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WHEN DESIGNED OUTCOMES ARE "UNFORESEEABLE": PROXIMATE CAUSATION IN THE OPIOID CRISIS

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I. INTRODUCTION

"Police respond to more than half a dozen overdoses in Huntington" read a tweet posted at 4:50 PM from the Cabell County 911 Twitter account in August 2016.[1] At 8:50 PM the same day, the account tweeted "26 Heroin Overdoses in Huntington in 4 hours."[2] The head of the emergency medical services for Huntington, a city with a population of about 50,000 people, described the day as "like

* Oliver Kassenbrock is a third year law student at UIC School of Law. He would like to thank all of his colleagues at the UIC Law Review who offered their insight and assistance, and his wife Claire who makes everything possible. The opioid crisis is very much ongoing, and he would like to encourage everyone to support harm reduction measures in their communities, like access to naloxone and drug testing equipment, needle exchange programs, and safe injection sites.

1. Cabell County 911 (@CabellCounty911), TWITTER (Aug. 15, 2016, 4:49 PM), twitter.com/CabellCounty911/status/765304425913065472 [perma.cc/K2UT-AVEU].

2. Cabell County 911 (@CabellCounty911), TWITTER (Aug. 15, 2016, 8:50 PM), twitter.com/CabellCounty911/status/765365143425257476 [perma.cc/6DAM-HBHR].

a mass casualty event."[3] While it is unusual to have a cluster like this of cases so close together, the town in West Virginia – a state experiencing some of the harshest effects of the opioid crisis – is used to handling eighteen to twenty overdose calls in an average week.[4]

The ongoing opioid crisis is a public health matter of grave concern, with nearly a quarter of a million Americans dying due to overdoses involving prescription opioids in the last two decades.[5] The Centers for Disease Control (CDC) estimate that approximately 136 people die each day in the United States from opioid overdose and that over seventy percent of all drug overdose deaths involve some kind of opioid.[6]

Part II of this Comment will introduce the necessary factual and historical background for understanding the opioid crisis in the United States and the role pharmaceutical companies have played in exacerbating it. It will also discuss how liability has been allocated to drug companies in the past and briefly introduce how various parties are currently seeking redress during the opioid crisis and some of the major factors that affect the proximate cause analysis in these cases.

Part III of this Comment will delve deeper into specific aspects of proximate cause in various causes of action that are being advanced by state and municipal governments to hold pharmaceutical companies accountable. It will discuss some of the major difficulties in proving these causes of action, analyzing four key aspects of proximate cause: (1) issues stemming from the remoteness of damages, (2) issues of foreseeability, (3) breaks in the causal chain because of the learned intermediary doctrine, and (4) intervening factors in the form of other relevant parties as precluding liability.

Part IV of this Comment will suggest that the context of the opioid crisis requires the courts to take a broader view of proximate causation than may be required in other cases with fewer

3. Tony Marco, *West Virginia City has 27 Heroin Overdoses in 4 Hours*, CNN (Aug. 18, 2016), www.cnn.com/2016/08/17/health/west-virginia-city-has-27-heroin-overdoses-in-4-hours/index.html [perma.cc/GSF5-J6EY].

4. *Id.*

5. *See What is the U.S. Opioid Epidemic?*, DEP'T OF HEALTH & HUM. SERVS. (Feb. 19, 2021), www.hhs.gov/opioids/about-the-epidemic/index.html [perma.cc/S2G2-84VG] (stating that the U.S. Department of Health and Human Services declared the opioid crisis a public health emergency in 2017 and offering a collection of various related statistics); *Drug Overdose Deaths: Prescription Opioids Overview*, CDC (Mar. 17, 2021), www.cdc.gov/drugoverdose/deaths/prescription/overview.html [perma.cc/M4UP-T4D] (noting nearly 247,000 deaths between 1999-2019, with the rate of overdose more than quadrupling in that timeframe).

6. *Understanding the Epidemic*, CDC (Mar. 17, 2021), www.cdc.gov/opioids/basics/epidemic.html [perma.cc/EF56-RSBT].

contributing parties or simpler timelines. It posits that for civil suits to be a successful tool for municipalities to address harm stemming from the opioid crisis and to effectively deter future wrongdoing, proximate cause cannot serve as a bar to successful litigation. Removing proximate causation as a bar will likely require coordinated efforts in multiple areas, including changes in the application of current legal doctrine, creation of new statutory causes of action, and the complementary use of other legal tools alongside litigation.

Part V concludes that a more accommodating understanding of proximate cause will allow civil litigation to play more of a role in the remediation of this issue. As some of the largest pharmacies[7] work their way through bankruptcy proceedings, litigation continues to develop across the country and overdoses have hit record highs in all fifty states, demonstrating the urgency of addressing the crisis quickly and efficiently.[8]

II. BACKGROUND

The civil litigation being undertaken in response to the opioid crisis cannot be fully analyzed without understanding the development of the crisis itself. This section will first provide historical context of the role pharmaceutical companies played in igniting the opioid crisis in the United States, and some perspective as to the state of the crisis now. Then, this section will briefly discuss drug companies' liability generally and include an introduction to multidistrict litigation and what opioid litigation looks like at this moment.

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7. Geoff Mulvihill, *No New Settlement Yet of Opioid Claims Against Purdue Pharma*, ABC NEWS (Feb. 17, 2022), www.abcnews.go.com/Health/wireStory/settlement-opioid-claims-purdue-pharma-82958706 [perma.cc/67RW-C3AK] (discussing ongoing controversy and negotiations in the Purdue Pharma bankruptcy proceedings); Daniel Gill & James Nani, *Endo Follows Bankruptcy Playbook, With a Few Twists*, BLOOMBERG L. (Aug. 18, 2022), news.bloomberglaw.com/bankruptcy-law/endo-follows-opioid-bankruptcy-gameplan-with-a-few-twists [perma.cc/S8ZX-ARKY] (describing pharmaceutical company Endo's plans for bankruptcy settlements).

8. *See* AM. MED. ASS'N, 2021 OVERDOSE EPIDEMIC REPORT: PHYSICIANS' ACTIONS TO HELP END THE NATION'S DRUG-RELATED OVERDOSE AND DEATH EPIDEMIC—AND WHAT STILL NEEDS TO BE DONE 4-5 (2021), www.end-overdose-epidemic.org/wp-content/uploads/2021/09/AMA-2021-Overdose-Epidemic-Report_92021.pdf [perma.cc/K6XB-V698] (describing trends in the opioid crisis and medical recommendations for managing its effects); Morning Edition, *< 3 of America's Biggest Pharmacy Chains Have Been Found Liable for the Opioid Crisis*, NPR (Nov. 23, 2021), www.npr.org/transcripts/1058539458 [perma.cc/S9UY-UV8H] (detailing the inconsistent outcomes of a few specific lawsuits in various states).

A. A Brief History of Opioids

Opioids are a class of medications that have been used for their ability to treat pain for thousands of years, with recorded medical applications at least as far back as ancient Egyptian and ancient Sumerian civilizations.[9] They have been employed in medicine, religious ceremonies, and for recreational purposes for centuries.[10] Because of their high efficacy but similarly high potential for abuse, addiction, or overdose, opioids have fallen in and out of favor in medical tradition over the many years that they have been in use.[11]

Opioids broadly fall into three categories: naturally occurring opiates (including opium, morphine, and codeine), semisynthetic (oxycodone, hydrocodone, etc.), and fully synthetic (most notably Demerol and fentanyl,[12] though there are many varieties).[13] While the term "opiate" is specific to naturally occurring compounds, the term "opioid" can refer to any or all of these categories.[14] The naturally occurring opioids were discovered and used first, with opium being the earliest recorded.[15] Morphine and codeine were

9. *See* Michael J. Brownstein, *A Brief History of Opiates, Opioid Peptides, and Opioid Receptors*, 90 PROCS. NAT'L. ACAD. SCI. U.S. 5391, 5391 (1993), www.pnas.org/content/pnas/90/12/5391.full.pdf [perma.cc/9SRQ-FQ4J]. Ancient cultures used opioids medically for purposes of pain relief and as sleep aids, as well as including them in other forms of medicine given to treat a wide variety of diseases. *Id.*

10. *See id.* (discussing the origin of opium use as a euphoric agent in religious rituals with use then spreading to therapeutic and medical applications via priests with specialized knowledge in rituals and healing).

11. *See id.* (noting that records documenting opium abuse, tolerance, and addiction date back to at least the sixteenth century).

12. Methadone is also a notable synthetic opioid but has medical properties distinct from many other opioids and can therefore be used to treat opioid use disorder and ease withdrawal symptoms. *See generally How Do Medications Used to Treat Opioid Use Disorder Work?*, NAT'L INST. ON DRUG ABUSE (June 2018), www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/how-do-medications-to-treat-opioid-addiction-work [perma.cc/6R7F-XH4K] (describing in greater detail the development and use of medications to treat opioid use disorder). Methadone, used to treat opioid use disorder and opioid withdrawal, as well as the similar medication buprenorphine, reduce the symptoms of withdrawal but do not produce the euphoric "high" that other opioids do when used within the clinical dosing range. *Id.* They can be used to help taper slowly off opioids without the danger and discomfort of stopping rapidly or as a long-term treatment method for those with opioid use disorder that allows normal functioning in day-to-day life by treating the physical symptoms of opioid dependence. *Id.*

13. *Commonly Used Terms*, CDC (Jan. 26, 2021), www.cdc.gov/opioids/basics/terms.html [perma.cc/X6J7-84GJ] (providing definitions to opioid related vocabulary).

14. *Id.*

15. *See* Brownstein, *supra* note 9, at 5391 ("There is general agreement that the Sumerians, who inhabited what is today Iraq, cultivated poppies and isolated opium from their seed capsules at the end of the third millennium

developed near the beginning of the nineteenth century with the goal to create a safer opioid with less potential for abuse – a goal which was not met.[16]

Further developments in opioids led to two of the most commonly available prescription opioids available today: oxycodone, developed in 1916, and hydrocodone created in 1920.[17] When originally introduced to the market, these medications were both generally available as prescription painkillers, and in dosages that were combined with acetaminophen.[18] In 1995, Purdue Pharma (a relatively small company at the time) released OxyContin, a prescription painkiller with a controlled release of only oxycodone, rather than a combined formula, and available at significantly higher dosages.[19] Many sources point to the release of OxyContin as the inciting incident for the opioid crisis in the United States.[20]

Upon releasing OxyContin, Purdue Pharma set out on "the most aggressive marketing campaign for a powerful and potentially addicting narcotic ever undertaken by the pharmaceutical industry."[21] Strong narcotic pain medications like morphine had historically been used sparingly, in cases of severe pain associated with cancer or terminal illnesses and end of life care.[22] Purdue

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B.C.").

16. *See id*. ("[A] great deal of energy was spent trying to develop a safer, more efficacious, nonaddicting opiate. In 1898, heroin was synthesized and pronounced to be more potent than morphine and free from abuse liability. This was the first of several such claims for novel opiates. To date, none has proven valid.").

17. Mohammad Moradi et al., *Use of Oxycodone in Pain Management*, 1 ANESTHESIOLOGY & PAIN MED. 262, 262 (2012); *Life Without Vicodin?*, N.Y. MAG. (July 2, 2009), www.nymag.com/news/intelligencer/topic/57770/ [perma.cc/UR9C-MSJP].

18. BARRY MEIER, PAIN KILLER: AN EMPIRE OF DECEIT AND THE ORIGIN OF AMERICA'S OPIOID EPIDEMIC 8 (2d ed. 2018).

19. *See id.* ("In terms of pure narcotic firepower, OxyContin was a nuclear weapon."). The name OxyContin was chosen to reflect the time release properties, with Oxy being short for oxycodone and Contin being short for continuous release. *Id.* While other oxycodone-based drugs at the time often contained 5mg of oxycodone, combined with aspirin or Tylenol, OxyContin started at pills of 10mg and increased to doses of up to 160mg. Patrick Radden Keefe, *The Family That Built an Empire of Pain*, NEW YORKER (Oct. 23, 2017), www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain [perma.cc/FH82-J456].

20. *See, e.g.*, Keefe, *supra* note 19 ("[T]hough many fatal overdoses have resulted from opioids other than OxyContin, the crisis was initially precipitated by a shift in the culture of prescribing—a shift carefully engineered by Purdue."); MEIER, *supra* note 18, at xi ("OxyContin was not a 'wonder' drug. It was the gateway drug to the most devastating public-health disaster of the twenty-first century.").

21. MEIER, *supra* note 18, at xi.

22. *See* Sackler Dep. 142-43 (Aug. 28, 2015) (acknowledging the "stigma" of morphine as an "end-of-life" drug). PDF transcript of Richard Sackler's deposition in the Pike Circuit court for Commonwealth of Ky., ex rel. v. Purdue

Pharma aggressively sought to change those prescribing patterns with regard to OxyContin, marketing to doctors and patients alike that it should be used to treat more patients and more types of pain than previous narcotic medications.[23] The marketing targeted directly toward prescribers included advertising in medical journals, hosting symposiums, and paying some physicians to essentially act as brand ambassadors.[24] Marketing materials were made to intentionally exploit misconceptions about the potency in order to increase the number and strength of prescriptions sold.[25] The Food and Drug Administration (FDA) permitted Purdue Pharma to make claims about the lower potential for addiction and abuse based off of the controlled release formula that were fully hypothetical.[26] Misleading advertisements claimed that the drug would be effective for twelve hours.[27] The company had no data on potential for abuse and made no effort to ascertain how addictive the drug was until years later when complaints had already begun to flow.[28]

The time and money that Purdue Pharma invested proved to be effective; an internal company document from 1996 showed that doctors who had attended sponsored seminars, presentations, and

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Pharma, L.P, (No. 07-CI-01303) 2015 Ky. App. Unpub. LEXIS 401 (2015) available for download at sacklergallery.com [perma.cc/KAW4-VYT8].

23. *See* Sackler Dep., *supra* note 22, at 91 (citing an internal Purdue Pharma communication as saying "Marketing has decided that the effects of the Phase IV team should be predominantly focused on expanding OxyContin use for non-cancer pain.").

24. *See id*. at 194, 207 (discussing the 3,000 physicians enlisted to be on a "speakers bureau" for Purdue Pharma and company guidelines on developing materials for "marketing programs, symposia, clinical study manuscripts and any other items that discuss the use of OxyContin.").

25. *See id*. at 93 (noting a commonly held misconception that OxyContin was less potent than a previous Purdue Pharma drug and citing to an email cautioning people not to change that perception).

