaceuticals*, 28 CORNELL J.L. & PUB. POL’Y 399, 425 (2019).

¹³⁴ *Id.*

¹³⁵ See Steven Garber, *Economic Effects of Product Liability and Other Litigation Involving the Safety and Effectiveness of Pharmaceuticals*, RAND INST. FOR CIV. JUST. (2013).

¹³⁶ *Id.* at xi.

¹³⁷ *Id.* at xiii.

¹³⁸ *Id.* at xiv.

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

certain drug may potentially have an impact on the manufacturer's profits, however, such impact is unlikely to be significant in the grand scheme of the industry.

The potential cost of a legal judgment against a drug manufacturer is in the billions of dollars. Thus, many pharmaceutical manufacturers like to weigh the risks and benefits before engaging in a plan that could cause financial harms later on, and "company decision-makers are likely to be willing to sacrifice substantial amounts in profits in the near term to avoid behavior that they view as substantially increasing their future exposure to mass torts."¹⁴² Logically, a plaintiff's success in asserting a RICO claim against a pharmaceutical manufacturer based on its false or misleading drug promotion likely has a substantial effect on deterring the wrongful conduct. Particularly, the rule on drug off-label use promotion has only gotten more tolerant over time based on various First Amendment challenges. It is, therefore, essential to have a strict level of oversight based on products liability theories to enforce the rule that pharmaceutical manufacturers must only engage in truthful drug promotions. Although the *Holmes* Court makes it clear that the general interest of deterring injurious conduct cannot justify holding a defendant liable under RICO, from a policy perspective, the society would certainly benefit from this extra layer of legal protection in the profit-driven pharmaceutical industry.

VI. CONCLUSION

An analysis under the current case law supports the conclusion that, in a legal claim against a pharmaceutical manufacturer brought under RICO by a plaintiff patient or a plaintiff TPP, alleging that the manufacturer's false or misleading promotion is the proximate cause for the plaintiff's financial injury incurred from paying for the fraudulently promoted drug, a prescribing physician's independent action of prescribing the drug should not constitute an intervening cause severing the link required to establish proximate causation. In terms of financial injuries, patients and TPPs are the most direct victims of a pharmaceutical manufacturer's false or misleading promotional scheme. While a prescribing physician may be harmed by the fraudulent promotion scheme in other ways, there is no financial injury involved. To hold that a prescribing physician's involvement in the causal chain prevents a financially injured plaintiff from seeking remedy is unfair and unjustifiable.

It is logical to suggest the need to evaluate whether prescribing physicians actually rely on the false or misleading drug information provided by pharmaceutical manufacturers, and the extent of which the physicians rely on the information when making prescribing decisions. However, the subjective nature of such inquiries, combined with other uncontrollable factors, make it improbable to assess the true states of mind of those

¹⁴² *Id.* at xv.

prescribing physicians. Under a different approach, the relation between physicians' prescribing practices and pharmaceutical manufacturers' tailored marketing strategies toward physicians has been analyzed by professionals in both the medical field and the legal field. Studies have shown a direct correlation between a physician's exposure to false or misleading drug promotion and the physician's prescribing practices concerning the promoted drug. These studies suggest that physicians in fact rely on drug information provided by pharmaceutical manufacturers when making prescribing decisions. In fact, one of the main goals of drug promotional activities is to induce physicians to change their prescribing practices to prescribe the promoted drugs. Because of a physician's direct reliance on a manufacturer's fraudulent promotion, a patient or a TPP is likely to suffer a financial injury. While the physician should not be faulted for this inevitable outcome, courts should offer the financially injured parties a way to seek remedy from those causing the problems. By attaching liability to engaging in false or misleading drug promotion, the law plays an important role in preventing future fraudulent acts and promoting public health.