26. *See* Keefe, *supra* note 19 ("Purdue had conducted no clinical studies on how addictive or prone to abuse the drug might be. But the F.D.A., in an unusual step, approved a package insert for OxyContin which announced that the drug was safer than rival painkillers, because the patented delayed-absorption mechanism 'is believed to reduce the abuse liability.'"). The FDA shares some level of blame in the opioid crisis for its failure to properly regulate OxyContin, which could have limited the amount of damage that was done. *Id*. The FDA director at the time has called the de-stigmatization of opioids in the U.S. one of the "great mistakes" of modern medicine. *Id.* The examiner in charge of authorizing OxyContin for market use left the agency shortly afterward and was employed by Purdue Pharma less than two years later. *Id.*

27. *See id.* (noting that the overestimated effectiveness window led to breakthrough pain before the next dose, which in turn would lead to higher dosages being prescribed).

28. *Cf. id.* (noting that rejections of prescriptions from benefits plans based on likelihood of abuse began as early as 1997, and company officials had records indicating that the twelve-hour dosing window was not accurate as early as 1998).

conferences were writing twice as many prescriptions for OxyContin as those who did not.[29] The hope expressed at an internal event from the former president of the company, Richard Sackler, that the launch of OxyContin would be followed by "a blizzard of prescriptions," was evidently well-founded.[30] Purdue Pharma paid out millions of dollars in bonuses and commissions to its sales representatives, and pushed them with training documents to "sell, sell, sell OxyContin!"[31]

Other pharmaceutical companies and drug distributors reaped the benefits of Purdue Pharma's tactics.[32] The intentionally orchestrated shift in perception to boost Purdue Pharma's sales also benefited distributors, pharmacies, and competing companies with opioids of their own to sell.[33] Other pharmaceutical companies that became heavily involved in perpetuating and propagating the misinformation that drove the opioid crisis include Johnson & Johnson (and its parent company Janssen), Cephalon, and Endo.[34] The specific allegations against the companies include using third party organizations to advocate for more prescriptions of opioid

29. *See id.* ("[I]nternal Purdue records indicate that doctors who attended these seminars in 1996 wrote OxyContin prescriptions more than twice as often as those who didn't.").

30. *Last Week Tonight with John Oliver: Opioids II* (HBO television broadcast Apr. 15, 2019), available at www.youtube.com/watch?v=-qCKR6wy94U [perma.cc/4UQD-ZL2Z].

31. Sackler Dep., *supra* note 22, at 339.

32. *See Last Week Tonight with John Oliver: Opioids II*, *supra* note 30 (calling OxyContin "the drug that arguably kick-started [the opioid] crisis" and quoting news reports saying that Purdue Pharma owners, the Sackler family, "engineer[ed] the opioid epidemic . . .").

33. *See* Keefe, *supra* note 19 (quoting Andrew Kolodny of the Opioid Policy Research Collaborative as saying "If you look at the prescribing trends for all the different opioids, it's in 1996 that prescribing really takes off. It's not a coincidence. That was the year Purdue launched a multifaceted campaign that misinformed the medical community about the risks.").

34. *See* Sixth Am. Compl. at 20-21, The People v. Purdue Pharma, 2021 Cal. Super. LEXIS 31743 (Sup. Ct. Cal. June 8, 2018) (No. 30-2014-00725287-CU-BT-CXC) [hereinafter Sixth Amended Complaint] (available at counsel.sccgov.org/high-profile-matters/opioids [perma.cc/JFN7-8GY6]) (alleging misconduct from pharmaceutical manufacturers, distributors, and pharmacies). The State of California made allegations including deceptive marketing and misrepresentation of risks in order to increase sales against all of these companies in its case *The People of the State of California v. Purdue Pharma et al. Id.*

painkillers,[35] promoting dangerous and unapproved off-label uses,[36] and downplaying the risks of addiction from prescribed use of opioid medications.[37] Overall, the prescription of opioid pain medications almost tripled in a period of roughly two decades, from 76 million prescriptions in 1991 to 207 million by 2013.[38] Hydrocodone and oxycodone combined comprise about seventy-eight percent of the controlled prescription drugs sold to retail consumers; the 9.7 billion dosage units distributed in 2019 marked the first time since 2010 that the number fell under ten billion.[39] Despite falling prescriptions, people who have developed dependencies continue to use opioids after losing a prescription and may even turn to illicit opioids to fill the need.[40]

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35. *Id.* at 16 ("Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Defendants, these 'Front Groups' – which include, but are not limited to, the American Pain Foundation (APF) and the American Academy of Pain Medicine – generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy.").

36. *See id*. at 34 (citing specifically to Cephalon's practices of marketing extremely powerful fentanyl-based products for chronic pain which were approved only for cancer pain in individuals already tolerant to other opioid medications and were explicitly rejected by the FDA for other uses due to the risk of "serious and life threatening adverse events" and abuse).

37. *See id*. at 18 (giving as one example multiple publications and websites hosted by Endo making claims like "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.").

38. *America's Addiction to Opioids: Heroin and Prescription Drug Abuse: Hearing Before the S. Caucus on Int'l Narcotics Control*, 113th Cong. (2014) (statement of Nora D. Volkow, M.D.) (transcript available at archives.drugabuse.gov/testimonies/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse [perma.cc/SZ84-KAF7]).

39. DRUG ENF'T ADMIN., 2020 NATIONAL DRUG THREAT ASSESSMENT 39 (Mar. 2021), www.dea.gov/sites/default/files/2021-02/DIR-008-21%202020%20National%20Drug%20Threat%20Assessment_WEB.pdf [perma.cc/Q2A2-P6T5]. The decline in prescriptions is due largely to the recognition of the dangers and potential harms of over-prescription of opioid medications, as well as the introduction of stricter prescribing guidelines. *Id.* However, rigidly enforced guidelines without nuance can lead to a number of issues. Brian Owens, *Opioid Prescriptions Down But Some Patients Fear Doctors Now Too Strict*, 191 CAN. MED. ASS'N J., 546, 546 (2019). The risk of cutting off access to appropriate pain management for patients for whom the benefits of opioid therapy genuinely outweigh the risks cannot be disregarded. *Id.* There are also potential physical dangers of withdrawal for patients who have developed tolerance to opioids who may have difficulty accessing appropriate refills. *Id.*

40. Marco, *supra* note 3 ("In Huntington, we began prescribing much less . . . [w]e thought we were becoming more responsible, and people would stop using opioids when we stopped prescribing them. But then they turned to heroin. In many cases it wasn't to get high, it was just to keep from going into withdrawal. It's a very miserable existence for people, but heroin is cheaper," quoting Michael Kilkenny, Director of the Cabell-Huntington Health Department).

B. The Opioid Crisis as it Stands Now

Based on the 2020 National Survey on Drug Use and Health, nearly ten million Americans have misused prescription opioids within the past year, while 2.7 million meet the criteria for diagnosable opioid use disorders.[41] Additionally, abuse of prescription opioids significantly elevates the risk of an individual using or becoming dependent on heroin.[42] In fact, roughly eighty percent of heroin users report having used prescription opioids prior to using heroin.[43] Opioids are among the most dangerous classes of drugs, with one or more opioids playing a role in the majority of overdose deaths in the United States in recent years.[44] Synthetic opioids and heroin rank as the two deadliest drugs in terms of overdose deaths in the U.S. each year, respectively.[45]

Approximately 232,000 people died in the United States between 1999 and 2018 from prescription-involved opioid overdoses.[46] The rate rose dramatically, from less than 4,000 deaths in 1999 to more than 15,000 in 2018.[47] That represents roughly forty-one deaths each day and makes up about thirty-two percent of

41. DOUGLAS RICHESSON & JENNIFER M. HOENIG, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE UNITED STATES: RESULTS FROM THE 2020 NATIONAL SURVEY ON DRUG USE AND HEALTH 4 (2021), www.samhsa.gov/data/sites/default/files/reports/rpt35325/NSDUHFFRPDFWHTMLFiles2020/2020NSDUHFFR1PDFW102121.pdf [perma.cc/C6V6-FY2T]; *What is the U.S. Opioid Epidemic?*, DEP'T OF HEALTH & HUM. SERVS. (Feb. 19, 2021), www.hhs.gov/opioids/about-the-epidemic/index.html [perma.cc/R5FA-PBFZ]. Misuse of prescription medication can be occasional or even one-time use of a medication in a manner other than prescribed, while a use disorder (often used interchangeably with the term "addiction") must meet clinical threshold levels of dependence and/or impairment of regular functioning. *Commonly Used Terms*, *supra* note 13.

42. *Prescription Opioid Use Is a Risk Factor for Heroin Use*, NAT'L INST. ON DRUG ABUSE (Jan. 2018), www.drugabuse.gov/publications/research-reports/prescription-opioids-heroin/prescription-opioid-use-risk-factor-heroin-use [perma.cc/39WX-R5JT].

43. *Id.*

44. *Understanding the Epidemic*, *supra* note 6. Heroin and fentanyl are among the deadliest drugs in the country because of their combination of high potency and unregulated quality. *Id.* While fentanyl is available as a prescription, most fentanyl that is consumed in the US is illicitly manufactured street fentanyl. *Id.* Many drug overdose deaths include a combination of more than one drug. *Id.*

45. DRUG ENF'T ADMIN., *supra* note 39, at 11. At this time, the overdoses in the "synthetic opioids (other than methadone)" category are heavily dominated by the opioid fentanyl. *Opioid Data Analysis and Resources*, CDC (Mar. 10, 2021), www.cdc.gov/opioids/data/analysis-resources.html [perma.cc/XH9R-8B9K].

46. DRUG ENF'T ADMIN., *supra* note 39, at 37-38.

47. *Id.* at 38.

all opioid overdose deaths.[48] When all categories of opioids are considered, the United States has lost roughly half a million people to the opioid crisis.[49]

C. Drug Company Liability in General

Liability for drug companies can come in several general categories.[50] Strict liability and breach of warranty claims may be brought against products that are alleged to be defective or inherently dangerous.[51] Failure to warn is another widely available cause of action, based on the widely-accepted duty to provide adequate information on potential risks of drugs and other medical products.[52] When drug companies engage in actively misrepresenting or suppressing the potential dangers of a product, available claims may include fraud or intentional misrepresentation.[53] For cases where the actions of the companies fall somewhere between actively fraudulent practices and simply failing to warn, some states have developed a cause of action for negligent misrepresentation.[54] In a few jurisdictions, pharmaceutical companies that develop brand name medications may be held liable for injuries caused by the generic versions of drugs that they develop.[55] Because manufacturers of generic medications are required to use identical labeling, the brand name manufacturer is liable for failure to warn of a defect or side effect on both the branded medication and its generic counterparts.[56] This

48. *Id.* at 37.

49. *Opioid Data Analysis and Resources*, *supra* note 45.

50. *See generally* 1A, FRANK C. WOODSIDE, III, DRUG PRODUCT LIABILITY Ch. 14 § 14.01 (discussing liability for drug manufacturers and distinctions between drugs and other products). The more general language "drug companies" is used here to include both pharmaceutical companies and companies that sell tobacco or e-cigarette products.

51. *See id.* at Ch. 14 § 14.06; RESTATEMENT (SECOND) OF TORTS § 402A (AM. L. INST. 1965) (discussing strict liability generally).

52. *See* WOODSIDE, *supra* note 50, at Ch. 14 § 14.02 (discussing required warnings and elements of failure to warn claims).

53. *See id.* at Ch. 14 § 14.05 (distinguishing types of fraud and misrepresentation).

54. *See id.* (listing among states that have declined to adopt or in some way restricted the cause of action for negligent misrepresentation: Arkansas, Indiana, Maine, Minnesota, Idaho, Iowa, Nevada, Alabama, and Kentucky).

55. *Compare* Rafferty v. Merck & Co., 479 Mass. 141, 156-157 (2018) (adopting the theory of innovator liability in Massachusetts in cases that rise beyond general negligence to reckless or intentional acts), *with* Huck v. Wyeth, Inc., 850 N.W.2d 353, 377 (Iowa 2014) (rejecting innovator liability for economic and policy reasons).

56. *See Rafferty*, 479 Mass. at 157 ("We therefore hold that a brand-name manufacturer that controls the contents of the label on a generic drug owes a duty to consumers of that generic drug not to act in reckless disregard of an unreasonable risk of death or grave bodily injury.").

so-called "innovator liability" has not been widely adopted.[57] As a last resort in civil liability, unjust enrichment may be pleaded in the alternative "if there is no adequate remedy at law."[58]

If the medication itself causes injury, the argument is intuitive – drug companies should be held liable for products they develop that are unnecessarily dangerous or defective.[59] A particularly famous case of this was the prescription drug Vioxx, which was linked to significant cardiovascular risks and potentially contributed to thousands of heart attacks before the drug was pulled from the market.[60] Punitive and compensatory damages were awarded in a small number of individual cases while many others were defended successfully before the pharmaceutical company Merck & Co. eventually settled around 27,000 claims for $4.85 billion in 2007.[61]

The water is muddied somewhat if the risk is that of addiction, rather than injury or death stemming directly from the medication. However, there is also precedent in holding drug companies liable specifically for harm based upon the addictive nature of the products that they sell.[62] Manufacturers of tobacco products have

57. *See In re* Zantac (Ranitidine) Prods. Liab. Litig., 546 F. Supp. 3d 1192, 1199 (S.D. Fla. 2021) (noting that innovator liability theory has been accepted by California and Massachusetts and actively rejected in 35 states, while others have yet to directly address it).

58. City of Boston v. Purdue Pharma, LP, No. 1884CV02860, 2020 Mass. Super. LEXIS 2, at *30-31 (Mass. Super. Ct. Jan. 3, 2020).

59. *See* RESTATEMENT (SECOND) OF TORTS § 402A (AM. L. INST. 1965) (discussing strict liability for sellers of "unreasonably dangerous" products). *But see id.* at cmt. k (noting that with "unavoidably unsafe products" like drugs in particular, a significantly higher level of risk may be deemed "reasonable" based on the potential benefits).

60. *See* Alex Berenson, *Merck Agrees to Settle Vioxx Suits for $4.85 Billion*, N.Y. TIMES (Nov. 9, 2007), www.nytimes.com/2007/11/09/business/09merck.html [perma.cc/9MBE-7ZHM] (discussing the 47,000 sets of plaintiffs suing on behalf of themselves or family members injured or killed in connection with the drug). Merck successfully defended a series of lawsuits surrounding Vioxx due to difficulties in proving causation of the injuries caused to the plaintiffs, the issue to be discussed in the following sections of this comment, before reaching this large settlement. *Id.*

61. *Compare* Barnett v. Merck & Co. (*In re* Vioxx Prods. Liab. Litig.), 523 F. Supp. 2d 471, 475 (E.D. La. 2007) (upholding victory for the plaintiff but modifying the amount of damages; the plaintiff appealed on the amount of damages and the case was ultimately settled), *with* Merck & Co. v. Ernst, 296 S.W.3d 81, 90, 100 (Tex. App. 2008) (reversing a $26 million award for a specific plaintiff but still acknowledging that the medication in question likely did harm people due to dangerous side effects). Merck successfully defended cases in state courts in California, Florida, New Jersey, Illinois, and Louisiana in 2006-2007 before the settlement was reached. *See* Berenson, *supra* note 60.

62. *See* Graham v. R.J. Reynolds Tobacco Co., 857 F.3d 1169, 1175 (11th Cir. 2017) (citing to precedent established in multiple previous tobacco cases of medical professionals testifying to the dangerous and addictive nature of cigarettes in determining liability and damages).

been subject to strict liability and negligence actions for downplaying and intentionally misrepresenting the danger of their products.[63] A significant factor in this was that "tobacco companies 'have the technology to make a safer cigarette' but not one that is profitable," suggesting that the companies failed to mitigate the risks in addition to their failure to warn.[64]

Similarly, e-cigarette manufacturers, particularly earlier in the development and popularization of the products, overwhelmingly failed to warn customers of the risk of addiction and the potential adverse health effects of e-cigarette use.[65] E-cigarettes were advertised as a safer, less addictive product than traditional cigarettes when there was insufficient data to support this claim.[66] Because of these misleading and deceptive advertising practices and the danger created by the products themselves, e-cigarette companies were open to civil liability.[67] E-cigarette company Juul Labs has reached multimillion dollar settlements with multiple states that include significant restrictions on future marketing campaigns as a result of these lawsuits.[68] Some of these themes in liability – misrepresented rates of addiction and marketing that downplayed these risks – may transfer to the opioid crisis context.

Liability for addictive prescription medications is not a novel concept either. Courts have held pharmaceutical companies liable for danger related to opioid medications predating the onset of the modern opioid crisis by at least two decades.[69] In 1967, the potential

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63. *See id.* at 1189, 1191 (holding that state police powers give states the authority to impose tort liability on tobacco companies for harms caused by their products and marketing practices).

64. *Id.* at 1175.

65. *In re* Juul Labs, Inc., Mktg., Sales Pracs., & Prods. Liab. Litig., 497 F. Supp. 3d 552, 588, n.50 (N. D. Cal. 2020) (noting that complaints against the vaping device manufacturer included allegations "that JLI 'failed to warn' about alleged risks of nicotine addiction and physical harm . . ." and that "JUUL is not measurably safer and may be measurably worse," to be further investigated in discovery).

66. *See id.* ("JLI advertised JUUL products are 'reasonable alternatives' to combustible cigarettes when they were not.").

67. *Id.* at 589 (holding that Juul was liable for "deadly safety defects" and "statements that were 'false and misleading'" in spite of federal preemption claims that it made about FDA warnings).

68. Bob Christie, *Juul to Pay $14.5 Million to Settle Arizona Vaping Lawsuit*, ABC NEWS (Nov. 23, 2021), www.abcnews.go.com/Health/wireStory/juul-pay-145-million-settle-arizona-vaping-lawsuit-81361734 [perma.cc/H5BB-CKKZ] (describing a $14.5 million settlement with the State of Arizona that requires Juul not to market near schools or to anyone under 21); *Juul to Pay $40m in US Lawsuit Over Teen Targeting Claims*, BBC NEWS (June 28, 2021), www.bbc.com/news/business-57640905 [perma.cc/AAE6-VXHJ] (describing a $40 million settlement with the State of North Carolina that requires Juul not to advertise to anyone under the age of 35).

69. *E.g.*, Crocker v. Winthrop Lab'ys, 514 S.W.2d 429, 429 (Tex. 1974)

risks of a new prescription opioid medication called Talwin (a combination of pentazocine and naloxone) were significantly downplayed by the manufacturer.[70] The company was liable for a patient's addiction and later overdose death because the company falsely claimed that there was no risk of addiction with the new medication.[71] However, the sheer scope of the opioid crisis and the number of interconnected factors makes it distinct from these earlier cases.

D. Civil Litigation and the Current Opioid Crisis

On a small scale, individual plaintiffs have had some success in suing healthcare providers that negligently over-prescribe opioid medications.[72] Although some class action lawsuits by consumers have had limited success, they have overall struggled to gain significant traction.[73] This is due both to the highly individualized injuries, making class certification difficult, and to similar issues of proximate causation that will continue to be common threads throughout this Comment.[74] While individuals or even classes

(upholding initial trial court ruling for the plaintiff in a case where the pharmaceutical company misrepresented the risks of an opioid painkiller to a physician who then prescribed it to a patient).

70. *Id.* at 429-31 (noting the "positive misrepresentation by the drug company that Talwin was non-addictive.").

71. *See id.* (noting that a representative from the drug company had assured the prescribing doctor personally that the narcotic medication was "as harmless as aspirin . . ."). Talwin was later reformulated to reduce the abuse potential by adding naloxone, an antagonist that blocks some of the effects of opioids, with significant success. Carlene Baum et al., *The Impact of the Addition of Naloxone on the Use and Abuse of Pentazocine*, 102(4) PUB. HEALTH REPS. 426, 427 (1987).

72. *See* Halloran v. Kiri, 173 A.D.3d 509 (N.Y. App. Div. 2019) (holding that a patient's death by overdose was not unforeseeable when the patient showed signs of addiction and the doctor continued to prescribe opioids); Koon v. Walden, 539 S.W.3d 752 (Mo. Ct. App. 2017) (ruling in favor of plaintiff-patient where the doctor rapidly increased the dosage without properly assessing or discussing risks and ignored signs of addiction and physical dependency).

73. *Compare* Enriquez v. Johnson & Johnson, No. CAM-L-4677-18, 2019 N.J. Super. Unpub. LEXIS 2131, at *56-57 (N.J. Super. Ct. Law Div. Oct. 10, 2019) (granting defendant pharmaceutical companies' motion to dismiss a class action suit), *and* Wethington v. Purdue Pharma LP, 218 F.R.D. 577, 589 (S. D. Ohio 2003) (denying class certification), *with* Howland v. Purdue Pharma, L.P., 2003-Ohio-3699 (Ohio Ct. App. 2003) (granting class certification for those who suffered addiction, physical, mental, or emotional harm, or death/loss of consortium as a result of use of prescribed OxyContin), *rev'd*, 821 N.E.2d 141 (Ohio 2004) (reasoning in a 4-3 split decision that the learned intermediary doctrine and the individualized nature of determining injury and damages made class certification inappropriate).

74. *See* Howland v. Purdue Pharma L.P., 821 N.E. 2d 141, 146 (Ohio 2004) (noting that class certification was improper because the case relied on "individualized question[s] of fact" and that the learned intermediary doctrine "precludes manufacturer liability for failure to warn the consumer when an

struggle to make appreciable change at a macro level, most states are currently involved in the ongoing large-scale litigation intended to hold pharmaceutical companies accountable, along with thousands of smaller county and municipal governments.[75]

The many government plaintiffs currently involved in litigation have brought various claims against major players with differing involvement in the opioid crisis.[76] The types of claims brought are not identical, but there are many common themes throughout.[77] A growing number of these municipalities have joined in filing litigation since some of the earliest claims began in 2014.[78] In 2017, the pretrial proceedings for all of the claims in this category were consolidated into the multidistrict litigation, housed in the United States District Court for the Northern District of Ohio.[79]

Multidistrict litigation in the federal court system is governed by 28 U.S.C. § 1407, which establishes a judicial panel on multidistrict litigation and covers the procedures for establishing and conducting multidistrict litigation proceedings.[80] Only the pretrial portions of the cases are consolidated; if and when a case

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adequate warning has been given to a 'learned intermediary,' e.g., the consumer's physician.").

75. *See AG Shapiro Sues OxyContin Creator Purdue Pharma for Role in Fueling the Opioid Epidemic*, OFF. ATT'Y GEN. JOSH SHAPIRO (May 14, 2019), www.attorneygeneral.gov/taking-action/press-releases/ag-shapiro-sues-oxycontin-creator-purdue-pharma-for-role-in-fueling-opioid-epidemic/ [perma.cc/9K4Q-TVTE] (announcing the state of Pennsylvania filing suit and adding to the growing number of cases already filed) [hereinafter AG Shapiro Press Release]; Soo Youn, *Thousands of US Cities and Counties in Federal Opioid Lawsuit File for Class Status*, ABC NEWS (June 14, 2019), www.abcnews.go.com/US/thousands-us-cities-counties-federal-opioid-lawsuit-file/story?id=63714873 [perma.cc/Q952-B2QC] (noting that over 1800 municipalities were involved in the litigation by that time).

76. *See, e.g.*, *In re* Nat'l Prescription Opiate Litig., 458 F. Supp. 3d 665, 672 (N.D. Ohio 2020) (listing three major groups of defendants – distributors, pharmacies, and manufacturers – with some claims applying to only one group and others applying to all defendants).

77. *In re* Nat'l Prescription Opiate Litig., 290 F. Supp. 3d 1375, 1378-79 (J.P.M.L. 2017) ("All of the actions can be expected to implicate common fact questions as to the allegedly improper marketing and widespread diversion of prescription opiates into states, counties and cities across the nation.").

78. *See* Daniel DeMaina, *Mass. Cities and Towns Join Opioid Lawsuits*, MASS. MUN. ASS'N (Feb. 23, 2018), www.mma.org/mass-cities-and-towns-join-opioid-lawsuits/ [perma.cc/KGV9-A4S6] (noting "Chicago was the first city in the U.S. to file such a lawsuit, in 2014," and "[m]ore than 30 Massachusetts cities and towns have committed to joining a nationwide movement of suing pharmaceutical companies and distributors for municipal costs resulting from the opioid abuse epidemic.").

79. *In re Nat'l Prescription Opiate Litig.*, 290 F. Supp. at 1378 ("Plaintiffs variously bring claims for violation of RICO statutes, consumer protection laws, state analogues to the Controlled Substances Act, as well as common law claims such as public nuisance, negligence, negligent misrepresentation, fraud and unjust enrichment.").

80. 28 U.S.C. § 1407 (2022).

goes to trial, it returns to the district in which it originated.[81] The use of multidistrict litigation is reserved for circumstances where common, complex issues of fact are likely to make discovery too costly and repetitive if proceedings are not combined.[82] While multidistrict litigation allows for each individual case to be remanded and sent to trial, it is statistically far more likely that the cases will be settled or terminated in the transferred consolidation district.[83] Multidistrict litigation has previously been used as a tool for large-scale products liability actions.[84] It has specifically been used a number of times before to handle questions surrounding pharmaceutical products.[85] Because of the volume of litigation working its way through the courts related to the opioid crisis, more

81. 28 U.S.C. § 1407(a) (2022). While a class action lawsuit consolidates plaintiffs into a common class (or group of subclasses) for the entirety of a lawsuit, multi-district litigation consolidates the suits only through pretrial motions and discovery, remanding them to their original districts if and when they go to trial. *Id.* Additionally, while class action under Rule 23 of the Federal Rules of Civil Procedure requires "questions of law or fact common to the class," multi-district litigation focuses specifically on "common questions of fact." FED. R. CIV. P. 23(a)(2).

82. *See* 3 FRANK C. WOODSIDE, III, DRUG PRODUCT LIABILITY Ch. 30 § 30A.02 (discussing the role of the Judicial Panel on Multidistrict Litigation in drug product liability litigation).

83. *See* Danielle Oakley, *Is Multidistrict Litigation a Just and Efficient Consolidation Technique? Using Diet Drug Litigation as a Model to Answer this Question*, 6 NEV. L. J. 494, 501 (2005) ("Of the 179,071 actions consolidated in multidistrict litigation as of September 30, 2002, 129,594 were terminated in the transferee courts.").

84. *E.g.*, *In re* Asbestos Prods. Liab. Litig., 771 F. Supp. 415, 416 (J.P.M.L. 1991) (consolidating personal injury litigation concerning asbestos related harm); *In re* Volkswagen "Clean Diesel" Mktg., Sales Pracs., & Prods. Liab. Litig., 148 F. Supp. 3d 1367, 1370 (J.P.M.L. 2015) (consolidating litigation regarding false advertising claims about fuel efficiency and environmental impact for Volkswagen vehicles). Both of these MDL have reached settlements with affected plaintiffs and the courts are still managing those claims as necessary. *See* MDL 875 *In re: Asbestos Prods. Liab. Litigation (No. VI)*, U.S. DIST. CT. E. DIST. PA. (July 8, 2021), www.paed.uscourts.gov/documents2/mdl/mdl875 [perma.cc/6XCY-C9CQ]; *In re: Volkswagen "Clean Diesel" MDL*, U.S. DIST. CT. N. DIST. CAL. (last visited Nov. 20, 2021), www.cand.uscourts.gov/judges/breyer-charles-r-crb/in-re-volkswagen-clean-diesel-mdl/ [perma.cc/JHA4-WMPW].

85. *See, e.g.*, *In re* Plavix Mktg., Sales Prac., & Prods. Liab. Litig., 923 F. Supp. 2d 1376, 1380 (J.P.M.L. 2013) (consolidating litigation over blood thinner Plavix after initially denying to do so for some but not for all of the cases); *In re* Propecia (Finasteride) Prod. Liab. Litig., 856 F. Supp. 2d 1334, 1335 (J.P.M.L. 2012) (consolidating suits into MDL to address the side effects of sexual dysfunction in some men who took Propecia because doing so would serve the main functions of MDL: to "eliminate duplicative discovery; prevent inconsistent pretrial rulings; and conserve the resources of the parties, their counsel, and the judiciary . . ."); *In re* Diet Drugs Prods. Liab. Litig., 990 F. Supp. 834, 835-36 (J.P.M.L. 2012) (consolidating cases concerning multiple medications with multiple pharmaceutical company defendants, similar to the opioid MDL).

than 3,000 lawsuits filed by cities, counties, and other municipal governments have been consolidated into the Opioid Multidistrict Litigation ("MDL").[86] The suits include common law claims like fraud, unjust enrichment, negligence, and public nuisance.[87]

Popular common law claims include negligent misrepresentation and fraud.[88] In the context of the opioid crisis, these causes of action both involve companies providing consumers with false or misleading information.[89] Fraud requires willful misrepresentation or omission, reliance upon which causes harm.[90] Negligent misrepresentation has a lower bar, requiring instead that the defendant "fail[s] to use reasonable care or competence in obtaining or communicating the information."[91] However, both require evidence that the false statements caused the plaintiff's injuries.[92] The plaintiffs allege that the manufacturers used marketing tactics that intentionally or negligently misled patients and doctors about the risks of long-term opioid use and that "[d]istributors gave public false assurances of their compliance with anti-diversion obligations."[93] One of the most common causes of action brought by government plaintiffs in the MDL is that of public nuisance.[94] The government cannot make a public nuisance claim for the infringement of a personal or individual right on behalf of a person or group of people.[95] Though the exact requirements for a

86. Valerie Bauman, *States, Cities Eye $26 Billion Deal: Opioid Litigation Explained*, BLOOMBERG L. (July 26, 2021), news.bloomberglaw.com/health-law-and-business/states-cities-eye-26-billion-deal-opioid-litigation-explained [perma.cc/V28S-RKVR].

87. *See In re Nat'l Prescription Opiate Litig.*, 290 F. Supp. 3d at 1378.

88. *See id.* (listing common claims in the MDL).

89. *See City of Boston*, 2020 Mass. Super. LEXIS 2, at *27-29 (discussing misrepresentations as key to both types of claims).

90. *See id*. at *29 ("[A] plaintiff alleging fraud must identify the persons making the representation, its contents, and where and when it took place; the plaintiff should also specify the materiality of the misrepresentation, its reliance thereon, and resulting harm.").

91. Blackfeet Tribe of the Blackfeet Indian Reserv. v. AmerisourceBergen Drug Corp. (*In re* Nat'l Prescription Opiate Litig.), MDL No. 1:17-cv-02804, 2019 U.S. Dist. LEXIS 101659, at *122 (N.D. Ohio Apr. 1, 2019) (quoting Hayes v. AMCO Ins. Co., No. CV 11-137-MDWM, 2012 U.S. Dist. LEXIS 155001, at *4 (D. Mont. Oct. 29, 2012)).

92. *See id.* at 123, 127-28 (noting, as an element of negligent misrepresentation, that "the plaintiff, as a result of its reliance, must sustain damage" and that in the case of common law fraud, "proximate cause depends on a defendant's ability to reasonably foresee the 'natural and probable consequence' of the alleged wrongful conduct.").

93. *Id.* at 123 (further concluding that "Defendants intended that Plaintiff would rely on the false statements and that Plaintiff had no means to know the truth.").

94. *See, e.g.*, City & Cnty. of San Francisco v. Purdue Pharma, L.P., 491 F. Supp. 3d 610, 672, 676 (N. D. Cal. 2020) (alleging public nuisance among other claims).

95. *See* City of Chicago v. Beretta U.S.A. Corp., 821 N.E.2d 1099, 1115-1116

plaintiff to prove a claim of public nuisance vary somewhat by jurisdiction, it is generally "an unreasonable interference with a right common to the general public."[96] Jurisdictions differ on whether defendants are required to have actual knowledge that their conduct will cause the nuisance.[97] However, all public nuisance claims require plaintiffs to show the causation between the defendants' wrongful conduct and the damages incurred.[98] In these claims, the government entities allege that affirmative conduct on the part of the defendants caused significant and ongoing interference with public health through their contributions to creating the opioid crisis.[99]

Statutory claims advanced by the plaintiffs have included both state and federal law claims.[100] Among the statutory claims alleged are violations of consumer protection laws, the Controlled Substances Act ("CSA"), and the Racketeer Influenced and Corrupt Organizations ("RICO") Act, as well as various state analogues of the CSA and RICO Act.[101] The CSA and similar state laws impose duties on companies involved in manufacturing and distributing medications to collect and share information on suspicious orders, report suspicious prescriptions, and refuse to fill suspicious prescriptions.[102] Opioid medications (with a few limited exceptions) are Schedule II substances under the CSA, the most restricted

(Ill. 2004) (holding that the city could not successfully pursue a public nuisance claim against gun manufacturers for increased crime and costs of policing); Kristen S. Jones, *The Opioid Epidemic: Product Liability Or One Hell of a Nuisance?*, 39 MISS. C. L. REV. 32, 37 (2021) ("[S]tatutorily approved government entities or officials may bring suits for public nuisance.").

96. RESTATEMENT (SECOND) OF TORTS § 821B (AM. L. INST. 1965) (outlining further that one such circumstance is "significant interference with the public health [and] the public safety.").

97. *Compare City & Cnty. of San Francisco*, 491 F. Supp. 3d at 672, 676 (maintaining public nuisance claims against drug manufacturers and distributors and holding that the court did not need to determine if the element of actual knowledge was required for public nuisance claims in the State of California because it was met in this case regardless), *with* City of Chicago v. Purdue Pharma L.P., No. 14 CV 4361, 2021 U.S. Dist. LEXIS 62151, 47 (N. D. Ill. Mar. 31, 2021) (requiring only foreseeability–and not actual knowledge–in a public nuisance claim).

98. *See City & Cnty. of San Francisco*, 491 F. Supp. 3d at 676 (quoting Melton v. Boustred, 183 Cal. App. 4th 521, 542 (Cal. App. 6th Dist. 2010)) ("The elements of a cause of action for public nuisance include . . . causation.").

99. *See id.* at 669 ("The City alleges that Defendants' conduct created a public nuisance—the opioid epidemic—in San Francisco.").

100. *See In re Nat'l Prescription Opiate Litig.*, 290 F. Supp. 3d at 1378 (listing federal statutes such as the Controlled Substances Act in addition to the state law claims).

101. *See id.* (outlining the most common claims set forth by plaintiffs).

102. *See* Controlled Substances Act (CSA), 21 U.S.C. § 832 (2022) (outlining the suspicious order monitoring requirement in place since 2018); Dunaway v. Purdue Pharma L.P., 391 F. Supp. 3d 802, 806 (M.D. Tenn. 2019) (describing Tennessee state law requirements for the analogous law).

category recognized as having a valid medical use, and defined in the act as:

> SCHEDULE II
>
> (A) The drug or other substance has a high potential for abuse.
>
> (B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
>
> (C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.[103]

The most rigorous registration standards are set for manufacturers and distributors of Schedule I and II substances.[104]

Another significant statutory claim brought by plaintiffs comes under the RICO Act or its state analogues.[105] The plaintiffs allege that the marketing and distributor defendants engaged in a coordinated effort to improperly increase the prescription and sale of opioids and skirt the regulations in place to prevent diversion of the controlled substances.[106] The elements of a RICO Act claim include "(1) standing; (2) causation; (3) the existence of an enterprise; and (4) predicate acts."[107] Relevant examples of the racketeering acts committed by defendants in these cases include wire and mail fraud and violations of anti-diversion obligations.[108] RICO claims require a particularly high degree of direct causation between the wrongful actions and the harmful outcomes.[109] While the elements of these different causes of action vary considerably, there are common challenges that plaintiffs will face in proving liability in these suits.

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103. 21 U.S.C. § 812(b)(2) (2022).

104. *See* 21 U.S.C. § 823(a)-(b) (2022) (outlining different standards for registration of manufacturers and distributors of Schedule I & II as opposed to Schedule III, IV, & V). For both manufacturers and distributors, a key consideration for registration is "maintenance of effective controls against diversion of particular controlled substances." *Id.*

105. *See In re Nat'l Prescription Opiate Litig.*, 290 F. Supp. 3d at 1378 ("Plaintiffs variously bring claims for violation of RICO statutes . . .").

106. *In re Nat'l Prescription Opiate Litig.*, 458 F. Supp. 3d at 687-88 (noting additionally the allegations of mail fraud and wire fraud that were included in the RICO claims).

107. *Id.* at 687 (listing elements of the claim that the defendant challenged).

108. *See, e.g.*, *id*. at 688 (listing defendants' alleged offenses that justified maintaining a RICO claim against a motion to dismiss).

109. *See* Cnty. of Summit v. Purdue Pharma L.P. (*In re* Nat'l Prescription Opiate Litig.), Nos. 1:170md-2804, 18-op-45090, 2018 U.S. Dist. LEXIS 213657, at *64 (N.D. Ohio Dec. 19, 2018) (agreeing with defendants' assertion that proximate cause for a RICO claim must show "an uninterrupted, direct, and not overly attenuated causal chain from conduct to injury . . .").

E. Proximate Causation

Proving proximate causation between the bad acts and the damages suffered is key to the causes of action put forward by the plaintiffs in these cases.[110] Proximate causation (as the complement to causation-in-fact) has been described by the Supreme Court as "the judicial tools used to limit a person's responsibility for the consequences of that person's own acts."[111] Generally, proximate cause "bars suits for alleged harm that is 'too remote' from the defendant's unlawful conduct."[112] There are multiple aspects of proximate causation relevant to the discussion of pharmaceutical company liability here.[113]

This Comment will continue to analyze how proving proximate causation serves as a barrier to recovery of damages in opioid litigation by focusing on four facets of the proximate cause analysis: (1) remoteness, (2) foreseeability, (3) breaks in the causal chain through the learned intermediary doctrine, and (4) attributing causation to other parties. While remoteness and foreseeability are related concepts, drawing a distinction between the two is sometimes significant.[114] Additionally, "it is well-settled that a disconnected and efficient intervening cause may break the causal chain."[115] In this Comment, this principle has been subdivided into two main arguments set forth: the more traditional application of the separate actions of a third party breaking the chain of causation, and the dilution of responsibility by other parties engaging in similar behaviors.

Remoteness refers to the length of the causal chain between the conduct and injuries alleged.[116] The threshold for what is considered "too remote" is not uniform across all contexts; some

110. *See, e.g.*, *City of Boston*, 2020 Mass. Super. LEXIS 2, at *22-23 ("[T]he Cities will ultimately have to prove that the injuries for which they seek compensation are the foreseeable results of each defendant's conduct, and that the defendant's role in causing the harm was not insignificant.").

111. Holmes v. Sec. Inv. Prot. Corp., 503 U.S. 258, 268 (1992).

112. Lexmark Int'l, Inc. v. Static Control Components, Inc., 572 U.S. 118, 133 (2014) (quoting *Holmes*, 503 U.S. at 268-70).

113. *See City of Boston*, 2020 Mass. Super. LEXIS at 22 (discussing the element of foreseeability); *Cnty. of Summit*, 2018 U.S. Dist. LEXIS 213657, at *65 (describing the aspect of remoteness, describing it as the "relation between the injury asserted and the injurious conduct alleged . . .").

114. West Boca Med. Ctr., Inc. v. AmerisourceBergen Drug Corp. (*In re* Nat'l Prescription Opiate Litig.), 452 F. Supp. 3d 745, 763 (N.D. Ohio 2021) ("Though foreseeability is an element of the proximate cause analysis, it is distinct from the requirement of a direct injury.").

115. *Id.* at 764.

116. *See Holmes*, 503 U.S. at 269-71 (describing the number of intervening factors between cause and effect and deciding that the harm was too remote for the plaintiff to recover).

causes of action require a more direct connection than others.[117] For example, "[w]hile a RICO claim cannot satisfy proximate cause absent a direct relationship between the conduct and injury, a public nuisance claim satisfies proximate cause if the defendant's conduct is likely to cause a significant invasion of a public right."[118] Foreseeability is also a key element of proximate cause and may allow a longer causal chain to hold together in some cases.[119] At its core, "an injury is 'foreseeable' if the defendant knew or should have known that his act was likely to result in harm to someone."[120]

Proximate cause may be broken by intervening acts of third parties.[121] Specifically in the case of pharmaceuticals, the learned intermediary doctrine has traditionally broken the chain of proximate causation where a prescribing health care provider is required before a medication can reach the hands of a consumer.[122] This prescribing provider is presumed to make an "independent and educated prescribing decision" that interrupts the chain of proximate causation.[123] Additionally, some defendants in the opioid litigation at hand have made arguments that they cannot have proximately caused the detrimental effects being suffered by the plaintiffs if other parties can be shown to have caused them.[124] The next section will analyze these aspects of proximate cause as they relate to the various causes of action being brought in the MDL and the challenges that come with proving proximate cause in an issue as multifactorial as the opioid crisis.

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117. *See City & Cnty. of San Francisco*, 491 F. Supp. 3d at 679 (discussing the differences in proximate cause analysis between RICO claims and public nuisance claims).

118. *Id.*

119. *See id.* (rejecting a defendant's argument that proximate cause was not met because "[m]anufacturers could reasonably foresee the intervening acts of third parties.").

120. *Cnty. of Summit*, 2018 U.S. Dist. LEXIS 213657, at *106.

121. *See* Richard C. Ausness, *The Current State of Opioid Litigation*, 70 S.C. L. REV. 565, 599 (2019) ("[P]roximate cause is often invoked to cut off liability when other causes have intervened between the defendant's conduct and the plaintiff's harm.").

122. *See* Reyes v. Wyeth Lab'ys, 498 F.2d 1264, 1276 (5th Cir. 1974) ("Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a 'learned intermediary' between manufacturer and consumer.").

123. *City of Boston*, 2020 Mass. Super. LEXIS 2, at *21 (noting additionally that "the chain of causation would not be broken if the prescribing decision was affected by the deceptive and misleading conduct of the manufacturer.").

124. *See, e.g.*, *id.* at *36-37 (rejecting a defendant's argument that entering the opioid medication market later absolved them of potential blame).

III. ANALYSIS

This section will analyze specific aspects of proximate cause that have been raised as defenses in the opioid civil litigation context. These facets of analysis include remoteness, the foreseeability of injuries, breaking the causal chain through the learned intermediary doctrine, and proximate causation being interrupted or superseded by other relevant parties. Government plaintiffs currently involved in the MDL have advanced several different claims in the attempt to seek restitution from pharmaceutical companies for stoking the opioid crisis.[125] These causes of action all have challenges due to the complex nature of the opioid crisis; some of the issues are specific to certain types of claims and others are general to all of the litigation.[126] Each type of claim has weaknesses that may make it difficult to succeed – a likely reason that so many different liability theories have been advanced.[127]

A. Issues with Remoteness of Damages for State, County, and Municipal Plaintiffs

For government plaintiffs involved in opioid litigation, it can be difficult to prove damages in a sufficiently direct manner.[128] Proving that damages are not too remote is more difficult for some causes of action than for others.[129] In a claim for public nuisance, a plaintiff must only show that the defendant's actions were a substantial factor in the injuries caused.[130] Foreseeability of the injuries is also a key component of the analysis.[131] In contrast, RICO statute claims typically take a narrower view than other causes of action.[132] They also often require a more direct line, tolerating fewer

125. *See In re Nat'l Prescription Opiate Litig.*, 290 F. Supp. 3d at 1378 (discussing different claims, plaintiffs, and defendants involved in the litigation).

126. *See generally* Ausness, *supra* note 121 (discussing merits and likely outcomes of various causes of action and defenses).

127. *See id*. at 606 (discussing specifically the weaknesses of many of the most popular claims being advanced).

128. *See id.* (naming proximate cause among issues facing government plaintiffs in opioid litigation).

129. *See City & Cnty. of San Francisco*, 491 F. Supp. 3d at 679 (comparing the proximate cause standards between claims).

130. *See id.* at 676 ("A plaintiff must establish causation in fact, which requires facts demonstrating that the defendant's conduct was a 'substantial factor in bringing about the result.'").

131. *See id.* ("Unlike RICO, courts place great emphasis on "foreseeability of harm" in determining whether a public nuisance claim sufficiently alleges proximate cause.").

132. *See* Sarah M. Kelley, *Chain, Chain, Chain--Chain of (Pharma) Fools: Why Third Party Payors Maintain the Proximate Causal Chain Under RICO §*

intermediate steps than other types of claims.[133] The Supreme Court discussed the specifics of proximate cause and remoteness in RICO claims in *Holmes v. Securities Investor Protection Corp.*[134] The Court provided a policy rationale for requiring such directness in RICO cases based on the difficulty of ascertaining damages correctly for multiple plaintiffs and the likelihood that the cases with the most direct injury were most likely to succeed.[135] Still, despite the difficult standard of proximate cause that RICO claims must meet, the specificity in the other elements of these statutory claims and the potential issues for government plaintiffs with other types of claims may still make them one of the more successful options.[136]

The analysis of RICO claims in opioid litigation is fact-specific to the impact suffered by individual communities and depends on the actual injuries alleged.[137] RICO claims in Summit County, Ohio and Monroe County, Michigan survived challenges from defendants while the RICO claims in the City and County of San Francisco were dismissed because the injuries alleged were "too attenuated to satisfy RICO's narrow definition of proximate cause."[138] A key difference in the cases was that the County of Summit specifically alleged a category of damages flowing from costs associated with stopping the flow of opioids into the local community.[139] In dismissing the City and County of San Francisco's RICO claims, the court specifically noted that the alleged injury of preventative costs

1964(c), 62 B.C. L. REV. E. SUPP. 44, 48 (2021) (discussing the proximate cause requirements of RICO as applied to less direct injuries from pharmaceutical companies' misconduct, here in the context of third party payors rather than government entities).

133. *See Cnty. of Summit*, 2018 U.S. Dist. LEXIS 213657, at *67-69 (accepting a causal chain in a RICO claim with three steps from conduct to injury and rejecting a version requiring seven steps).

134. 503 U.S. at 269-270.

135. *Id.* In *Holmes*, the case involved an alleged conspiracy in stock trading, rather than anything to do with pharmaceuticals. *Id.* at 262-265. However, the framework involving alleged wrongful acts that go through levels of intermediaries before the eventual plaintiff is harmed still provides some analogy.

136. *See* Ausness, *supra* note 121, at 606 (raising issues with meeting certain elements of various common law claims, the directness of damages for claims of unjust enrichment, and the difficulty of proving civil conspiracy).

137. *See City & Cnty. of San Francisco*, 491 F. Supp. 3d at 661 ("Summit County is therefore distinguishable because the City's injuries here are more attenuated from the injury-causing conduct.").

138. *Id.* at 653. *But see Cnty. of Summit*, 2018 U.S. Dist. LEXIS 213657, at *70 ("Plaintiffs have sufficiently alleged proximate cause for their RICO claims."); *In re Nat'l Prescription Opiate Litig.*, 458 F. Supp. at 687 ("[D]ismissal of Monroe's RICO claims at the pleading stage is unwarranted.").

139. *See Cnty. of Summit*, 2018 U.S. Dist. LEXIS 213657, at *67-68 (citing specifically to this among thirteen alleged categories of damages).

like these had not been recognized in that jurisdiction.[140] Where a defendant can argue that there are more intermediate steps (in this case, drug use by residents in the area and subsequent damage to city property), the increased remoteness of the injury may be sufficient for the claim to fail.[141]

Another issue raised by defendants is the "municipal cost recovery rule" (alternately called the "free public services doctrine"), which can bar recovery for a significant portion of the damages claimed.[142] The doctrine suggests that damages alleged by municipalities are too remote to recover against the defendants because "the cost of public services . . . is to be borne by the public as a whole, not assessed against the tortfeasor whose negligence creates the need for the service."[143] Many localities involved in the litigation are alleging increased costs for policing and emergency services related to preventing and treating opioid overdoses, managing increased illegal drug activity, and coping with increased mortality.[144]

In recent opioid litigation, courts have increasingly declined to apply the municipal cost rule where the cost is due to a prolonged public nuisance rather than a one-time event requiring emergency response.[145] Governments are not barred from recovery for municipal expenditures spurred by wrongful conduct where circumstances "forced Plaintiffs to go far beyond what a governmental entity might ordinarily be expected to pay to enforce

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140. *See City & Cnty. of San Francisco*, 491 F. Supp. 3d at 661 ("Summit County's causal chain focused on RICO injuries that the MDL court defined as "costs associated with . . . attempts to stop the flow of opioids into local communities." That is not an injury this Court recognizes.").

141. *See, e.g.*, *id.* ("The City's failure to adequately allege proximate cause is fatal to its RICO claims.").

142. *See, e.g.*, *City of Boston*, 2020 Mass. Super. LEXIS 2, at *31-32 (describing the common law rule that tortfeasors are generally not responsible for the cost of emergency services required because of their negligence).

143. *Id.* at 31 (quoting Flagstaff v. Atchison, Topeka & Santa Fe Ry. Co., 719 F.2d 322, 323 (9th Cir. 1983)).

144. *See, e.g.*, *City of Boston*, 2020 Mass. Super. LEXIS 2, at *31-32 (citing to "fatalities, overdoses, and other related costs in the Cities during the relevant time . . ."); *Cnty. of Summit*, 2018 U.S. Dist. LEXIS 213657, at *78 (listing among the injuries the plaintiff asserted costs for providing medical care, training emergency medical technicians, providing first responders with naloxone, emergency responses to opioid overdoses, and an increased burden on the local judicial system).

145. *See City of Boston*, 2020 Mass. Super. LEXIS 2, at *32 (noting the trend away from application of the "free public services doctrine" in opioid litigation specifically). *See also* State *ex rel.* Jennings v. Purdue Pharma L.P., No. N18C-01-223, 2019 Del. Super. LEXIS 65, at *20 (Del. Super. Ct. Feb. 4, 2019) ("In five separate courts, and in the multi-district federal litigation based in Ohio, judges have rejected the notion that the municipal cost recovery rule bars recovery for public costs.").

the laws or promote the general welfare."[146] Courts have recognized the magnitude of the opioid crisis in understanding and tracing the damages suffered by state and local governments.[147] This particular issue in proving causation in these claims seems to be trending more positively for the plaintiffs in the litigation, especially in the last few years.[148] Still, as seen in *City and County of San Francisco v. Purdue Pharma L.P.*, both remoteness of injuries in RICO claims and the municipal cost doctrine bar recovery in a portion of the litigation brought as a result of the opioid crisis.[149]

B. Issues of Foreseeability

A separate but related consideration to the remoteness of the damages is whether they were foreseeable.[150] In many cases, harm that is more remote may still be said to have been proximately caused if it is foreseeable that the harm would result from the defendant's conduct.[151] Similarly, an intervening act by another party may not break the causal chain where that party's action was foreseeable to the defendant.[152] Defendants in these opioid actions also attack the claims based on the alleged lack of foreseeability of

146. *Cnty. of Summit*, 2018 U.S. Dist. LEXIS 213657, at *83-84.

147. *See id.* ("Plaintiffs have been forced to expend vast sums of money far exceeding their budgets to attempt to combat the opioid epidemic. . . . Cities and Counties should be able to recover costs greatly in excess of the norm, so long as they can prove the costs were incurred due to Defendants' alleged RICO violations.").

148. *See* Muscogee (Creek) Nation v. Purdue Pharma L.P. (*In re* Nat'l Prescription Opiate Litig.), Nos. 17-md-2804, 18-op-45749, 2019 U.S. Dist. LEXIS 101657, at *94 (N.D. Ohio June 13, 2019) ("The current trend among state court judges ruling in opioid-related cases around the country is that the municipal cost recovery rule does not apply when, as alleged here, an ongoing and persistent course of intentional misconduct creates an unprecedented, man-made crisis that a governmental entity plaintiff could not have reasonably anticipated as part of its normal operating budget for municipal, county, or in this case, tribal services.").

149. *City & Cnty. of San Francisco*, 491 F. Supp. 3d at 651, 661 (discounting costs spent on healthcare and emergency services as ordinary, rather than extraordinary, governmental expenditure and judging the City's RICO claim to be too remote to satisfy proximate cause).

150. *Cf. id.* at 676 ("[Defendants] argue that (1) the City has failed to plead facts demonstrating that the nuisance would not have occurred but-for Defendants' conduct, (2) nor has the City demonstrated that the alleged harms were foreseeable.").

151. *See id.* at 681(concluding that manufacturers who were aware of the risks of opioids and thus could reasonably foresee the potential issues of introducing them into a community at a high volume were not insulated from proximate causation).

152. *See id.* ("[H]ere the intervening acts—including decisions by prescribers, patients, distributors, pharmacies, and third-party criminals—are reasonably foreseeable, and thus not superseding acts.").

the harm that would stem from their conduct.[153] The defendants advance multiple versions of the argument that the outcome was unforeseeable.[154] In some cases, the defendants argue that the increases in addiction, illness, and death was unforeseeable, while in others they advance the view that harmful impacts to the government in the form of increased burden on emergency personnel, hospitals, and judicial systems was the unforeseeable result.[155]

The first argument – that increases in addiction, illness, and death due to opioid medications were unforeseeable – can be dismissed by virtue of the drugs' classification as Schedule II narcotics under the CSA.[156] Where violations of the CSA or similar state laws regarding controlled substances are alleged, foreseeability is difficult to discount.[157] Even in cases where the specific statutes are not invoked in the litigation, additional information and guidelines released by federal agencies similarly in more recent years support the idea that harm from overuse of opioids is foreseeable.[158]

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153. *See State ex rel. Jennings*, 2019 Del. Super. LEXIS 65, at *23 (denying defendants' motion to dismiss because the State had met its pleading requirements for foreseeability in consumer fraud claims).

154. *See City of Chicago*, 2021 U.S. Dist. LEXIS 62151, at *40-42 (identifying the allegedly unforeseen outcome as including "black markets for diverted prescription opioids; and a concomitant rise in heroin and fentanyl abuse" and "costs associated with addressing increased rates of opioid use, addiction, and overdoses"); *Muscogee (Creek) Nation*, 2019 U.S. Dist. LEXIS 101657, at *83 (identifying the allegedly unforeseen outcome as the "collective misuse of opioids.").

155. *Compare Muscogee (Creek) Nation*, 2019 U.S. Dist. LEXIS 101657, at *83 ("[T]he Muscogee Nation member's collective misuse of opioids is a reasonably foreseeable result of Defendants' alleged failure to prevent diversion."), *with City of Chicago*, 2021 U.S. Dist. LEXIS 62151, at *39-41 (calling the negative community outcomes and increased expenditures a "direct and foreseeable result" of the defendant pharmaceutical company's behavior, and therefore holding that the City had properly alleged proximate cause for its deceptive advertising claims).

156. *See City of Chicago*, 2021 U.S. Dist. LEXIS 62151, at *41-42 (pointing out that the existence of duties to mitigate harm under the CSA would not exist if there were not an acknowledged likelihood of harm from the drugs in question).

157. *See id.* at 41 (quoting *City & Cnty. of San Francisco*, 491 F. Supp. 3d 610 (N.D. Cal 2020)) ("[T]he 'very existence of the duties to maintain effective controls supports the notion that opioid misuse is foreseeable.'").

158. The FDA initiated a "Safe Use" program for opioid prescribing in 2009, as one of several measures undertaken to try to stem the tide of opioid overdoses and deaths that began to increase in the early 2000s. *Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse*, FDA (Oct. 1, 2021), www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-opioid-misuse-and-abuse [perma.cc/AK6S-K7WM]. The CDC's full prescribing guide was not issued until 2016 (now replaced with the 2022 version of the prescribing guide), but the organization was involved in discussions with other agencies, including the

The second argument is that harmful impacts on government institutions and resources were unforeseeable.[159] However, courts have held that while these overdoses, injuries, and deaths causing an increased burden on city resources may be an additional step in the proximate cause analysis, the impacts were at least potentially foreseeable.[160] Even in upholding the City of Boston's claims against a motion to dismiss, the court acknowledges in *City of Boston v. Purdue Pharma, L.P.*, that proving the foreseeability element "may very well be difficult to do."[161]

C. Breaks in the Causal Chain Through the Learned Intermediary Doctrine

In addition to issues of remoteness and foreseeability, defendants allege that the proximate cause chain is broken when a doctor is required to write a prescription before the medication reaches patients.[162] Defendants in the MDL have regularly raised the argument that intervening acts are sufficient to break the causal chain between their bad acts and the damages alleged by the plaintiffs.[163] In the case of pharmaceutical company liability for opioid medications, this most frequently arises in the form of the learned intermediary doctrine.[164]

FDA, as early as 2001. *Id.*; *Process for the Development of the 2022 Clinical Practice Guideline for Prescribing Opioids for Pain*, CDC (Nov. 3, 2021), www.cdc.gov/opioids/guideline-update/index.html [perma.cc/2V5V-953T].

159. *See City & Cnty. of San Francisco*, 491 F. Supp. 3d at 680 ("Manufacturers dispute that their conduct could foreseeably cause the full extent of the City's harm.").

160. *See id.* at 682 ("[T]he City has sufficiently pled proximate causation because its alleged harms—costs associated with addressing increased rates of opioid use, addiction, and overdoses . . . are the foreseeable result of Manufacturers' conduct.").

161. *City of Boston*, 2020 Mass. Super. LEXIS 2, at *22-23 ("In order to show proximate cause, the Cities will ultimately have to prove that the injuries for which they seek compensation are the foreseeable results of each defendant's conduct, and that the defendant's role in causing the harm was not insignificant. Proving that may very well be difficult to do.").

162. *Cf.* Broward Cnty. v. Purdue Pharma L.P. (*In re* Nat'l Prescription Opiate Litig.), No. 17-md-2804, 2020 U.S. Dist. LEXIS 73744, at *100 (N.D. Ohio Apr. 27, 2020) (upholding a negligence claim against a motion to dismiss because "the learned intermediary doctrine is inapplicable" where increased prescription was a goal of the defendants).

163. *See id*. (listing the learned intermediary doctrine precluding proximate cause among the defendants' arguments in a motion to dismiss); *City of Boston*, 2020 Mass. Super. LEXIS 2, at *21 (dismissing the defendants' raising of the learned intermediary doctrine); *City & Cnty. of San Francisco*, L.P., 491 F. Supp. 3d at 688 (stating that the manufacturers' argument using the learned intermediary doctrine "ignores the crux of the City's allegations. . .").

164. *See City & Cnty. of San Francisco*, 491 F. Supp. 3d at 688-89 (rejecting learned intermediary doctrine theory suggested by defendants).

The learned intermediary doctrine historically has been applied as a full break in the causal chain between a pharmaceutical company and damages that may occur from prescription-only medication.[165] The premise of the doctrine is that when an educated expert in the field, here a physician or other prescriber, is required for a patient to receive the product created by the company, the duty of the company ends at "warn[ing] health-care providers of those risks" associated with the product.[166] However, courts in opioid litigation cases have used two main theories to limit its application in the case of opioid pain killer prescription: direct-to-consumer advertising exceptions, and deceptive advertising claims targeted to prescribers directly.[167]

The learned intermediary doctrine defense can be undermined by direct-to-consumer advertising for prescription products and medications.[168] Where consumers are encouraged to request specific medications from their physicians by commercials and advertisements[169] without being adequately warned of all potential risks, the liability of drug companies for failing to put out sufficient warnings or for creating potentially unsafe products does not end with the requirement for a prescription.[170] In a healthcare system that looks very different than it did when the learned intermediary doctrine was adopted, patients have more agency in making medical decisions, and therefore have a greater need to be informed.[171]

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165. *See* Tamar V. Terzian, *Direct-to-Consumer Prescription Drug Advertising*, 25 AM. J. L. & MED. 149, 161-62 (1999) (discussing the traditional rule that pharmaceutical companies fully avoided liability to consumers for prescription drug failure to warn claims on the theory that prescribing physicians and other medical providers have the duty to warn).

166. Perez v. Wyeth Lab'ys Inc., 734 A.2d 1245, 1247 (N.J. 1999).

167. *Compare id.* at 1257 ("When a patient is the target of direct marketing, one would think, at a minimum, that the law would require that the patient not be misinformed about the product."), *with City of Boston*, 2020 Mass. Super. LEXIS 2, at *21 ("[T]he chain of causation would not be broken if the prescribing decision was affected by the deceptive and misleading conduct of the manufacturer.").

168. *See Perez*, 734 A.2d at 1255 (noting that of the factors supporting the creation of the learned intermediary doctrine as an exception to the duty to warn patients, "all are . . . absent in the direct-to-consumer advertising of prescription drugs . . .").

169. An example of one of the direct-to-consumer advertisements at issue in *Perez*, a magazine advertisement for birth control implant Norplant, is available at digital.library.wayne.edu/item/wayne:Swanger1777_5_15_01/file/FILE [perma.cc/5CBC-4ME9].

170. *See Perez*, 734 A.2d at 1255 ("Direct advertising of drugs to consumers alters the calculus of the learned intermediary doctrine.").

171. *See id.* at 1262-63 ("We must consider as well a case in which a diabetic patient might have been influenced by advertising to request a drug from a physician without being warned by the manufacturer or the physician of the special dangers posed to a diabetic taking the drug. If an overburdened physician does not inquire whether the patient is a diabetic, the question remains whether the manufacturer should be relieved entirely of

Currently in the United States, the FDA does not preapprove direct-to-consumer advertisements from drug companies for their content prior to publishing.[172] The FDA also does not regulate the amount spent by companies on direct-to-consumer advertising or bar companies from directly advertising drugs with serious risks.[173] After a thorough review of how direct-to-consumer marketing has changed the U.S. healthcare landscape, the New Jersey Supreme Court ultimately concluded that "[i]n the case of direct marketing of drugs, we believe that neither the physician nor the manufacturer should be entirely relieved of their respective duties to warn."[174]

Many of the suits claim deceptive advertising was targeted directly toward the prescribing health care providers, which also creates a wrinkle in the learned intermediary doctrine defense for drug companies.[175] Where deceptive marketing materials and statements by drug manufacturers and distributors are directed toward health care professionals, it can help maintain the causal link that may otherwise be broken by the learned intermediary doctrine.[176] Multiple pharmaceutical companies have been accused of intentionally misleading doctors and other prescribers about the dangers of addiction and overdose of various prescription opioid medications.[177] Purdue Pharma, Endo Health Solutions, Janssen

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responsibility.").

172. *Prescription Drug Advertising: Questions and Answers*, FDA (June 19, 2015), www.fda.gov/drugs/prescription-drug-advertising/prescription-drug-advertising-questions-and-answers [perma.cc/2XUF-U45T].

173. *Id.*

174. *Perez*, 734 A.2d at 1263.

175. *See State ex rel. Jennings*, 2019 Del. Super. LEXIS 65, at *8 (citing a multimillion-dollar advertising campaign including promotional materials, conferences, and publications specifically targeted toward doctors in denying a motion to dismiss a deceptive marketing claim); Grewal v. Janssen Pharm., Inc., No. C-80-18, 2019 N.J. Super. Unpub. LEXIS 5766, 2 (N.J. Super. Ct. Ch. Div. Oct. 21, 2019) (upholding claims based on the defendants "disseminating misleading and inaccurate statements to both patients and prescribers, regarding the risks and benefits of Janssen products and of opioids generally."); *City of Chicago*, 2021 U.S. Dist. LEXIS 62151, at *7-8 (detailing five different marketing techniques primarily aimed at misleading doctors and other healthcare professionals on the relative risks and benefits of opioids).

176. *See City of Boston*, 2020 Mass. Super. LEXIS 2, at *21, *29-30 (holding that the learned intermediary rule would not absolve pharmaceutical companies of liability where there was a demonstrated "complex scheme of disinformation" that included misinformation distributed through medical journals and directly to doctors' offices).

177. *See City of Chicago*, 2021 U.S. Dist. LEXIS 62151, at *7-8 (discussing the deceptive advertising practices of Purdue Pharma); *Grewal*, 2019 N.J. Super. Unpub. LEXIS 5766, at *2 (discussing the misleading claims made by Janssen Pharmaceuticals). *See also Court's Ruling Clears the Way for April Trial Against Opioid Manufacturers*, CNTY. OF SANTA CLARA OFF. OF COMMC'NS. & PUB. AFFS. (Mar. 15, 2021), news.sccgov.org/news-release/courts-ruling-clears-way-april-trial-against-opioid-manufacturers [perma.cc/YH4G-D7M3] (noting that the first government-initiated lawsuit against opioid

Pharmaceuticals, and Cephalon are among the pharmaceutical companies that propagated the concept of "pseudo-addiction" to opioid medications.[178] "Pseudo-addiction" theory proponents recommended treating signs of opioid addiction with increased doses of opioid painkillers, a protocol not supported by medical science.[179]

Pharmaceutical companies are also accused of making false claims about the risks and rates of addiction for patients using opioid medications to manage chronic pain as companies tried to increase sales for non-cancer pain treatment.[180] The methods of spreading this misinformation were also specifically targeted toward healthcare professionals, and included advertisements in medical journals,[181] direct sales visits to doctors' offices,[182] and

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manufacturers made claims of deceptive marketing against pharmaceutical companies Johnson & Johnson, Endo, Teva, and Allergan).

178. *See* Marion S. Greene & R. Andrew Chambers, *Pseudoaddiction: Fact or Fiction? An Investigation of the Medical Literature*, 2 CURRENT ADDICTION REPS. 310, 311-12 (2015), www.ncbi.nlm.nih.gov/pmc/articles/PMC4628053/pdf/40429_2015_Article_74.pdf [perma.cc/N6FH-G7M8]. "Pseudo-addiction" was a concept pioneered largely by Dr. David Haddox (later employed by Purdue Pharma) that posited that the signs of opioid addiction – including withdrawal and tolerance symptoms – were signs of untreated pain that should be managed by treating with higher doses of the opioid medications that were potentially causing the issues. *Id.* at 311.

179. *See* Sixth Amended Complaint, *supra* note 34, at 20 ("Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon 'pseudoaddiction.'"). Medical protocols currently support the use of a small number of specific medications to treat opioid dependence, most prominently methadone and buprenorphine. *See What Are Misconceptions About Maintenance Treatment?*, NAT'L INST. ON DRUG ABUSE (June 2018), www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/what-are-misconceptions-about-maintenance-treatment [perma.cc/T293-T8HP]. These medications may be used to slowly taper patients off opioids (sometimes over periods lasting months or years) or may be used indefinitely as maintenance medications to allow patients with opioid use disorders to function without the painful and unpleasant symptoms of withdrawal. *Id*. They may be paired with other forms of treatment like behavioral interventions. *Id.* Methadone and buprenorphine are on the World Health Organization's list of essential medicines. *Id.*

180. *See* Sixth Amended Complaint, *supra* note 34, at 18-19 ("Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction"); Keefe, *supra* note 19 ("Even after it became clear that OxyContin was being widely abused, Purdue refused to concede that it posed risks.").

181. Keefe, *supra* note 19 ("The company advertised in medical journals, sponsored Web sites about chronic pain, and distributed a dizzying variety of OxyContin swag . . .").

182. AG Shapiro Press Release, *supra* note 75 (citing that Purdue Pharma sales representatives made over 530,000 direct visits to doctors' offices in Pennsylvania alone).

sponsored speakers and conferences for medical providers.[183] Where both the message and the method of delivery were targeted at the supposed "learned intermediary," the premise of having an independent third party decision maker becomes weak.[184] If prescribers are acting on the misrepresentations of company representatives and sponsored materials, they can only make decisions with the information available to them.[185] Because of this, courts in many cases have declined to hold that the learned intermediary doctrine breaks the chain of proximate cause as a matter of law.[186] However, companies are generally free to continue to advance the theory when persuading the trier of fact.[187]

D. Denying Proximate Causation Based on Other Parties

In addition to the learned intermediary doctrine invoked as a defense, some pharmaceutical companies have argued that their relatively small market share further insulates them from liability.[188] While the share of responsibility may be proportional to the actions taken, having a relatively smaller share of the blame is not sufficient to absolve a company of responsibility entirely.[189]

183. *In re* Nat'l Prescription Opiate Litig. v. Purdue Pharma L.P., Nos. 17-md-02804, 18-op-45459, 2019 U.S. Dist. LEXIS 101660, at *86 (N.D. Ohio Apr. 1, 2019) ("Manufacturers also allegedly recruited and 'heavily funded' pain management physicians to serve as ostensibly objective 'Key Opinion Leaders' who would spread the nine categories of misrepresentations to fellow physicians, taking advantage of the great confidence physicians place on 'seemingly independent peers.'").

184. *Cf. City & Cnty. of San Francisco*, 491 F. Supp. 3d at 688 ("The learned intermediary doctrine stems from the rationale that a prescribing doctor typically serves as an intervening party that cuts off the causal chain.").

185. *See id.* (noting that "both the public and prescribers were misled.").

186. *See, e.g.*, *West Boca Med. Ctr., Inc.*, 452 F. Supp. 3d at 763 ("[T]he court declines to find that the physicians' act of writing prescriptions breaks the causal chain, as a matter of law.").

187. *See In re* Nat'l Prescription Opiate Litig., 17-md-2804, 2020 U.S. Dist. LEXIS 204908, at *55-56 (N. D. Ohio Nov. 3, 2020) ("Plaintiffs asked the Court to preclude Defendants from asserting the learned intermediary doctrine absolved Defendants from liability. The Court granted the motion in part, noting that whether Defendants' warnings were adequate, and whether the advice of doctors may have served to break the causal chain, were clearly questions for the jury.").

188. *See In re* Nat'l Prescription Opiate Litig., No. 17-md-2804, 2020 U.S. Dist. LEXIS 13107, at *67-68 (N.D. Ohio Jan. 27, 2020) ("[Defendant] DDM maintains it could not have created a public nuisance because it captured only a small market share and distributed only to its own pharmacies.").

189. *Cf. City of Boston*, 2020 Mass. Super. LEXIS 2, at *37 ("That [defendants] may, at some point in the future, be deemed less responsible than other defendants (or absolved entirely) is not a basis to dismiss the Springfield Complaint before any discovery has been conducted.").

Some of the defendants attempt to diminish or avoid their liability in the opioid crisis by arguing that too many other parties have been involved in creating the harm for their company to hold any individual responsibility.[190] Companies that more recently entered the opioid medications market have claimed that their liability, when taken in comparison to the larger companies marketing some of the most well-known opioid products, is negligible in contributing to the opioid crisis.[191] Similarly, companies that sold relatively small portions of the products in question, when looked at in a broad context, may still have contributed enough to support a finding of proximate cause for a particular area or community.[192]

Just as manufacturers occupying a smaller market share cannot avoid culpability, distributors have been unsuccessful in arguing that they should not be held liable because manufacturers were responsible for the marketing that created the new standard of care.[193] Factual distinctions – like the difference between manufacturers of brand name medications and generic medications – are significant in determining how liability will be apportioned between interconnected players, but these factors do not fully shield a company from liability.[194] However, the Supreme Court of Oklahoma did appear to take this line of reasoning into account as one potential factor in dismissing a public nuisance claim against Johnson & Johnson where "[e]vidence at trial demonstrated that J&J sold only 3% of all prescription opioids statewide," suggesting that defendants may still have some success with this kind of

190. *See id.* at *36-38 (citing arguments that companies entered the opioid market late or produced generic medications and therefore should not be subject to liability).

191. *See id.* (citing a complaint that, among other examples, "reasonably allege[d] that [opioid manufacturer] Collegium engaged in misleading sales practices that served to exacerbate an already existing opioid crisis.").

192. *See In re* Nat'l Prescription Opiate Litig., 2020 U.S. Dist. LEXIS 13107, at *67-68 (noting that the "0.9% of the opioids shipped" into the area cited by the defendants still accounted for "nearly 12 million dosage units to its pharmacies in Cuyahoga County and over 3.4 million dosage units to its pharmacies in Summit County between 2006 and 2014.").

193. *See City of Boston*, 2020 Mass. Super. LEXIS 2, at *36-37 ("That [a defendant with small market share] may, at some point in the future, be deemed less responsible than other defendants (or absolved entirely) is not a basis to dismiss the Springfield Complaint before any discovery has been conducted."); *cf. City & Cnty. of San Francisco*, 491 F. Supp. 3d at 683 (rejecting defendant distributors' claim that they could not be held liable because the actions of the manufacturer defendants were the true cause, and their conduct could not be considered a concurrent cause).

194. *See In re Nat'l Prescription Opiate Litig.*, 2019 U.S. Dist. LEXIS 101660, at *120-21 (finding some state law claims against companies that only manufactured generic drugs preempted but maintaining "any of Plaintiff's state law claims . . . founded upon allegations that the Generic Manufacturers engaged in aggressive and misleading marketing and inadequate anti-diversion activities.").

argument.[195]

These aspects of proximate cause are among some of the significant barriers to civil recovery faced by governmental plaintiffs seeking restitution for harm caused in the opioid crisis.[196] The following section will propose modified approaches to the issues discussed above that would allow civil litigation to more effectively play a role in holding pharmaceutical companies accountable and aiding in the recovery from the opioid crisis.

IV. PROPOSAL

This section asserts potential solutions to issues with proving proximate causation that arise in civil litigation regarding the opioid crisis. Among these are a generally broader approach to proximate causation for all types of claims in this issue, reducing or eliminating the use of the learned intermediary doctrine, and the potential use of more statutory causes of action in which proximate causation will play a diminished role. It also briefly discusses the likelihood that many of the claims currently in litigation will ultimately be solved through settlements or bankruptcy proceedings.

The opioid crisis has cost hundreds of thousands of human lives and billions of dollars in the past few decades.[197] Preventing future injury, mitigating the damage that is already in progress, and repairing some of the harm already done has an enormous price tag.[198] Estimates of what an opioid master settlement agreement might look like do not come close to the estimated costs of managing the crisis as it stands today.[199] As states and municipalities struggle

195. State *ex rel.* Hunter v. Johnson & Johnson, 499 P.3d 719, 729 (Okla. 2021).

196. Ausness, *supra* note 121, at 606-607 (concluding that with various barriers to civil litigation, including issues of proximate cause, "there is no assurance that government plaintiffs will necessarily satisfy state law requirements in every state.").

197. *See* Selena Simmons-Duffin, *The Real Cost Of The Opioid Epidemic: An Estimated $179 Billion In Just 1 Year*, NPR (Oct 24, 2019), www.npr.org/sections/health-shots/2019/10/24/773148861/calculating-the-real-costs-of-the-opioid-epidemic [perma.cc/9BNM-L9LK] (estimating opioid related deaths at approximately 400,000 since 1999 and the annual cost from mortality, healthcare, lost productivity, criminal justice system costs, and child, family, and education services cost increases from the opioid epidemic in the U.S. for 2018 to be $179.4 billion).

198. *See id.* (citing professor Christopher Ruhm's work on an opioid epidemic abatement plan in Oklahoma that put the single year cost for the state at $836 million; scaling up this would be approximately $69 billion for the U.S. per year).

199. *See id.* (noting that in addition to scaling up from the state level, there are likely to be additional costs at a federal level to increase the $69 billion figure).

under the financial burden of the damage, it is tremendously important that no unnecessary barriers stand in the way of potential financial recovery through litigation.

A. Broaden the Application of Proximate Cause Analysis

The analysis for proximate cause is not currently uniform. Even in a single cause of action, proximate cause analysis has significant flexibility to uphold the policy goals of maintaining a direct relationship between the responsible parties and the injury.[200] Because proximate cause exists for policy reasons to "limit a person's responsibility for the consequences of that person's own acts," a more expansive application can be justified when the defendants in question took numerous affirmative, intentional actions as they did here.[201] Extending the chain of causation to foreseeable consequences of the defendants' desired results, rather than just their initial outcomes may be one such expansion. Additionally, using past events, scientific consensus, or expert testimony as primary factors to determine what is reasonably foreseeable may be another expansion, particularly in cases where there are predictable medical or public health outcomes.

Additionally, where defendants raise issues of proximate cause based on the results of their actions being "unforeseeable," that argument should fail where the defendants' clear intent was for that outcome to occur.[202] Where manufacturers have spent millions of dollars on marketing medications, they should not be able to argue that a dramatic increase in opioid prescriptions was not foreseeable and therefore breaks the chain of proximate cause.[203] The same logic should extend to increases in dosages, frequencies of prescriptions written, and the number of patients using the medication long-term, which was known to come with serious risk of dependence.[204] Where

200. *See* Bridge v. Phoenix Bond & Indem. Co., 553 U.S. 639, 654 (2008) (quoting *Holmes*, 503 U.S. at 272) ("Proximate cause . . . is a flexible concept that does not lend itself to 'a black-letter rule that will dictate the result in every case.'").

201. *Id.*

202. *See In re Nat'l Prescription Opiate Litig.*, 458 F. Supp. 3d at 698 (stating "the Court declines to find 'the physicians' act of writing prescriptions breaks the causal chain, as a matter of law, when the very purpose of the Defendants' alleged scheme was to achieve exactly that result.").

203. *See City & Cty. of San Francisco*, 491 F. Supp. 3d at 681 (noting that intervening acts like decisions by prescribers and patients were foreseeable in the proximate cause analysis for a public nuisance claim).

204. *See id.* (quoting Dent v. Nat'l Football League, 902 F.3d 1109, 1119 (9th Cir. 2018)) ("A lack of reasonable care in the handling, distribution, and administration of controlled substances can foreseeably harm the individuals who take them. That's why they're 'controlled' in the first place.").

a company has spent considerable time and resources trying to achieve a result, that result should be presumed to be a foreseeable outcome of those efforts.

B. Drastically Reduce the Role of the Learned Intermediary Doctrine

The learned intermediary doctrine is significantly out of step with the way medicine is practiced in the United States today.[205] The United States is one of only two countries in the world that allow advertisements to consumers for prescription medications.[206] Pharmaceutical companies spend upwards of ten billion dollars each year marketing these products directly to consumers.[207] The advertisements for prescription drugs are overseen by the FDA, but do not have to be approved in advance of publication for accuracy or other compliance with guidelines.[208] When pharmaceutical companies have such a significant line of communication open with the end users of prescription-only medications, invoking a defense based on the intermediary between the parties is out of sync with the modern system.[209]

While the use of the learned intermediary doctrine is declining, its use in opioid litigation (along with most other pharmaceutical litigation in the United States) should be eliminated. The MDL, in evidentiary rulings, has stopped short of limiting the learned intermediary doctrine's use altogether.[210] While it was held to be

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205. *See Perez*, 734 A.2d at 1246 ("Our medical-legal jurisprudence is based on images of health care that no longer exist.").

206. C. Lee Ventola, *Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?*, 36 PHARMACY & THERAPEUTICS 669, 669 (2011), www.ncbi.nlm.nih.gov/pmc/articles/PMC3278148/pdf/ptj3610669.pdf [perma.cc/T244-QDR5]. The other country that allows such advertisements is New Zealand. *Id.*

207. *See* Lindsey Tanner, *US Medical Marketing Reaches $30 billion, Drug Ads Top Surge*, ABC NEWS (Jan. 8, 2019), www.abcnews.go.com/Health/wireStory/us-medical-marketing-reaches-30-billion-drug-ads-60237108 [perma.cc/JP25-DSPY] (citing 2016 statistics that showed direct-to-consumer marketing occupying one third of prescription drug marketing budgets).

208. *See Prescription Drug Advertising: Questions and Answers*, *supra* note 172. Among the many ways an advertisement could violate regulations are "mak[ing] claims that are not supported by adequate evidence," "overstat[ing] the drug's benefits," and "leav[ing] out or downplay[ing] risk information." *Id.* According to the FDA, the first step of enforcement as "send[ing] a letter to the drug company" and "ask[ing] the drug company to remove the ad and stop the unlawful behavior." *Id.* The organization also states that it can seek an injunction or bring criminal charges against a company if required. *Id.*

209. *See Perez*, 734 A.2d at 1255 (electing to change the approach to the learned intermediary doctrine in New Jersey, citing reduced length of appointments, increased advertising, and that "with rare and wonderful exceptions, the 'Norman Rockwell' image of the family doctor no longer exists.").

210. *See In re Nat'l Prescription Opiate Litig.*, 2020 U.S. Dist. LEXIS

"wholly inapplicable" to dispensing-related claims, defendants are still allowed to use the doctrine in some form for both distribution and marketing claims.[211] The doctrine should be inapplicable to all of these claims as a matter of law where the behavior of those learned intermediaries has been carefully manipulated to fulfill the company's goals. If these supposedly impartial third parties have been manipulated by false messaging, it deprives them of the ability to properly operate as a neutral intervening force, and therefore should not destroy proximate causation.

There may be a limited role for the doctrine in rare cases limited to generic medications or in cases where advertisements are not directed toward consumers, but where medications are the subject of advertising campaigns, its use should be significantly curtailed. In these cases, it may still serve its original intended purpose if the patient is still primarily relying on the expertise of a healthcare provider rather than any external messaging. Many experts would like to see a future where prescription drug advertisements to both consumers and prescribers were either significantly limited or eliminated as a matter of policy.[212] If in the future, advertisements for prescription medications are banned or more stringently restricted (like they are in many parts of the world) then the learned intermediary doctrine may once again find a larger role in the proximate cause analysis. As it stands, pharmaceutical companies should not be able to abdicate responsibility for communicating the risks of their medications to consumers when they are all too willing to extol the virtues.[213] The

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204908, at *55-56 (declining to extend further restrictions on the use of the learned intermediary doctrine).

211. *See id.* (distinguishing between dispensing claims, where the learned intermediary doctrine is inapplicable, and marketing and distribution claims where the doctrine's applicability is a question for the jury).

212. Jon Kelvey, *How Advertising Shaped the First Opioid Epidemic: And What it Can Teach Us About the Second*, SMITHSONIAN MAG. (Apr. 3, 2018), www.smithsonianmag.com/science-nature/how-advertising-shaped-first-opioid-epidemic-180968444/ [perma.cc/9DRY-BJN7] (citing David Herzberg, a professor and historian focusing on the history of prescription narcotics in the U.S., suggesting the elimination of advertising toward consumers and practitioners of any controlled narcotics, stimulants, and sedatives); *Direct-to-Consumer Advertisement of Prescription Drugs*, AMER. MED. ASS'N, www.ama-assn.org/delivering-care/ethics/direct-consumer-advertisement-prescription-drugs [perma.cc/84KS-SG5X] (last visited Jan. 9, 2022) (giving the AMA Code of Medical Ethics Opinion 9.6.7 on Direct-to-Consumer advertising of prescription medications in general, which cites "the risk of creating unrealistic expectations for patients and conflicts of interest for physicians, adversely affecting patients' health and safety, and compromising patient physician relationships.").

213. *See Perez*, 734 A.2d at 1252 (quoting Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141 (1997)) ("Third, having spent $1.3 billion on advertising in 1998 drug manufacturers can hardly be said to 'lack effective means to

learned intermediary doctrine is built on an outdated understanding of the relationship between patients, doctors, and pharmaceutical companies that no longer reflects reality.[214] It is time to reflect the changes in modern healthcare with corresponding changes in the doctrines employed.

C. Statutory Causes of Action that Require Limited Proximate Causation Analysis

Among the claims most likely to be successful in this litigation are those based on statutory violations.[215] In many cases, such as in RICO violations, statutory claims still require proving proximate causation.[216] Government plaintiffs may be more likely to succeed if there are statutory violations that can be litigated without the need to prove proximate cause of damages at all. State-level enactment of deceptive advertising or consumer protection statutes may be beneficial in solving the opioid crisis.[217] While some causes of action under these statutes require proving causation and damages on the government's part, penalties automatically triggered by violations may still be useful in both deterring unlawful behavior from the pharmaceutical companies and providing municipalities with funding to respond to the opioid crisis.[218]

The available penalties as currently structured are unlikely to sufficiently address this problem without significant reformation. The disproportionate risks and rewards that pharmaceutical companies are looking at for deceptive advertising statutes are unlikely to have a significant deterrent effect; while Illinois imposes

communicate directly with patients.'"). In comparison, the advertising spending in 2020 was roughly $6.58 billion. Beth Snyder Bulik, *The Top 10 Ad Spenders in Big Pharma for 2020*, FIERCE PHARMA (Apr. 19, 2021), www.fiercepharma.com/special-report/top-10-ad-spenders-big-pharma-for-2020 [perma.cc/TR6F-Y42N].

214. *See Perez*, 734 A.2d at 1246-47 ("At an earlier time, medical advice was received in the doctor's office from a physician who most likely made house calls if needed . . . it is safe to say that the prevailing attitude of law and medicine was that the 'doctor knows best.' . . . For good or ill, that has all changed.").

215. *See* Ausness, *supra* note 121, at 606 (citing clear elements for analysis as part of the reasoning for this).

216. *See, e.g.*, *West Boca Med. Ctr., Inc.*, 452 F. Supp. 3d at 763 (quoting Trollinger v. Tyson Foods, Inc., 370 F.3d 602, 613 (6th Cir. 2004)) ("'RICO's civil-suit provision imposes two distinct but overlapping limitations on claimants—standing and proximate cause.'").

217. *See, e.g.*, 815 ILL. COMP. STAT. 505(7)(a)-(b) (2022) (authorizing civil actions on behalf of the state for deceptive marketing claims and penalties in amounts up to $50,000 per violation for unlawful business practices).

218. *Cf.* 815 ILL. COMP. STAT. 505(7)(c) (2022) (describing the statutory scheme for imposing additional fines for elderly victims and directing those funds to projects designed to help those victims; this is a potentially analogous statutory scheme).

a potential penalty of up to $50,000, Michigan caps its civil penalty at $25,000 for persistent and knowing violation(s).[219] In comparison, opioids are worth around thirteen billion dollars per year for the pharmaceutical industry.[220] Even the higher criminal penalties may not be deterrents when the amount of the fine is disproportionate to the profit that companies are making from their opioid products.[221] Appropriately scaling up these civil penalties without causing potentially disproportionate harm to small companies or individuals that violate the statutes may be difficult to execute. Fines in set amounts per infraction may be devastating to a small operation and completely ineffective against pharmaceutical companies that have multibillion dollar profits each year. Increasing penalties per infraction, calculating fines based on company profits, and including restrictions on future marketing could be potential mitigations to this disproportionate impact.[222] The existing foundation may provide the framework for creating statutory penalties and causes of action available to municipal plaintiffs in the opioid crisis or potential future litigation of a similar nature that bypasses the difficulties of proving proximate cause.

At a federal level, some steps have been taken in this direction already, including the creation of reporting duties and the nationwide suspicious order database under the CSA in 2018.[223] Financial penalties for violating those will only be an effective deterrent when it outstrips the profitability of the prohibited behaviors. Imposing fines with sufficiently high dollar values or

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219. 815 ILL. COMP. STAT. 505(7)(a)-(b) (2022); MICH. COMP. LAWS § 445.905(1) (2022).

220. Rebecca L. Haffajee et al., *Drug Companies' Liability for the Opioid Epidemic*, 377 NEW ENG. J. MED. 2301, 2305 (2017).

221. *See* Keefe, *supra* note 19 (quoting former Senator Arlen Specter, who called fines issued to Purdue Pharma "expensive licenses for criminal misconduct."); Clare Wilson, *Record $8 Billion Payout Won't Turn Back the Clock on US Opioid Crisis*, NEWSCIENTIST (Oct. 23, 2020), www.newscientist.com/article/2258122-record-8-billion-payout-wont-turn-back-the-clock-on-us-opioid-crisis/ [perma.cc/DJZ3-WZ2H] (quoting Dr. Andrew Kolodny of Brandeis University as saying "Criminal charges against corporations don't work. They're seen by companies as the cost of doing business.").

222. While this is not common practice in corporate fines, many countries employ a similar concept of "day-fines," or fines scaled by an individual's income for some types of violations. Joe Pinsker, *Finland, Home of the $103,000 Speeding Ticket*, ATLANTIC (Mar. 12, 2015), www.theatlantic.com/business/archive/2015/03/finland-home-of-the-103000-speeding-ticket/387484/ [perma.cc/8K52-EGPG]. In Finland, this has resulted in a $39,000 speeding ticket for NHL player Teemu Selanne and a $103,000 ticket for a Nokia executive. *Id.*

223. *See* 21 U.S.C. § 832 (2022) (creating the suspicious order database and mechanisms for reporting and sharing information on orders or series of orders of controlled substances).

enforcing the regulations consistently with repeated or even increasing penalties for every infraction may be enough to provide a noticeable deterrent effect. If the money collected from financial penalties like these is then channeled back toward reparative efforts in the harmed communities, it may even serve both key purposes of preventing future harm and addressing the harm that has already been done. Similar increases in the stringency of prescription drug marketing requirements may be an effective tool but would need to be coupled with the mechanisms and resources required for the FDA to sufficiently enforce them.[224] Statutory measures like these are generally not helpful in recovering for injuries already inflicted, so they would be insufficient on their own. However, having these structures in place may reduce the need for litigation in future instances of pharmaceutical company misconduct and enable government entities to meet their burdens of proof where it is required.

Ultimately, recovery from the opioid crisis is likely to involve legal action in many different forms. There will very likely be a Master Settlement Agreement ("MSA") like the one in 1998 with the major tobacco companies.[225] The tobacco companies reached a deal with state governments to pay out hundreds of billions of dollars over a twenty-five year period, but the handling of the settlement has been widely criticized for its failure to include requirements for how the money should be spent to address the problems created by the tobacco industry.[226] Already the settlements coming in the opioid litigation are more fragmented in nature than the 1998 tobacco deal. The three major distributors and manufacturer Johnson & Johnson reached a $26 billion settlement finalized in

224. *See* Tanner, *supra* note 207 ("The analysis suggests that the surge in medical marketing has led to spotty oversight . . . [W]hile company submissions more than doubled over the two decades, reaching nearly 100,000, FDA violation letters for misleading drug marketing dropped from 156 to 11. That could mean drug companies are doing a better job of self-policing but . . . it's more likely regulators are overwhelmed by the volume and can't keep up.").

225. *See* Ausness, *supra* note 121, at 607 (listing a global settlement along the lines of the tobacco master settlement agreement as the most likely outcome). Criticisms of how the funds from the tobacco MSA have been spent by states have prompted several organizations to work on creating guidelines for how funds from a potential opioid global settlement should be spent to avoid similar pitfalls. *Principles for the Use of Funds from the Opioid Litigation*, JOHNS HOPKINS BLOOMBERG SCH. PUB. HEALTH, opioidprinciples.jhsph.edu/about/ [perma.cc/5A26-J7U9] (last visited Nov. 21, 2021).

226. *15 Years Later, Where Did All the Cigarette Money Go?*, NPR (Oct. 13, 2013), www.npr.org/2013/10/13/233449505/15-years-later-where-did-all-the-cigarette-money-go [perma.cc/AY93-DVBH] (discussing some of the criticisms of the tobacco master settlement agreement spending). A tool to track many of the opioid litigation settlements being reached and plans for spending settlement funding can be found at www.opioidsettlementtracker.com [perma.cc/9LBD-T4L5].

February 2022, while other defendants operate separately.[227] Native American tribes reached a separate settlement with this same group of defendants, acting independently from other governmental plaintiffs.[228] In a separate action, the manufacturer Teva made a unique settlement offer – a hybrid of cash payments and orders of the overdose-reversing drug Narcan, which it manufactures, allotted to the involved municipalities at no cost.[229]

Purdue Pharma, one of the largest players in the opioid market, opted to avoid litigation by restructuring the company through bankruptcy proceedings and reaching a settlement agreement.[230] While the bankruptcy settlement was originally

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227. *See* Jan Hoffman, *Companies Finalize $26 Billion Deal with States and Cities to End Opioid Lawsuits*, N.Y. TIMES (Feb. 25, 2022), www.nytimes.com/2022/02/25/health/opioids-settlement-distributors-johnson.html [perma.cc/74Y6-HZ43]. Some states look as though they intend to opt out of the settlement deal between most of the state and local government plaintiffs and defendants Johnsons & Johnson, McKesson, Cardinal Health, and AmerisourceBergen in favor of continuing litigation. *Id.* Those that do settle have primarily procedural steps left, with the bulk of the substantive work now completed. *Id.* This settlement has gained the approval of 42 states, a sufficient majority to move forward, but less than the 46 that signed onto the Tobacco Master Settlement Agreement in the 1990s. *State Opioid Settlement Statuses*, OPIOID SETTLEMENT TRACKER (Oct. 4, 2022), www.opioidsettlementtracker.com/globalsettlementtracker/#statuses [perma.cc/S5KX-2BK3]. At least four states have opted out of some part of the settlement in favor of going to trial with one or more of the defendants. *Id.*

228. *See* Jan Hoffman, *Tribes Reach $590 Million Opioid Settlement with J. & J. and Distributors*, N.Y. TIMES (Feb. 1, 2022), www.nytimes.com/2022/02/01/health/opioids-native-american-tribes.html [perma.cc/6ZS6-7YUY] (describing the settlements with Johnson & Johnson and the major distributors, set to be paid out over the course of six and half years). This is possibly the first recognition of the collective 574 federally recognized tribes as a distinct litigating entity, separate from the other municipal plaintiffs in the MDL. *Id.*

229. *Opioids Maker Teva Agrees to $4.25 Billion Settlement: Preliminary Agreement Will Provide Cash and Naloxone to Address Opioids Crisis*, OFF. ATT'Y GEN. KEN PAXTON (July 29, 2022), www.texasattorneygeneral.gov/news/releases/opioids-maker-teva-agrees-425-billion-settlement-preliminary-agreement-will-provide-cash-and [perma.cc/S7WP-QX24]. Narcan, produced by Teva, is the brand name for nasal spray administered naloxone, a drug that can be administered to reverse opioid overdose and save lives. *Lifesaving Naloxone*, CDC (Sept. 7, 2022), www.cdc.gov/stopoverdose/naloxone/index.html [perma.cc/Q88H-C9RF]. While it may be a questionable way for the drug manufacturer to lower its contribution, there is no doubt that naloxone is a crucial part of the response to the opioid crisis. Last Week Tonight with John Oliver: Opioids (HBO television broadcast Oct. 23, 2016) (available at www.youtube.com/watch?v=5pdPrQFjo2o [perma.cc/5LGZ-6RDF]). John Oliver shows a clip of a fireman describing naloxone nasal spray as "a piece of equipment we can't go without, just like we have the hose" and stating that every firefighter "from the chief down" had been called on to use it because "we tend to have more overdoses than we do fires." *Id.*

230. Geoff Mulvihill & John Seewer, *Purdue Pharma, U.S. States Agree to New Settlement for Opioid Crisis*, PBS (Mar. 3, 2022), www.pbs.org/newshour/politics/purdue-pharma-u-s-states-agree-to-new-settlement-for-opioid-crisis

granted, a contentious series of appeals followed, largely surrounding the broad-reaching immunity demanded by Purdue Pharma and its owners, the Sackler family.[231] The settlement, finalized in March 2022, requires the Sackler family to pay about $6 billion of their own money and leaves them open to potential criminal charges, but does preclude civil suits against the family or the company.[232] Fellow manufacturer Endo has followed suit in declaring bankruptcy, filing in August 2022.[233] The settlement has not yet been finalized, but looks to include direct payments from Endo, trusts established to cover future claims, and a restriction on any future marketing of Endo's opioid products.[234]

However, even with all these alternative avenues for legal resolution, there will undoubtedly continue to be litigation for years to come.[235] For civil suits to effectively play a role in the resolution

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[perma.cc/RNC9-NG33].

231. *See* Jan Hoffman, *Judge Overturns Purdue Pharma's Opioid Settlement*, N.Y. TIMES (Dec. 16, 2021), www.nytimes.com/2021/12/16/health/purdue-pharma-opioid-settlement.html [perma.cc/QU3A-7VYA] (reviewing the issues related to the grant of civil immunity for Purdue Pharma owners the Sackler family when the company, but not the individuals, filed for bankruptcy); Jan Hoffman, *Sacklers Raise Their Offer to Settle Opioid Lawsuits by More Than $1 Billion*, N.Y. TIMES (Feb. 17, 2022), www.nytimes.com/2022/02/18/health/sacklers-opioids-lawsuit.html [perma.cc/EKZ6-WSBX] (discussing the Sacklers' offer to increase their financial contribution up to a possible six billion dollars but continued demand for civil immunity, which several states continue to object to); Maria Chutchian & Jonathan Stempel, *Purdue Pharma Can Appeal Rejection of Bankruptcy Plan*, REUTERS (Jan. 7, 2022), www.reuters.com/business/healthcare-pharmaceuticals/purdue-pharma-can-appeal-rejection-bankruptcy-plan-2022-01-07/ [perma.cc/8QJL-9YFU] (describing the ruling to allow immediate appeal).

232. *See* Mulvihill & Seewer, *supra* note 230 (detailing the terms of the settlement, which include a higher payout than earlier offers, a public forum for victims to address the Sackler family, and compensation directly to victims and families, with payments to be made over a period of roughly 16 years).

233. *Endo Files for Bankruptcy as U.S. Opioid Litigation Drags*, REUTERS (Aug. 17, 2022), www.reuters.com/legal/massachusetts-ag-reaches-settlement-with-opioid-maker-endo-2022-08-17/ [perma.cc/KLN5-34JQ].

234. *Id.*

235. *See* Brendan Pierson, *Pharmacy Operators Walmart, Walgreens, Kroger begin Opioid Trial in New Mexico*, REUTERS (Sept. 6, 2022), www.reuters.com/legal/pharmacy-operators-walmart-walgreens-kroger-begin-opioid-trial-new-mexico-2022-09-06/ [perma.cc/VCQ9-JT3Y] (noting a recently initiated trial in New Mexico); *AG Slattery Sues Walgreens for Unlawful Distribution and Sale of Opioids*, OFF. ATT'Y GEN. JONATHAN SKRMETTI (Aug. 3, 2022), www.tn.gov/attorneygeneral/news/2022/8/3/pr22-29.html [perma.cc/QE2P-8E67] (announcing the filing of a lawsuit by the state of Tennessee against retailer Walgreens); Lacie Pierson, *Judges Set Firm Deadline in Opioid Case Against Pharmacies, Trial Moved to June 2023*, HERALD-DISPATCH (Sep. 20, 2022), www.herald-dispatch.com/news/judges-set-firm-deadline-in-opioid-case-against-pharmacies-trial-moved-to-june-2023/article_132ca56e-1af8-5cdf-9f99-4725514b2c5e.html [perma.cc/7Q2S-BBZ7] (reporting the rescheduling of a West Virginia trial against multiple pharmacy defendants for summer 2023).

of a complex issue like the opioid crisis, there must be a plausible way for plaintiffs to show proximate cause. The majority of the energy is justifiably focused on settlements that are likely to resolve the majority of these claims. Still, it is imperative that litigation can clear the proximate causation hurdle to provide the bellwether decisions that guide negotiations and to provide a pathway to municipalities that choose to opt out of these overarching agreements.

V. CONCLUSION

There is abundant evidence of the coordinated and intentional marketing strategy created and furthered by pharmaceutical manufacturers and distributors with the intent to change the prescribing protocol for opioid medications and to increase profits.[236] The marketing strategies proved highly effective as opioids became hugely popular across the United States, snowballing into the public health crisis that is now responsible for tens of thousands of overdose deaths each year.[237] As state and local governments struggle to meet the rising needs of their citizens and communities, many have turned to civil litigation against pharmaceutical companies that line their pockets through unscrupulous business practices.[238] One of the biggest roadblocks to meaningful financial recovery is proving proximate causation.[239] For civil litigation to play a significant and useful role in recovering from the opioid crisis, the courts must approach proximate cause more broadly. Legal action should primarily focus on repairing ongoing harm. However, with the opioid crisis far from over,[240] legislative and judicial action must be taken to deter further misconduct and prevent future harm as well.

See also Ausness, *supra* note 121, at 606-09 (discussing the likelihood that final resolutions will take several years to reach, whether through "protracted case-by-case litigation" or a global settlement likely to take years to work out).

236. *See generally* Keefe, *supra* note 19 (tracking numerous techniques used by Purdue Pharma to change prescribing behavior).

237. MEIER, *supra* note 18, at 173 (citing 250,000 deaths involving prescription opioids from 1995-2018).

238. *See In re Nat'l Prescription Opiate Litig.*, 290 F. Supp. 3d at 1378 (beginning the consolidation of these claims).

239. *See* Ausness, *supra* note 121, at 606 (evaluating chances of different litigation in the opioid crisis).

240. Overdose deaths in the U.S. reached a record high in 2021 with roughly 107,000 deaths, up around 15% from the previous record set in 2020. Mike Stobbe, *US Overdose Deaths Hit Record of 107,000 Last Year, CDC Says*, AP NEWS (May 11, 2022), www.apnews.com/article/overdose-deaths-opioids-fentanyl-8cb302a70ddbb6a435f9e8fbb19f153b [perma.cc/39HX-S4FX]. There have been waves of overdose deaths in the U.S. corresponding with opioid use, beginning with prescription opioids in the mid 1990's and including later waves associated with heroin and, most recently, fentanyl. *Id.*